FOR PATIENTS, SURVIVORS & THEIR CAREGIVERS

cure®

Cancer Updates, Research & Education®

SUMMER 2021

TOO MUCH MONEY FOR THE MEDICINE

NEWER CANCER THERAPIES EASILY COST UPWARD OF $100,000. WHY SO MUCH? WHO SETS THE PRICES AND WHAT CAN PATIENTS DO IF THEY CAN'T AFFORD THEM?

ALSO IN THIS ISSUE

curetoday.com

For adults with advanced melanoma,
KEYTRUDA could be your first treatment option.

“I want to share my story

so that other people with advanced melanoma can see there are options.” – **Summer,** *a real patient*

Summer thought she had melanoma figured out, but when it returned she realized there was a lot she still didn’t know. She wasn’t sure what to do next, but after talking with her doctor she started treatment with **KEYTRUDA**.

Ask your doctor today if KEYTRUDA is right for you.

KEYTRUDA is a prescription medicine used to treat a kind of skin cancer called melanoma.
KEYTRUDA may be used when your melanoma has spread or cannot be removed by surgery (advanced melanoma).

IMPORTANT SAFETY INFORMATION

KEYTRUDA is a medicine that may treat certain cancers by working with your immune system. KEYTRUDA can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen any time during treatment or even after your treatment has ended.

Call or see your health care provider right away if you develop any signs or symptoms of the following problems or if they get worse. These are not all of the signs and symptoms of immune system problems that can happen with KEYTRUDA:

- **Lung problems:** cough, shortness of breath, or chest pain.
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; or severe stomach-area (abdomen) pain or tenderness.
- **Liver problems:** yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen), dark urine (tea colored); or bleeding or bruising more easily than normal.
- **Hormone gland problems:** headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.
- **Kidney problems:** decrease in the amount of your urine; blood in your urine; swelling of your ankles; loss of appetite.
- **Skin problems:** rash; itching; skin blistering or peeling; painful sores or ulcers in your mouth or in your nose, throat, or genital area; fever or flu-like symptoms; swollen lymph nodes.
- **Problems can also happen in other organs and tissues.** Signs and symptoms of these problems may include: chest pain; irregular heartbeat; shortness of breath; swelling of ankles; confusion; sleepiness; memory problems; changes in mood or behavior; stiff neck; balance problems; tingling or numbness of the arms or legs; double vision; blurry vision; sensitivity to light; eye pain; changes in eyesight; persistent or severe muscle pain or weakness; muscle cramps; low red blood cells; bruising.
- **Infusion reactions that can sometimes be severe or life-threatening.** Signs and symptoms of infusion reactions may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feeling like passing out, fever, and back pain.
- **Rejection of a transplanted organ:** Your health care provider should tell you what signs and symptoms you should report and they will monitor you, depending on the type of organ transplant that you have had.

KEYTRUDA will not work for everyone. Results may vary.

Watch Summer's TRU story at
keytruda.com/summer

IMPORTANT SAFETY INFORMATION *(continued)*

- **Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with KEYTRUDA. Your health care provider will monitor you for these complications.

Getting medical treatment right away may help keep these problems from becoming more serious. Your health care provider will check you for these problems during treatment with KEYTRUDA. They may treat you with corticosteroid or hormone replacement medicines. They may also need to delay or completely stop treatment with KEYTRUDA if you have severe side effects.

Before you receive KEYTRUDA, tell your health care provider if you have immune system problems such as Crohn's disease, ulcerative colitis, or lupus; have had an organ transplant or have had or plan to have a bone marrow (stem cell) transplant that used donor stem cells (allogeneic); have had radiation treatment in your chest area; have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome.

If you are pregnant or plan to become pregnant, tell your health care provider. KEYTRUDA can harm your unborn baby. If you are able to become pregnant, you will be given a pregnancy test before you start treatment. Use effective birth control during treatment and for at least 4 months after your final dose of KEYTRUDA. Tell them right away if you think you may be pregnant or you become pregnant during treatment with KEYTRUDA.

Tell your health care provider if you are breastfeeding or plan to breastfeed. It is not known if KEYTRUDA passes into your breast milk. Do not breastfeed during treatment with KEYTRUDA and for 4 months after your final dose of KEYTRUDA.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Common side effects of KEYTRUDA when used alone include feeling tired; pain, including pain in muscles, bones or joints and stomach area (abdominal) pain; decreased appetite; itching; diarrhea; nausea; rash; fever; cough; shortness of breath; and constipation.

These are not all the possible side effects of KEYTRUDA. Talk to your health care provider for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call 1-800-FDA-1088.

Please read the adjacent Important Information About KEYTRUDA and discuss it with your oncologist.

Having trouble paying for your Merck medicine?

Merck may be able to help.
www.merckhelps.com

MERCK

IT'S TRU. KEYTRUDA® (pembrolizumab) Injection 100 mg

Important Information About KEYTRUDA® (pembrolizumab) injection 100 mg. Please speak with your healthcare professional regarding KEYTRUDA (pronounced key-true-duh). Only your healthcare professional knows the specifics of your condition and how KEYTRUDA may work with your overall treatment plan. If you have any questions about KEYTRUDA, speak with your healthcare professional. **℞ONLY**

What is the most important information I should know about KEYTRUDA?

KEYTRUDA is a medicine that may treat certain cancers by working with your immune system. KEYTRUDA can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including

Lung problems

- cough
- shortness of breath
- chest pain

Intestinal problems

- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness

Liver problems

- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

Hormone gland problems

- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Kidney problems

- decrease in your amount of urine
- swelling of your ankles
- blood in your urine
- loss of appetite

Skin problems

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in your mouth or in your nose, throat, or genital area
- fever or flu-like symptoms
- swollen lymph nodes

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with KEYTRUDA. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath, swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include:

- chills or shaking
- itching or rash
- flushing
- shortness of breath or wheezing
- dizziness
- feeling like passing out
- fever
- back pain

Rejection of a transplanted organ. Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

Complications, including graft-versus-host-disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These

Continued on the next page.

complications may happen if you underwent transplantation either before or after being treated with KEYTRUDA. Your healthcare provider will monitor you for these complications.

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during treatment with KEYTRUDA. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with KEYTRUDA if you have severe side effects.

Before receiving KEYTRUDA, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. KEYTRUDA can harm your unborn baby.

  Females who are able to become pregnant:

  - Your healthcare provider will give you a pregnancy test before you start treatment with KEYTRUDA.
  - You should use an effective method of birth control during and for at least 4 months after the final dose of KEYTRUDA. Talk to your healthcare provider about birth control methods that you can use during this time.
  - Tell your healthcare provider right away if you think you may be pregnant or if you become pregnant during treatment with KEYTRUDA.
- are breastfeeding or plan to breastfeed. It is not known if KEYTRUDA passes into your breast milk. Do not breastfeed during treatment with KEYTRUDA and for 4 months after your final dose of KEYTRUDA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive KEYTRUDA?

- Your healthcare provider will give you KEYTRUDA into your vein through an intravenous (IV) line over 30 minutes.
- In adults, KEYTRUDA is usually given every 3 weeks or 6 weeks depending on the dose of KEYTRUDA that you are receiving.
- In children, KEYTRUDA is usually given every 3 weeks.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will do blood tests to check you for side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of KEYTRUDA?
KEYTRUDA can cause serious side effects. See "What is the most important information I should know about KEYTRUDA?"

Common side effects of KEYTRUDA when used alone include: feeling tired, pain, including pain in muscles, bones or joints and stomach-area (abdominal) pain, decreased appetite, itching, diarrhea, nausea, rash, fever, cough, shortness of breath, and constipation.

Side effects of KEYTRUDA when used alone that are more common in children than in adults include: fever, vomiting, upper respiratory tract infection, headache, and low levels of white blood cells and red blood cells (anemia).

Common side effects of KEYTRUDA when given with certain chemotherapy medicines include: feeling tired or weak, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, trouble breathing, fever, hair loss, inflammation of the nerves that may cause pain, weakness, and paralysis in the arms and legs, swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina, mouth sores, and headache.

Common side effects of KEYTRUDA when given with axitinib include: diarrhea, feeling tired or weak, high blood pressure, liver problems, low levels of thyroid hormone, decreased appetite, blisters or rash on the palms of your hands and soles of your feet, nausea, mouth sores or swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina, hoarseness, rash, cough, and constipation.

These are not all the possible side effects of KEYTRUDA.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of KEYTRUDA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about KEYTRUDA that is written for health professionals.

Based on Medication Guide usmg-mk3475-iv-2011r036 as revised November 2020.

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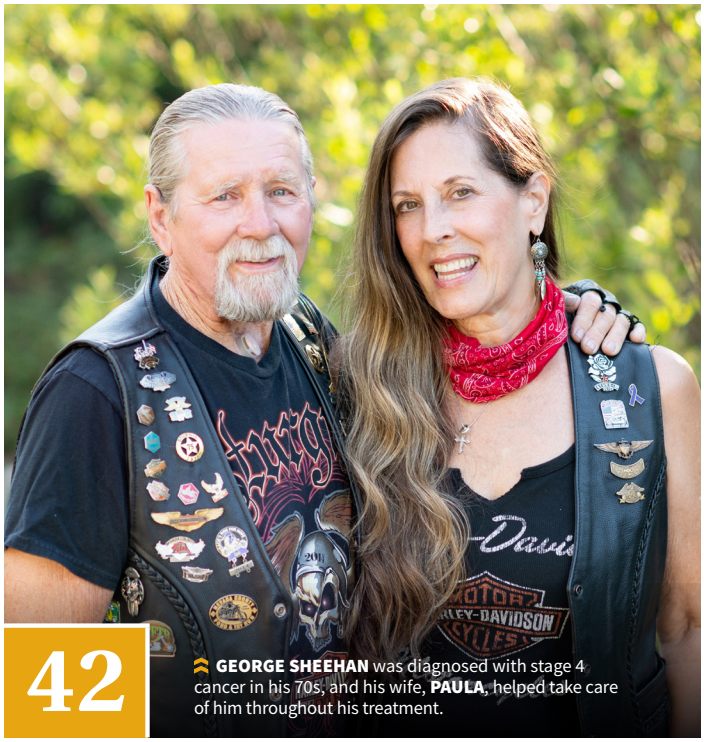
cure® Contents

SUMMER ISSUE · 2021

NEWS & INSIGHTS



42 **GEORGE SHEEHAN** was diagnosed with stage 4 cancer in his 70s, and his wife, **PAULA**, helped take care of him throughout his treatment.

62 **SHYREECE POMPEY** underwent biomarker testing to find which targeted therapy would potentially be effective for her stage 4 NSCLC.

cure® ONLINE EXCLUSIVES

- videos
- podcasts
- newsletters

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COVER ART: GANG / STOCK.ADOBE.COM; SHEEHAN BY JENNIFER POPE; POMPEY BY MARITA MADELONI; DARIEN BY BEN HIDER

GWEN DARIEN had to decide between taking on debt or paying for her cancer treatment.

52

FEATURES

ALSO IN THIS ISSUE

CURE® CONNECTIONS

EXTRAORDINARY HEALER®

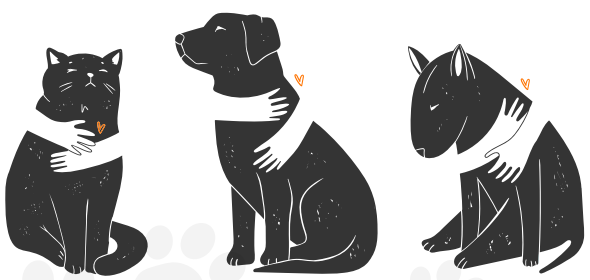
PARTNER PERSPECTIVES

FDA UPDATES

BOOKSHELF CORNER

VOICES

SPEAKING OUT



30

« Caring for a pet may help patients be more optimistic and physically active during cancer treatment.

INDICATIONS

KISQALI® (ribociclib) is a prescription medicine used in combination with:

- an aromatase inhibitor to treat pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic), as the first endocrine-based therapy; or
- fulvestrant to treat postmenopausal women with HR-positive, HER2-negative metastatic breast cancer as the first endocrine-based therapy or with disease progression following endocrine therapy

It is not known if KISQALI is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about KISQALI?

KISQALI may cause serious side effects, including:

Lung problems. KISQALI may cause severe or life-threatening inflammation of the lungs during treatment that may lead to death. Tell your health care provider right away if you have any new or worsening symptoms, including:

- trouble breathing or shortness of breath
- cough with or without mucus
- chest pain

Severe skin reactions. Tell your health care provider or get medical help right away if you get severe rash or rash that keeps getting worse; reddened skin; flu-like symptoms; skin pain/burning; blistering of the lips, eyes, or mouth; or blisters on the skin or skin peeling, with or without fever.

Heart rhythm problems (QT prolongation). KISQALI can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Your health care provider should check your heart and do blood tests before and during treatment with KISQALI. Tell your health care provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint.

Liver problems (hepatobiliary toxicity). KISQALI can cause serious liver problems. Your health care provider should do blood tests to check your liver before and during treatment with KISQALI. Tell your health care provider right away if you get any of the following signs and symptoms of liver problems:

- yellowing of your skin or the whites of your eyes (jaundice)
- dark or brown (tea-colored) urine
- feeling very tired
- loss of appetite
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking KISQALI and may result in infections that may be severe. Your health care provider should check your white blood cell counts before and during treatment with KISQALI. Tell your health care provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Your health care provider may tell you to decrease your dose, temporarily stop, or completely stop taking KISQALI if you develop certain serious side effects during treatment with KISQALI.

Live longer with KISQALI.

In clinical trials, combination treatment with KISQALI extended the length of time women were alive from the start of treatment—also called overall survival (OS). It also extended progression-free survival, which is the length of time a treatment puts cancer growth on pause.

In premenopausal women, the median OS was not reached for KISQALI + a nonsteroidal aromatase inhibitor (NSAI) + goserelin vs 40.7 months for an NSAI + goserelin. KISQALI + an NSAI + goserelin delayed disease progression for a median of 27.5 months vs 13.8 months for an NSAI + goserelin.

In postmenopausal women, median OS was not reached for KISQALI + fulvestrant vs 40 months for those taking fulvestrant alone. KISQALI + fulvestrant delayed disease progression for a median of 20.5 months vs 12.8 months for fulvestrant alone.

Ask your doctor if KISQALI can help you live longer and visit KISQALI.com.

What should I tell my health care provider before taking KISQALI?

Before you take KISQALI, tell your health care provider if you:

- have any heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have ever had a heart attack
- have a slow heartbeat (bradycardia)
- have problems with the amount of potassium, calcium, phosphorus, or magnesium in your blood
- have fever, chills, or any other signs or symptoms of infection
- have liver problems
- have any other medical conditions
- are pregnant, or plan to become pregnant. KISQALI can harm your unborn baby
  - If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with KISQALI.
  - Females who are able to become pregnant and who take KISQALI should use effective birth control during treatment and for at least 3 weeks after the last dose of KISQALI.
  - Talk to your health care provider about birth control methods that may be right for you during this time.
  - If you become pregnant or think you are pregnant, tell your health care provider right away.
- are breastfeeding or plan to breastfeed. It is not known if KISQALI passes into your breast milk. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI

Please see Summary of Important Information on the following page.

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. KISQALI and other medicines may affect each other, causing side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

What should I avoid while taking KISQALI?

Avoid eating grapefruit and avoid drinking grapefruit juice during treatment with KISQALI since these may increase the amount of KISQALI in your blood.

The most common side effects of KISQALI include:

- neutropenia
- nausea
- infections
- fatigue
- diarrhea
- leukopenia
- vomiting
- hair loss
- headache
- constipation
- rash
- cough

KISQALI may cause fertility problems if you are male and take KISQALI. This may affect your ability to father a child. Talk to your health care provider if this is a concern for you.

Tell your health care provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of KISQALI. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

SUMMARY OF IMPORTANT INFORMATION

What is KISQALI® (ribociclib)?

KISQALI is a prescription medicine used in combination with:

- an aromatase inhibitor to treat pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic), as the first endocrine-based therapy; or
- fulvestrant to treat postmenopausal women with HR-positive, HER2-negative metastatic breast cancer as the first endocrine-based therapy or with disease progression following endocrine therapy

It is not known if KISQALI is safe and effective in children.

What is the most important information I should know about KISQALI?

KISQALI may cause serious side effects, including:

Lung problems. KISQALI may cause severe or life-threatening inflammation of the lungs during treatment that may lead to death. Tell your health care provider right away if you have any new or worsening symptoms, including:

- trouble breathing or shortness of breath
- cough with or without mucus
- chest pain

Severe skin reactions. Tell your health care provider or get medical help right away if you get severe rash or rash that keeps getting worse; reddened skin; flu-like symptoms; skin pain/burning; blistering of the lips, eyes, or mouth; or blisters on the skin or skin peeling, with or without fever.

Heart rhythm problems (QT prolongation). KISQALI can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Your health care provider should check your heart and do blood tests before and during treatment with KISQALI. Tell your health care provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint.

Liver problems (hepatobiliary toxicity). KISQALI can cause serious liver problems. Your health care provider should do blood tests to check your liver before and during treatment with KISQALI. Tell your health care provider right away if you get any of the following signs and symptoms of liver problems:

- yellowing of your skin or the whites of your eyes (jaundice)
- dark or brown (tea-colored) urine
- feeling very tired
- loss of appetite
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking KISQALI and may result in infections that may be severe. Your health care provider should check your white blood cell counts before and during treatment with KISQALI. Tell your health care provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Your health care provider may tell you to decrease your dose, temporarily stop, or completely stop taking KISQALI if you develop certain serious side effects during treatment with KISQALI.

What should I tell my health care provider before taking KISQALI?

Before you take KISQALI, tell your health care provider if you:

- have any heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have ever had a heart attack
- have a slow heartbeat (bradycardia)
- have problems with the amount of potassium, calcium, phosphorus, or magnesium in your blood
- have fever, chills, or any other signs or symptoms of infection
- have liver problems
- have any other medical conditions
- are pregnant, or plan to become pregnant. KISQALI can harm your unborn baby
  - If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with KISQALI.
  - Females who are able to become pregnant and who take KISQALI should use effective birth control during treatment and for at least 3 weeks after the last dose of KISQALI.
  - Talk to your health care provider about birth control methods that may be right for you during this time.
  - If you become pregnant or think you are pregnant, tell your health care provider right away.
- are breastfeeding or plan to breastfeed. It is not known if KISQALI passes into your breast milk. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI

What other medications might interact with KISQALI?

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements (especially St. John's wort). KISQALI and other medicines may affect each other, causing side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

What should I avoid while taking KISQALI?

Avoid eating grapefruit and avoid drinking grapefruit juice during treatment with KISQALI since these may increase the amount of KISQALI in your blood.

What laboratory tests do I need if I am prescribed KISQALI?

Your doctor should check your heart rhythm, liver, and blood before you start KISQALI and periodically during your treatment with KISQALI. Your doctor may eventually stop checking some of these tests. If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with KISQALI.

The most common side effects of KISQALI include:

- neutropenia
- nausea
- infections
- fatigue
- diarrhea
- leukopenia
- vomiting
- hair loss
- headache
- constipation
- rash
- cough

KISQALI may cause fertility problems if you are male and take KISQALI. This may affect your ability to father a child. Talk to your health care provider if this is a concern for you.

Tell your health care provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of KISQALI. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

General information about the safe and effective use of KISQALI

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use KISQALI for a condition for which it was not prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them. You can ask your health care provider or pharmacist for more information about KISQALI.

For more information, go to www.kisqali.com or call 1-844-KIS-QALI (1-844-547-7254).

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KISQALI® ribociclib 200 mg tablets

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Questions Linger About the Origin of COVID-19

WAS IT NATURAL ZOONOTIC SPILLOVER that catapulted SARS-CoV-2 from an emerging virus into a pandemic pathogen or was it something much more sinister? Is it at all possible that a lab leak in Wuhan, China, was the spark that lit the fuse?

Debate and discussion about the origin of the virus that causes COVID-19 have been at the forefront of the global consciousness since the first cases were reported in December 2019.

Early on, whispers of a potentially engineered virus quickly grew to a roar and fueled speculation that China was behind the pandemic. This narrative was so pervasive that, in February 2020, a group of 27 public health scientists published a letter in *The Lancet* disputing the lab leak theory and announcing their support of their counterparts in China: the scientists, public health officials, and medical professionals combating the pandemic.

"The rapid, open, and transparent sharing of data on this outbreak is now being threatened by rumors and misinformation around its origins," wrote the authors, who all declared no competing interests in their disclosures as recommended by the International Committee of Medical Journal Editors. "We stand together to strongly condemn conspiracy theories suggesting that COVID-19 does not have a natural origin."

And although it's true that analyses of the genomic sequence of the virus subsequently pointed to natural origins, the questions regarding China's role persisted, led by pesky discrepancies and conflicting reports.

Fast forward to June 2021 and new evidence that has breathed new life into those origin questions. In an update to the February 2020 letter, *The Lancet* has published an addendum with revised disclosure statements from virologist and investigator Peter Daszak, one of the 27 authors. In the revised document, Daszak noted that his remuneration is paid solely in the form of a salary from EcoHealth Alliance, a New York-based nonprofit research foundation of which he is president. The company has reportedly worked directly with Wuhan laboratories and funded gain-of-function research at China's Wuhan Institute of Virology.

Consider, too, other odd associations. Recent reports have uncovered financial ties between Google and EcoHealth Alliance. This comes after accusations that the tech giant was censoring lab leak "conspiracy theory" stories in its search results. Google's health lead, David Feinberg, has dismissed those reports, insisting that the company is simply taking steps to protect users from unverified information. »

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chairman's letter

SUMMER ISSUE • 2021

Are these coincidences or "where there's smoke, there's fire" situations? It's unclear. But they add to the bank of troublesome questions standing in the way of the truth about COVID-19.

The questions extend beyond origin theory, though. With the Food and Drug Administration's green lighting of vaccines for adolescents and young adults comes hesitation over long-term effects: What is the effect on fertility? Do the vaccines cause heart inflammation? Dr. Robert Malone, the inventor of the mRNA technology, appeared on television recently, expressing strong concern over the risk-benefit analysis of vaccination for young adults, and the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recently met to discuss instances of myocarditis or pericarditis in people aged 30 years and younger who have received an mRNA COVID-19 vaccine.

> "The incredible strength and collaboration of the scientific community has allowed us to regain some semblance of normalcy."

Of course, the answer to our ultimate question is that we may never know.

We may never know where this virus came from. We may never know what triggered the global pandemic that has claimed more than 3.8 million lives. And we won't know the long-term effects until enough time has elapsed. What we do know for certain is that the incredible strength and collaboration of the scientific community have allowed us to regain some semblance of normalcy. The development and rollout of multiple effective vaccine options have been the medical miracle of our lifetime. That, right now, will have to be the only answer that matters. Thank you for reading.

MIKE HENNESSY SR.
Chairman and Founder
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Strength in Numbers

CURE® is proud to partner with several leading advocacy groups across the country. Our shared goal is to connect patients and their caregivers to valuable resources and support to assist with navigating the cancer journey.

Scan the QR code with your mobile device to visit curetoday.com and check out our advocacy group partnerships.

STRATEGIC cure® ALLIANCE

DR. DEBU TRIPATHY
EDITOR-IN-CHIEF
Professor of Medicine
Chair, Department of Breast Medical Oncology
The University of Texas MD Anderson Cancer Center

Making a Case for 'Basket' Trials

THE PAST TWO DECADES have seen an explosion in the field of tumor genomics. We have a much better understanding of mutations in the DNA of malignant cells that "drive" cancer properties like cell growth and invasion. We are increasingly using tumor gene DNA sequencing results to prescribe targeted therapies that work specifically with certain mutations. In fact, some of these mutations can be seen in many different tumor types even though they may have been tested and approved for only one type of cancer. This led to the National Cancer Institute's NCI-MATCH program, which tests biologically targeted therapies for a large range of cancer types that match a mutation known to be harbored by that tumor. The "basket trial" has become part of the cancer trial lingo since it allows the treatment of a diverse set of tumor types, including some rarer cancers based on the presence of the mutation that matches the drug being tested. Since the successful launch of that program, promising results are starting to come in showing responses in tumors that have been considered difficult to treat.

> "The 'basket trial' has become part of the cancer trial lingo since it allows the treatment of a diverse set of tumor types."

Now that genomic analysis is widely available, many new trials are coming online, sponsored by pharmaceutical/biotech companies, academic centers, the National Cancer Institute National Clinical Trials Network and others. The FDA has started to approve certain drugs on the basis of basket trials that can be used for a wide range of cancer types as long as the qualifying mutation is present. Many of the mutations that can be paired with a unique drug are rare, so testing patients with a wide range of cancer types that carry that genetic aberration will greatly speed up the completion of the trial and will allow a wider group of patients with cancer to benefit. However, not all cancers are "wired" in the same way, and some cancer types may be more sensitive to a specific drug than other types even though they carry the same mutation. Basket trials may be the initial step, but confirmation with larger trials of a single tumor might be needed in some cases.

Obtaining next-generation sequencing is now becoming more routine for patients with advanced cancers since they could be found to qualify for an approved treatment or a clinical trial that may not have been considered. Many of the genomic reports are now pages long, as they may list standard therapies or clinical trials that might be applicable to the results. Websites for clinical trials now have search engines for genes that might be mutated to help link patients to specific studies — including basket trials. It is through studies like this that we will have an expanding array of options, as well as unique combination therapies tailored to a person's tumor biology.

EDITOR'S NOTE: *In our Lung Cancer 2021 Special issue, the article titled "Early Introduction to Supportive Care Greatly Benefits Older Patients With Lung Cancer" was published with an incorrect institution for Dr. Christine Ciunci. She works at Penn Presbyterian Medical Center, not Penn Medicine.*

DEBU TRIPATHY BY MIKE KITADA; LUNG ART: SPECTRAL-DESIGN / STOCK.ADOBE.COM

LETTERS TO THE EDITOR

I JUST READ THE ARTICLE in the March 2021 issue of *CURE*® encouraging (patients with cancer) to continue with routine screenings during the pandemic.

The article lists measures taken by clinics to improve patient safety but says nothing about ventilation. Lately the CDC (Centers for Disease Control and Prevention) has been saying that improving ventilation and air filtering is key to preventing SARS-CoV-2 transmission.

The main reason I've delayed a mammogram or a clinic visit is that both take place in interior rooms with minimal ventilation. Some of the clinic rooms may not even have air vents; certainly, they don't have openable windows.

Doubtless the buildings were designed to minimize air flow to save energy.

I would feel much safer if clinics talked about ventilation and air filtration or even air filtration with SARS-CoV-2 detection.

DIANA LUTZ
Madison, Wisconsin

Dear Ms. Lutz,

Thank you for pointing out proactive measures that health care facilities can take to minimize risks of COVID-19 and other airborne transmissible infections. We need to do what we can for patients to feel safer, otherwise we cannot expect them to simply overcome their fears. They will make risk-balancing choices just like they should. In parallel, we need to make sure we prioritize for our patients what activities are most important to the extent we can demonstrate this with the best facts and science available. ***—DR. DEBU TRIPATHY***

I AGREE WITH RICHARD FARMER'S precept (*CURE*® Winter 2021) that, at least when it comes to surviving cancer diagnoses, "hope can influence the essence of fundamental human behavior." I can personally attest to the fact that my metastatic prostate cancer for the (past) 20 years has not been a death sentence due — at least in part — to my unbridled hopefulness. On the other hand, I would never sell short my ongoing treatments — radiation, chemo and pharmaceuticals — in the positive outcome, but I believe hope helped.

Although I respect Mr. Farmer's right to his beliefs, where I disagree is with his statement that "hope is an amazing gift from God." On the contrary, one can have hope without relying on supernatural entities and beliefs.

In my case, I have had steadfast confidence in the medical profession throughout my ordeal. A belief in science and medicine is quite enough. Nothing in science prevents us atheists from having hope. In fact, I would stack up my faith in science against anyone's faith in a deity.

MARK LEVY
Evergreen, Colorado

Dear Mr. Levy,

I agree that hope and science together make for the best quantity and quality of life. Hope can indeed come in many directions — internally, externally and through religion/faith, as well as from one's community and our many beliefs that motivate us individually. ***—DR. DEBU TRIPATHY***

I FOUND YOUR ARTICLE "Going Flat" quite interesting since I chose that option. Cancer is rampant on the maternal side of my family, so I made significant lifestyle changes in my 20s. I became a vegetarian and eliminated as many additives and chemicals as I could from my diet. I had always been athletic and continued to pursue vigorous activity over the decades.

Despite these precautions (I have my own theory as to cause), I discovered the lump at 68. I was never well blessed in the boob department, so perhaps the decision was easier for me and was actually conceived decades before in case of this eventuality. I told the doctors, surgeon and counselors I wanted a double with zero reconstruction. They were incredulous at my resolve and some insisted that I rethink, but I stuck with my decision. One counselor was dumbstruck and did not seem to know how to deal with me. I remember long minutes of waiting for her to say something.

I was already in good physical condition, but in the time before my surgery I embarked upon an intensive upper body routine which, I feel, contributed significantly to my very short downtime. I was released to full activity, no restrictions, 10 days post-surgery.

It's been four-and-a-half years and I am happy with my decision, absolutely no regrets.

T.A. SAMPSON
Cane Hill, Arkansas

Dear Ms. Samson,

Going flat is an option that is more popular and talked about, and I suspect the reasons are quite diverse. Among them may be growing awareness of breast cancer and surgery that is needed, so it raises more acceptance with this choice. Another may be that acceptance doesn't matter as much in this time of the rise in individualism. Everyone should feel comfortable in their own skin and with their decisions. Also, reconstructive options are not without their risks and sometimes have disappointing or unexpected results.

It is good to hear from our readers about their affirming decisions. Thanks for sharing. ***—DR. DEBU TRIPATHY***

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IMPORTANT FACTS ABOUT BLENREP

The risk information provided here is not comprehensive. To learn more, talk to your healthcare provider or pharmacist. Visit BLENREP.com or call 1-888-825-5249 to get FDA-approved product labeling, including Medication Guide.

What is BLENREP?

BLENREP is a prescription medicine used to treat adults with multiple myeloma who have received at least 4 prior medicines to treat multiple myeloma, **and** their cancer has come back or did not respond to prior treatment. It is not known if BLENREP is safe and effective in children.

BLENREP is approved based on patient response rate. Studies are ongoing to confirm the clinical benefit of BLENREP for this use.

What is the most important information I should know about BLENREP?

Before you receive BLENREP, you must read and agree to all of the instructions in the BLENREP REMS. Before prescribing BLENREP, your healthcare provider will explain the BLENREP REMS to you and have you sign the Patient Enrollment Form.

BLENREP can cause serious side effects, including:

Eye problems. Eye problems are common with BLENREP. BLENREP can cause changes to the surface of your eye that can lead to dry eyes, blurred vision, worsening vision, severe vision loss, and corneal ulcer. Tell your healthcare provider if you have any vision changes or eye problems during treatment with BLENREP.

- Your healthcare provider will send you to an eye specialist to check your eyes before you start treatment with BLENREP, prior to each dose of BLENREP, and for worsening symptoms of eye problems.
- Even if your vision seems fine, it is important that you get your eyes checked during treatment with BLENREP because some changes can happen without symptoms and may only be seen on an eye exam.
- You should use preservative-free lubricant eye drops at least 4 times per day during treatment with BLENREP as instructed by your healthcare provider.
- You should use caution when driving or operating machinery as BLENREP may affect your vision.
- Avoid wearing contact lenses during treatment with BLENREP unless directed by your eye specialist.

Decrease in platelets (thrombocytopenia) is common with BLENREP, and can also be serious. Platelets are a type of blood cell that help your blood to clot. Your healthcare provider will check your blood cell counts before you start treatment with BLENREP and during treatment. Tell your healthcare provider if you have bleeding or bruising during treatment with BLENREP.

Infusion reactions are common with BLENREP, and can also be serious. Tell your healthcare provider or nurse right away if you get any of the following signs or symptoms of an infusion reaction while receiving BLENREP:

- chills or shaking
- redness of your face (flushing)
- itching or rash
- shortness of breath, cough, or wheezing
- swelling of your lips, tongue, throat, or face
- dizziness
- feel like passing out
- tiredness
- fever
- feel like your heart is racing (palpitations)

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IN RELAPSED OR REFRACTORY MULTIPLE MYELOMA...

RESOLVE BROUGHT YOU THIS FAR

TALK TO YOUR DOCTOR TO SEE WHERE

BLENREP MAY TAKE YOU

BLENREP is an antibody-drug conjugate (ADC) that targets the B-cell maturation antigen (BCMA) protein.

BLENREP is the first and only medication of its kind to help you fight relapsed or refractory multiple myeloma. It is also a single agent, which means that it doesn't need to be combined with other treatments.

What is BLENREP?

BLENREP is a prescription medicine used to treat adults with multiple myeloma who have received at least 4 prior medicines to treat multiple myeloma, **and** their cancer has come back or did not respond to prior treatment. It is not known if BLENREP is safe and effective in children.

BLENREP is approved based on patient response rate. Studies are ongoing to confirm the clinical benefit of BLENREP for this use.

BLENREP is available only through a restricted program called the BLENREP REMS (Risk Evaluation and Mitigation Strategy).

The most common side effects of BLENREP include vision or eye changes such as findings on eye exam (keratopathy), decreased vision or blurred vision, nausea, low blood cell counts, fever, infusion-related reactions, tiredness, and changes in kidney or liver function blood tests.

How will I receive BLENREP?

- BLENREP will be given to you by your healthcare provider by intravenous infusion into your vein over approximately 30 minutes and is usually given every 3 weeks.
- Your healthcare provider will decide how many treatments you need and may decrease your dose, temporarily stop or completely stop treatment with BLENREP if you have serious side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

Before receiving BLENREP, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of vision or eye problems.
- have bleeding problems or a history of bleeding problems.
- are pregnant or plan to become pregnant. BLENREP can harm your unborn baby. **Females who are able to become pregnant:** Your healthcare provider may do a pregnancy test before you start treatment with BLENREP. You should use effective birth control during treatment with BLENREP and for 4 months after the last dose. Talk to your healthcare provider about birth control methods you can use during this time. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with BLENREP. **Males with female partners who are able to become pregnant** should use effective birth control during treatment with BLENREP and for 6 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if BLENREP passes into your breast milk. Do not breastfeed during treatment with BLENREP and for 3 months after the last dose.
- BLENREP may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

These are not all the possible side effects of BLENREP.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Find out more by visiting **BLENREP.com**

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FIRSTLINE

compiled *by* JAMIE CESANEK and DARLENE DOBKOWSKI, M.A.

CNN Anchor Christiane Amanpour Receiving Treatment for Ovarian Cancer

CHRISTIANE AMANPOUR

CHRISTIANE AMANPOUR, chief international anchor for CNN, announced on air on June 14 that she had received a diagnosis of ovarian cancer.

"I've had successful major surgery to remove it, and I'm now undergoing several months of chemotherapy for the very best possible long-term prognosis, and I'm confident," Amanpour said in her announcement.

Amanpour, 63, is known for her coverage of international conflicts. She was off the air for four weeks before the announcement. She is scheduled to anchor Mondays through Wednesdays on CNN while undergoing months of chemotherapy and was three weeks off the air in June, according to a story on CNN.

"I'm telling you this in the interest of transparency, but in truth, really mostly as a shout-out to early diagnosis, to urge women to educate themselves on this disease to get all the regular screenings and scans that you can, to always listen to your bodies and, of course, to ensure that your legitimate medical concerns are not dismissed or diminished," Amanpour said.

Singer With Cancer Gets the Golden Buzzer on 'America's Got Talent'

JANE MARCZEWSKI, 30, got the coveted Golden Buzzer during her audition for "America's Got Talent" in June with a performance of her original song, "It's OK."

Marczewski revealed before the performance that she has been dealing with cancer for a few years. She said she has a 2% chance of survival and that there is cancer in her lungs, spine and liver.

> "You can't wait until life isn't hard anymore before you decide to be happy."
>
> — *JANE MARCZEWSKI*

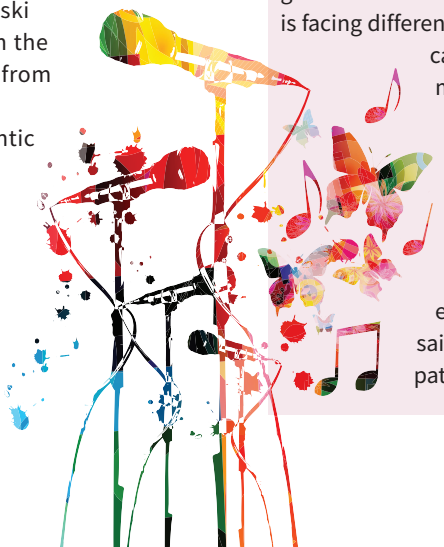
"It's important that everyone knows I'm so much more than the bad things that happened to me," Marczewski said.

After she performed, Marczewski received a standing ovation from the audience and positive feedback from the judges.

"That felt like the most authentic thing I have heard this season," said judge Howie Mandel.

Judge Simon Cowell hit the Golden Buzzer, which advanced Marczewski directly to the round of live shows in the competition.

"You can't wait until life isn't hard anymore before you decide to be happy," she said.



Hand to Heart Project Offers Massage Therapy to Patients With Cancer and Caregivers

THE HAND TO HEART PROJECT is a program that provides relaxing, supportive massage therapy to patients with cancer and their caregivers. It serves roughly 35 towns in New Hampshire and Vermont, delivering its services free of charge.

Clients are typically referred to the program through nurses, doctors, social workers or community organizations and receive therapy in their own homes. It is funded through grants, donations and fundraising events.

Steve Gordon, founder and executive director, created the project in 2007, though his interest began in 1999 when he entered massage therapy school.

"I had three people in my circle of awareness diagnosed with cancer. … I ended up doing a fair amount of massage with them, even when I was still in school, and it pulled my interest in that direction," Gordon said.

Patients report better sleep and less pain after sessions. Gordon said the program aims to consider that each person is facing different emotions during their cancer journey. The massage therapist's willingness to listen to clients often helps them feel better.

"For that one hour I forget about the battle and just let go of the emotions to focus on me," said Janette Coombs, a patient with breast cancer.

Filmmaker's Project Depicts Her Cancer Journey

TARA RULE RECEIVED a brain tumor diagnosis at 22 years old. She became severely sick from the disease, went through treatments and spent time in intensive care.

Rule decided to recreate the experience in a film with her friend, Laura LaFrate, to share her emotional story. The 50-minute film, "Cato," shows the challenges Rule faced, including treatment, severe symptoms and needing to use a wheelchair. The story is told from the perspective of Rule's cat, Cato.

"It felt like he needed me, and I know my family and friends needed me, too, but that day, when I was like, 'I can't do this anymore,' he just hopped up on me," Rule told Spectrum News. "I don't know what it was. He's kind of been this pillar for me."

The film premiered June 12 at the Madison Theatre in Albany, New York, with proceeds going to the Bernard and Millie Duker Children's Hospital at Albany Medical Center.

"There's a lot of missing pieces in my mind, and I think it helped me kind of see a point in my life that I wasn't really present for," Rule said.

Boy With Pediatric Cancer Has 'Army' of Supporters in His Montana City

JACK BERRY IS A 13-year-old from Missoula, Montana, with cancer. Throughout his cancer journey, which forced him to put activities including CrossFit, tennis, cycling, skiing, hockey, running and soccer on hold, he has received a great deal of support from his community.

"Obviously I want to be ... with my friends, and ... going to high school on the first day, but I mean, at some point, you just have to come to terms with (the fact that) you can't," Berry told KPAX. "And you know your life isn't the normal 13-year-old life. That's fine with me. I feel like I came to terms with that a while ago but it is kind of hard to not be doing what my friends are doing. But I think we do pretty well with enjoying our time here."

His supporters, coined "Jack's Army," have created signs of encouragement and fundraising events to support his treatment.

"Our goal is to make it so (Jack's father) doesn't have to think about work, so he can focus completely on his family," said Missoula Rural Fire District Captain Kory Burgess, a fellow firefighter who is a family friend. "We have guys step up and cover all his shifts for him so he can be 100% with his family, and not here, worried about work."

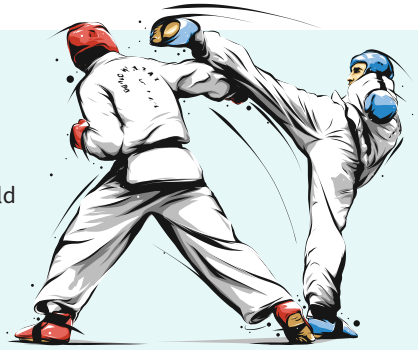
78-Year-Old Cancer Survivor Earns Black Belt in Taekwondo

TOM GUSTAFSON, 78, is a veteran and cancer survivor who has endured many other extensive medical procedures.

"I had cancer surgery in 2016. I have heart work. I have 11 stents and I am also diabetic," the Gulfport, Mississippi, resident told WLOX.

Gustafson started taking martial arts classes several years ago to stay healthy after his surgeon told him being active would improve his health.

"Both of my grandkids — actually all of my grandkids — went through taekwondo," Gustafson said, "so it encouraged me to go that way."



After three years of training, Gustafson was presented with a black belt in taekwondo in June. His wife had the privilege of tying the belt around his waist.

"I encourage especially elder people who sit down and hug the couch and watch TV to get active," Gustafson said.

TAEKWANDO: QUICKLINESTUDIO / STOCK.ADOBE.COM; FILM: IVECTOR / STOCK.ADOBE.COM

Medical World News®

LIVER CANCER

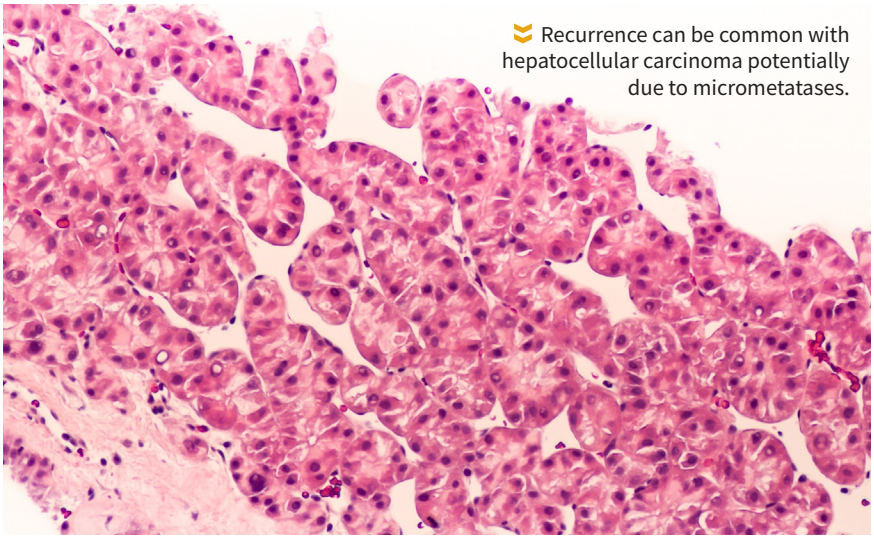
Neoadjuvant Libtayo Shows Promise

Twenty percent of patients with resectable hepatocellular carcinoma had a significant amount of cell death when receiving Libtayo before surgical intervention. *By* COLLEEN MORETTI

LIBTAYO (CEMIPLIMAB-RWLC), an immune checkpoint inhibitor, before surgery led to 20% of patients with resectable hepatocellular carcinoma experiencing significant tumor necrosis (the death of most or all cells in the organ due to disease), according to recent study results.

Surgery is the recommended first-line treatment for patients with early-stage hepatocellular carcinoma, although most tumors recur, which is hypothesized to be a result of micrometastases (small collections of cancer cells that shed from an original tumor and spread to another part of the body) after surgery. Neoadjuvant therapies such as Libtayo could improve these outcomes, although there is no recommended treatment in this setting.

"The pathological response data support larger trials to identify optimal clinical end points that correlate with improvement in survival and to establish the utility and safety of perioperative PD-1 in patients with resectable (hepatocellular carcinoma)," Dr. Thomas Urban Marron, assistant director of immunotherapy and early phase trials at the Tisch Cancer Institute and assistant professor at the Icahn School of Medicine at Mount Sinai in New York, said in a presentation on the data at the virtual American Association for Cancer Research Annual Meeting 2021.



Recurrence can be common with hepatocellular carcinoma potentially due to micrometatases.

DAVID A LITMAN / STOCK.ADOBE.COM

Twenty-one patients (median age, 68 years; 85.7% men) with hepatocellular carcinoma received 350 milligrams of Libtayo every three weeks for two cycles prior to the surgery, and then the same dosing regimen for eight cycles following the procedure for an additional eight cycles.

Significant tumor necrosis was defined as greater than 70% necrosis of the resected tumor and was reported in four out of 20 patients after treatment with Libtayo. Three patients (15%) achieved complete tumor necrosis and seven patients (35%) achieved at least 50% tumor necrosis.

There were 90.5% of patients who experienced at least one treatment-emergent side effect of any severity, and 28.6% of patients reported a side effect that was severe or worse.

The most common side effect was increased aspartate aminotransferase (which may indicate liver disease, heart issues or pancreatitis; 28.6%), increased alanine aminotransferase (potentially indicating liver diseases; 14.3%), increased blood creatine phosphokinase (injury or stress to the muscle tissue, heart or brain; 14.3%), constipation (14.3%) and fatigue (14.3%). The most common severe or worse side effects included elevated blood creatine phosphokinase (9.5%), increased aspartate aminotransferase (4.8%) and hypoalbuminemia (low level of albumin in the blood; 4.8%).

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Select Safety Information

CALQUENCE is a prescription oral treatment for adults with chronic lymphocytic leukemia or small lymphocytic lymphoma. May cause serious side effects including: serious infections, bleeding problems, decrease in blood cell count, new cancers, and heart rhythm problems. Some may lead to death. Tell your doctor if you experience infections such as flu-like symptoms; unexpected bleeding such as blood in your stool or urine; or heart rhythm problems such as fast or irregular heartbeat. Use sun protection when outside.

Please read Brief Summary of Prescribing Information on adjacent page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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CALQUENCE®
(acalabrutinib) 100 mg capsules

What is CALQUENCE?

CALQUENCE is a prescription medicine used to treat adults with:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

It is not known if CALQUENCE is safe and effective in children.

Before taking CALQUENCE, tell your healthcare provider about all of your medical conditions, including if you:

- have had recent surgery or plan to have surgery. Your healthcare provider may stop CALQUENCE for any planned medical, surgical, or dental procedure.
- have bleeding problems.
- have or had heart rhythm problems.
- have an infection.
- have or had liver problems, including hepatitis B virus (HBV) infection.
- are pregnant or plan to become pregnant. CALQUENCE may harm your unborn baby and problems during childbirth (dystocia).
  - If you are able to become pregnant, your healthcare provider may do a pregnancy test before you start treatment with CALQUENCE
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment with CALQUENCE and for at least 1 week after the last dose of CALQUENCE.
- are breastfeeding or plan to breastfeed. It is not known if CALQUENCE passes into your breast milk. Do not breastfeed during treatment with CALQUENCE and for at least 2 weeks after your final dose of CALQUENCE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking CALQUENCE with certain other medications may affect how CALQUENCE works and can cause side effects. Especially tell your healthcare provider if you take a blood thinner medicine.

How should I take CALQUENCE?

- Take CALQUENCE exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking CALQUENCE unless your healthcare provider tells you to.
- Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking CALQUENCE if you develop certain side effects.
- Take CALQUENCE 2 times a day (about 12 hours apart).

(continued)

- Take CALQUENCE with or without food.
- Swallow CALQUENCE capsules whole with a glass of water. Do not open, break, or chew capsules.
- If you need to take an antacid medicine, take it either 2 hours before or 2 hours after you take CALQUENCE.
- If you need to take certain other medicines called acid reducers (H-2 receptor blockers), take CALQUENCE 2 hours before the acid reducer medicine.
- If you miss a dose of CALQUENCE, take it as soon as you remember. If it is more than 3 hours past your usual dosing time, skip the missed dose and take your next dose of CALQUENCE at your regularly scheduled time. Do not take an extra dose to make up for a missed dose.

What are the possible side effects of CALQUENCE?

CALQUENCE may cause serious side effects, including:

- **Serious infections** can happen during treatment with CALQUENCE and may lead to death. Your healthcare provider may prescribe certain medicines if you have an increased risk of getting infections. Tell your healthcare provider right away if you have any signs or symptoms of an infection, including fever, chills, or flu-like symptoms.
- **Bleeding problems (hemorrhage)** can happen during treatment with CALQUENCE and can be serious and may lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider if you have any signs or symptoms of bleeding, including:
  - blood in your stools or black stools (looks like tar)
  - pink or brown urine
  - unexpected bleeding, or bleeding that is severe or you cannot control
  - vomit blood or vomit that looks like coffee grounds
  - cough up blood or blood clots
  - dizziness
  - weakness
  - confusion
  - changes in your speech
  - headache that lasts a long time
  - bruising or red or purple skin marks
- **Decrease in blood cell counts.** Decreased blood counts (white blood cells, platelets, and red blood cells) are common with CALQUENCE, but can also be severe. Your healthcare provider should do blood tests to check your blood counts regularly during treatment with CALQUENCE.

(continued)

- **Second primary cancers.** New cancers have happened in people during treatment with CALQUENCE, including cancers of the skin or other organs. Your healthcare provider will check you for skin cancers during treatment with CALQUENCE. Use sun protection when you are outside in sunlight.
- **Heart rhythm problems (atrial fibrillation and atrial flutter)** have happened in people treated with CALQUENCE. Tell your healthcare provider if you have any of the following signs or symptoms:
  - fast or irregular heartbeat
  - dizziness
  - feeling faint
  - chest discomfort
  - shortness of breath

The most common side effects of CALQUENCE include:

- headache
- diarrhea
- muscle and joint pain
- upper respiratory tract infection
- bruising

These are not all of the possible side effects of CALQUENCE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store CALQUENCE?

- Store CALQUENCE at room temperature between 68°F to 77°F (20°C to 25°C).

Keep CALQUENCE and all medicines out of the reach of children.

General information about the safe and effective use of CALQUENCE.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use CALQUENCE for a condition for which it was not prescribed. Do not give CALQUENCE to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about CALQUENCE that is written for health professionals.

What are the ingredients in CALQUENCE?

Active ingredient: acalabrutinib

Inactive ingredients: silicified microcrystalline cellulose, pregelatinized starch, magnesium stearate, and sodium starch glycolate.

Capsule shell contains: gelatin, titanium dioxide, yellow iron oxide, FD&C Blue 2, and black ink.

AstraZeneca

For more information, go to www.CALQUENCE.com or call 1-800-236-9933.

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US-34063 11/19

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 11/2019 US-34063 11/19

CLL

Imbruvica Plus Ublituximab Safely Improves Response Rate

Imbruvica plus ublituximab improved outcomes in relapsed/refractory high-risk chronic lymphocytic leukemia with minimal residual disease negativity.

By COLLEEN MORETTI

THE ADDITION OF UBLITUXIMAB to Imbruvica (ibrutinib) demonstrated a better overall response rate in patients with relapsed or refractory high-risk chronic lymphocytic leukemia compared with Imbruvica alone, according to data recently published in *The Lancet*.

Previously, patients with chronic lymphocytic leukemia and high-risk features had poor outcomes with Imbruvica. Based on this, researchers sought to discover if there was a benefit to adding ublituximab to Imbruvica for this population.

"To our knowledge, this is the first randomized trial to show improvement in progression-free survival with the addition of an anti-CD20 agent (ublituximab) to (Imbruvica) in chronic lymphocytic leukemia, which could meaningfully affect treatment choices for this disease," the study authors wrote.

This phase 3 study consisted of 126 patients who were assigned either Imbruvica plus ublituximab (64 patients; median age, 66 years) or Imbruvica alone (62 patients; median age, 67 years). Imbruvica was given orally at a 420-milligram dose every day for all cycles. Ublituximab was given intravenously in 28-day cycles at varying doses.

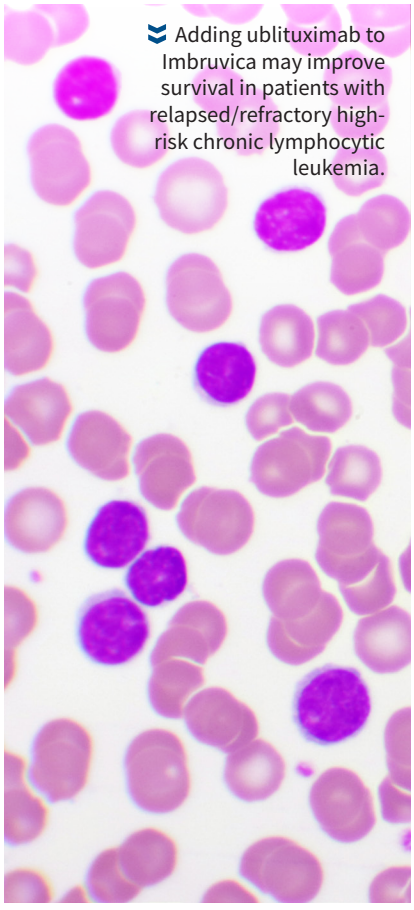
After a median follow-up of 41.6 months, the overall response rate ("defined as the proportion of patients who had a partial response, complete response or complete response with incomplete marrow recovery," according to the study authors) was 83% in the group that received the combination treatment and 65% in those who received Imbruvica alone.

A complete response was observed in 19% of patients assigned to the combination therapy, compared with 5% assigned to Imbruvica alone.

More patients achieved minimal residual disease negativity (no disease detected after treatment) in the combination group than in the group that only received Imbruvica (42% versus 6%, respectively).

The safety analysis included 117 patients (59 patients in the combination group and 58 patients in the Imbruvica alone group) who received at least one dose of their assigned treatment. Most side effects were considered mild or moderate. The most common severe or life-threatening side effects were low white blood cell counts, (19% and 12%, respectively), anemia (8% and 9%) and diarrhea (10% and 5%). The most common serious side effects were pneumonia (10% and 7%, respectively), rapid heart rate (7% and 2%), severe response to infection (7% and 2%) and fever (5% and 2%). One death was considered to be treatment related, due to cardiac arrest in the Imbruvica alone group.

"Despite ... limitations, clinically meaningful improvements in overall response rate, complete response and response were observed and translated into improved progression-free survival," the study authors wrote. "These findings indicate the benefit of adding the next-generation anti-CD20 antibody ublituximab to (Imbruvica) in patients with relapsed and refractory high-risk chronic lymphocytic leukemia."



Adding ublituximab to Imbruvica may improve survival in patients with relapsed/refractory high-risk chronic lymphocytic leukemia.

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Medical World News

KIDNEY CANCER

Higher BMI May Be Associated With Improved Overall Survival

Higher BMI may be associated with better survival among patients with metastatic renal cell carcinoma who were treated with immune checkpoint inhibitors.

By JAMIE CESANEK

AN ELEVATED BODY MASS INDEX (BMI) was associated with improved overall survival in patients with metastatic renal cell carcinoma who were treated with PD-1/PD-L1-based immune checkpoint inhibitors, according to data from a recent multinational analysis published in *JAMA Oncology*.

These findings were consistent with the clinical phenomenon referred to as the "obesity paradox," where patients with metastatic renal cell carcinoma with elevated BMI tend to experience better outcomes.

In an interview with *CURE*®, Dr. Aly-Khan Lalani, a medical oncologist and assistant professor at McMaster University and one of the study authors, went further in depth on the findings. "Previous studies had shown that patients with a higher BMI — typically defined as a measurement of 25 kg/m^2 or more — had a higher likelihood of being diagnosed with kidney cancer, but also tended to benefit more from targeted therapies for advanced disease," Lalani said. "Our study, conducted in the immunotherapy era, also showed that (metastatic renal cell carcinoma) patients with a higher BMI appear to have improved clinical outcomes compared to those with lower BMI."

After a shift in the treatment landscape included immune checkpoint inhibitors for most patients, the researchers sought to determine whether patients with metastatic renal cell carcinoma receiving this treatment fit with previous evidence of higher BMI as a positive prognostic factor. They also aimed to explore potential genomic alterations according to BMI status.

In their analysis, the researchers examined the association of BMI with overall survival, time to treatment failure and objective response. Genomic alteration frequencies and tumor mutational burden were also compared by BMI status in patients with available next-generation sequencing data.

A total of 735 patients with metastatic renal cell carcinoma were treated with a PD-1/PD-L1-based immune checkpoint inhibitor. Of the participants, 229 (31%) received first-line immune checkpoint inhibitors and 230 (31%) received a combination regimen. At the initiation of immune checkpoint inhibitor therapy, 274 (37%) had a low BMI (of less than 25) and 461 (63%) had a high BMI (defined as 25 or greater). Median follow-up was 13.5 months.

Overall, the researchers found that patients with a high BMI showed improved overall survival compared with those with a low BMI (one-year overall survival: 79% vs. 66%, respectively). Patients with higher BMIs also had a numerically higher overall response rate (30% versus 21%, respectively) and time to treatment failure (median, 7.4 months versus 4.9 months).

Of the 319 patients with available next-generation sequencing data, genomic alteration frequencies and tumor mutational burden were found to be similar between BMI groups. The authors noted that the study did have some limitations; particularly the lack of robust gene-expression profiling.

The clinical observations made in this study could be explained by several hypotheses, the authors explained. "Low fatty acid synthase gene expression, which is inversely correlated with BMI, was associated with longer (overall survival) in VEGF-treated patients," they wrote.

Other hypotheses include that patients with obesity may have tumors with increased gene signatures, denoting the development of new blood vessels. Patients with higher BMI may have adipose tissue, which stores energy in the form of fat, with increased hypoxia (low oxygen), inflammation and immune cell infiltration signatures, which could result in enhanced benefit from immunotherapy.

"Our study highlights that BMI alone is not the complete story for the patient's underlying health status," said Lalani. "There may be other important biological underpinnings at either the tumor level or from the adipose tissue level that we need to deeply understand."

"While BMI can be easily recorded when patients go into clinic, there are other relevant indicators of our patients' health status such as cancer cachexia or sarcopenia (where there's loss of muscle mass). Ultimately, our results provide further motivation to better understand the overall health status of our (metastatic renal cell carcinoma) patients — beyond their BMI — and how we can explain and improve their responsiveness to immunotherapy."

The authors noted that more work is necessary to explore the biological foundations for similar findings across other solid tumors treated with immune checkpoint inhibitors.

BREAST CANCER

Surge in Unhealthy Habits

Women who received a breast cancer diagnosis were more likely to develop unhealthy behaviors one and two years after diagnosis, even if they were considered healthy at time of their diagnosis.

By COLLEEN MORETTI

MOST WOMEN HAD HEALTHY lifestyles at the time of their breast cancer diagnosis, although several developed unhealthy behaviors such as tobacco use, alcohol consumption and weight gain one and two years after diagnosis, according to data published in *Cancer*.

Based on these results, researchers recommend that there should be a system to help this patient population combat unhealthy behaviors.

"At this point, we know that health behaviors are very important in cancer survivorship. Understanding the patterns of change and their determinants is important for us as oncologists to improve health behaviors over the course of the trajectory of survivors," Dr. Antonio Di Meglio, medical oncologist at the Breast Cancer Survivorship Research Program at Gustave Roussy Cancer Campus in Villejuif, France, said in an interview with *CURE*®.

Previous evidence has indicated that there are multiple benefits for a survivor to pursue a healthy lifestyle; however, unhealthy habits are still prevalent among women who have received a diagnosis of breast cancer, due to psychological and treatment effects.

Researchers sought to discover the prevalence of unhealthy behaviors at diagnosis, one year and two years after in 9,556 women (mean age, 56.3 years) who survived early-stage breast cancer.

"The question that we assessed in this specific study was whether cancer is truly a teachable moment for patients," Di Meglio said.

Unhealthy behaviors were defined as failure to meet physical activity recommendation (10 or more metabolic equivalent task-hours per week), failure to quit or reduce tobacco usage, failure to decrease alcohol consumption to less than daily or gaining substantial weight over time.

At the time women received a breast cancer diagnosis, 41.7% were inactive (they did not meet physical activity recommendations), 18.2% were using tobacco, 14.6% consumed alcohol daily and 48.9% were overweight or obese. The authors noted that one in three tobacco smokers and one in 10 women who consumed alcohol every day improved their behaviors after their breast cancer diagnosis.

"I think we now have sufficient data to support the notion that physical inactivity and persistent tobacco use, for example, are associated with a number of worse outcomes for survivors," Di Meglio noted. He added that obesity and being overweight can potentially worsen outcomes and quality of life.

After one and two years following diagnosis, 37% and 35.6% of patients, respectively, reported having unhealthy behaviors related to physical activity, respectively. This was also seen with tobacco usage (11.4% and 9.5%) and unhealthy alcohol consumption (13.1% and 12.6%, respectively).

After one year, 9.4% of women were originally underweight or normal weight and transitioned to overweight or obese. The rate of this occurring was 5.9% after two years. In women who were overweight and obese at diagnosis, at least 5% body weight was gained in 15.4% of women after one year and in 16.2% after two years.

Within a five-year increment, older women were more likely to report unhealthy alcohol consumption and were inactive. In contrast, these women were less likely to use tobacco. An increased risk for depression was associated with a lower likelihood of unhealthy tobacco use and a higher likelihood of unhealthy alcohol consumption. Women with a college education were less likely than those with a primary school education to report an unhealthy physical activity behavior and more likely to report an unhealthy alcohol consumption.

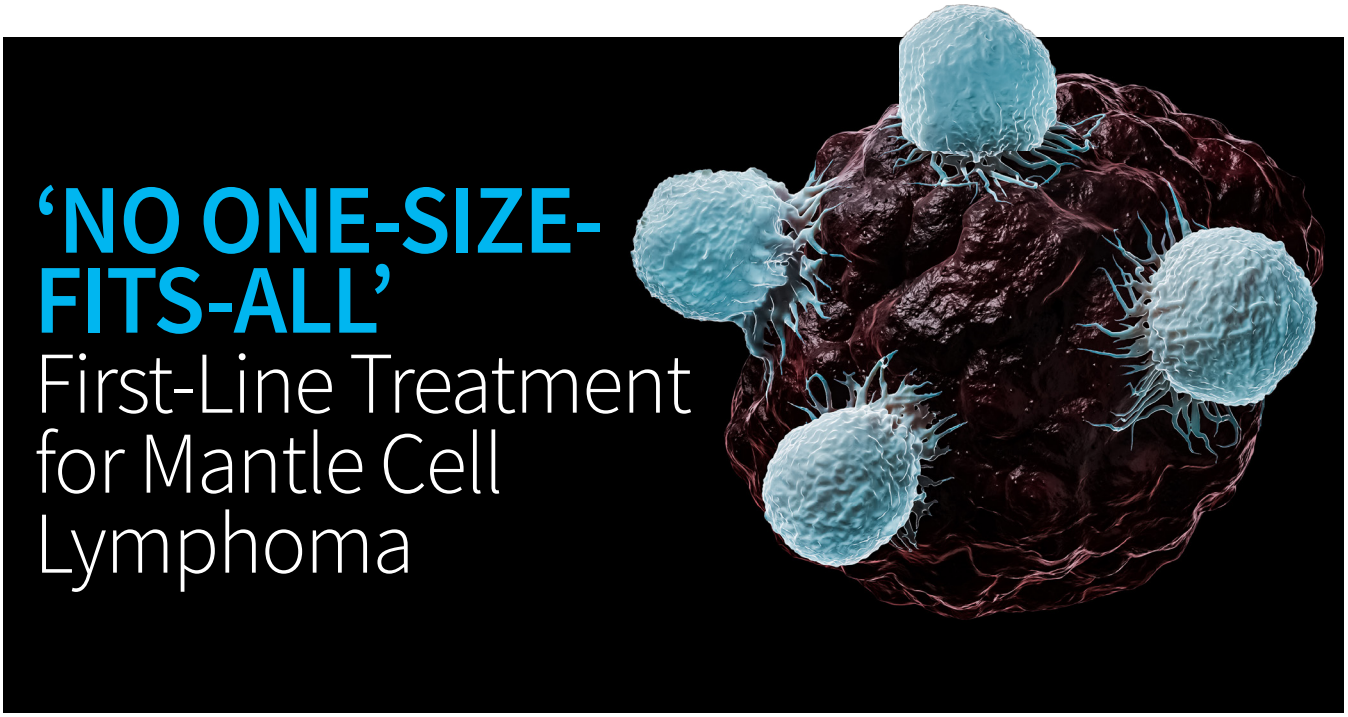
In women who were overweight or obese at the time of diagnosis, patients treated with chemotherapy were more likely to gain weight than those who did not.

"A cancer diagnosis doesn't seem, per se, to be a really strong motivator alone to change a patient's behavior, so we should always support and motivate patients," Di Meglio said.

He also mentioned using programs that are in place that can help facilitate healthy behaviors, although he understands not all patients have access to this.

"Behavioral change is very difficult," Di Meglio said. "There (are) a number of factors that actually influence behavior change. There (are) contextual factors, patient-related factors and also community and personal resources that have to be put in place to facilitate the change. If someone is not physically active at the moment of diagnosis, there (are) a lot of data that now support that improving physical activity and increasing activity may also help with general outcomes and cancer-specific outcomes." C

‘NO ONE-SIZE-FITS-ALL’ First-Line Treatment for Mantle Cell Lymphoma



Patients can now prioritize whether durable responses to treatment or avoiding certain side effects are more valuable to them. *By* DARLENE DOBKOWSKI, M.A.

PROGRESS IN TREATING mantle cell lymphoma (MCL) has allowed patients to weigh their options for first-line therapies. Despite this progress, disease progression or recurrence is still common in these patients, so patients must be aware of their quality of life when undergoing first-line and subsequent therapies.

During a presentation at the 2021 ASCO Annual Meeting, Dr. Brian K. Link, professor of internal medicine-hematology, oncology and blood and marrow transplantation at the University of Iowa in Iowa City, discussed how we can “unquestionably” do better regarding first-line therapies for MCL and why research focusing on quality-of-life outcomes is critical. *CURE®* spoke with Link to learn more about why frontline therapy for this disease is important even though the order in which treatment is administered may not impact outcomes as much as researchers previously believed.

Q: What is upfront therapy for MCL?

A: Mantle cell lymphoma is a serious disease. Most people, but not all, who are afflicted with mantle cell lymphoma will likely have their life shortened because of (the disease), and almost everybody will have their quality of life affected.

Invariably, for the vast majority of patients, we feel the need to alter that risk of suffering from lymphoma and/or dying from lymphoma by treating (it) with a variety of medical therapies. Surgery and radiation are not commonly part of the management plan. A high percentage of patients will have multiple courses of treatment intermittently over the course of their lifetime, and the first treatment chosen is generally what we refer to as upfront therapy.

Q: Why may the upfront therapy patients receive be important to outcomes?

A: The outcomes for mantle cell lymphoma have improved substantially over the past 10 to 15 years. Two of the abstracts discussed at ASCO essentially started around 2010. Back in 2010, the prevailing evidence suggested that half of patients who were diagnosed with mantle cell lymphoma would die within the first four years. At that time, accordingly, the choice of which therapy to use first was critically important in an effort to mitigate that risk of early death.

In the subsequent 10 to 15 years, the likelihood of dying within four years has substantially reduced such that we now look at upfront treatment options for patients with mantle cell lymphoma with an eye toward what is likely going to be the second

continued on page 26 »

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For the treatment of **mantle cell lymphoma**

BRUKINSA® (zanubrutinib) is a BTK inhibitor that was designed to completely block BTK

- Mantle cell lymphoma (MCL) is caused by rapid growth and spread of cancerous B cells
- Bruton's tyrosine kinase (BTK) is a protein that signals to cancerous B cells, helping them to grow and spread
- Blocking BTK can help stop this signaling

BRUKINSA has been shown to block 100% of BTK in blood cells and 94% to 100% of BTK in lymph nodes when taken at the recommended total daily dose of 320 mg. The significance of completely blocking BTK on treatment responses has not been established.

BRUKINSA is a BTK inhibitor for adults with mantle cell lymphoma who have received at least 1 prior therapy. BRUKINSA was approved based on response rate. There is ongoing evaluation to confirm clinical benefit for this use. It is not known if BRUKINSA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What should I tell my healthcare provider before taking BRUKINSA?

Before taking BRUKINSA, tell your healthcare provider about all of your medical conditions, including if you:

- have bleeding problems
- have had recent surgery or plan to have surgery. Your healthcare provider may stop BRUKINSA for any planned medical, surgical, or dental procedure.
- have an infection
- have or had heart rhythm problems
- have high blood pressure
- have liver problems, including a history of hepatitis B (HBV) infection.
- are pregnant or plan to become pregnant. BRUKINSA can harm your unborn baby. If you are able to become pregnant, your healthcare provider may do a pregnancy test before starting treatment with BRUKINSA.
  - **Females** should not become pregnant during treatment and at least 1 week after the last dose of BRUKINSA. You should use effective birth control (contraception) during treatment and for at least 1 week after the last dose of BRUKINSA.
  - **Males** should avoid getting female partners pregnant during treatment and for at least 1 week after the last dose of BRUKINSA.
- are breastfeeding or plan to breastfeed. It is not known if BRUKINSA passes into your breast milk. Do not breastfeed during treatment with BRUKINSA and for at least 2 weeks after your last dose of BRUKINSA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking BRUKINSA with certain other medications may affect how it works and can cause side effects.

What are the possible side effects of BRUKINSA?

BRUKINSA may cause serious side effects, including:

- **Bleeding problems (hemorrhage)** that can be serious and may lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider if you have any signs or symptoms of bleeding, including:
  - blood in your stools or black stools (looks like tar)
  - pink or brown urine
  - unexpected bleeding, or bleeding that is severe or you cannot control
  - vomit blood or vomit that looks like coffee grounds
  - cough up blood or blood clots
  - increased bruising
  - dizziness
  - weakness
  - confusion
  - changes in your speech
  - headache that lasts a long time
- **Infections** that can be serious and may lead to death. Tell your healthcare provider right away if you have fever, chills, or flu-like symptoms.
- **Decrease in blood cell counts.** Decreased blood counts (white blood cells, platelets, and red blood cells) are common with BRUKINSA, but can also be severe. Your healthcare provider should do blood tests during treatment with BRUKINSA to check your blood counts.
- **Second primary cancers.** New cancers have happened in people during treatment with BRUKINSA, including cancers of the skin. Use sun protection when you are outside in sunlight.
- **Heart rhythm problems (atrial fibrillation and atrial flutter).** Tell your healthcare provider if you have any of the following signs or symptoms:
  - your heartbeat is fast or irregular
  - feel lightheaded or dizzy
  - pass out (faint)
  - shortness of breath
  - chest discomfort

The most common side effects of BRUKINSA include:

- decreased white blood cells
- decreased platelet count
- rash
- diarrhea
- upper respiratory infection
- decreased red blood cells (anemia)
- bruising
- cough

These are not all the possible side effects of BRUKINSA. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

What is BRUKINSA?

BRUKINSA is a prescription medicine used to treat adults with mantle cell lymphoma (MCL) who have received at least one prior treatment for their cancer.

It is not known if BRUKINSA is safe and effective in children.

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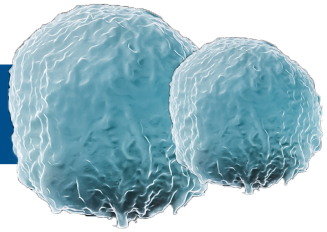

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treatment and the third treatment since now more patients will be living five, 10 and 15 years. None of the treatments yet will result in (a) cure, so we still anticipate there will be multiple treatments over the course of a lifetime, and the choice of upfront treatment may not be as important as it was 10 years ago.

Q: What are other takeaways from your presentation?

A: Because we now have many effective therapies, it's important to recognize that we as doctors do not agree on a one-size-fits-all (treatment). Thus, when patients ask "What's the best treatment for me?" they should recognize (that) their doctor may not know of one single, best upfront therapy. They may know other patients with mantle cell lymphoma who are getting other choices for upfront therapy. They may get a second or third opinion from other doctors who may not all agree on what the best choice is for upfront therapy for them.

Patients need to recognize increasingly (that) they have a choice. Some of their choice will be philosophical. As a rule of thumb, some of the more aggressive treatments in the upfront setting may last a little longer but may involve more impact on their quality of life up front. For some patients, that may be appropriate. For other patients, they may prefer a gentler approach, recognizing that the effects may not last as long.

Because there are now so many treatments available, there is less critical importance, perhaps, on which therapy is given as first choice because the second, third and fourth treatments may have as much impact on their overall quality and duration of life as the first-line (treatment).

Q: What is the impact to quality of life that patients may expect with these choices?

A: Some of the treatments require hospitalization to be administered. Others can be delivered as an outpatient basis. Some of the treatments are a little bit more intense but have a fixed duration of time, meaning three to six months of treatment and then there's a cessation of treatment with observation. Other therapies are given chronically, often with oral medications, but sometimes intravenous medications, but the therapy goes on for a period of many years. Patients will want to assess how (they) feel about chronically being treated.

And then other things are more subtle, such as some of the treatments would cause cosmetic changes, such as hair loss, while others may result in fatigue, bowel irregularities, long-term risk of heart damage or rashes. There's a whole variety of different side effects with the different therapies available, and patients should feel free to ask about all those options and then weigh for themselves which ones are least desirable.

Q: During your presentation, you said MCL may be increasingly recognized as a chronic disease. What do you think this may do to the treatment of MCL or the research within this disease state?

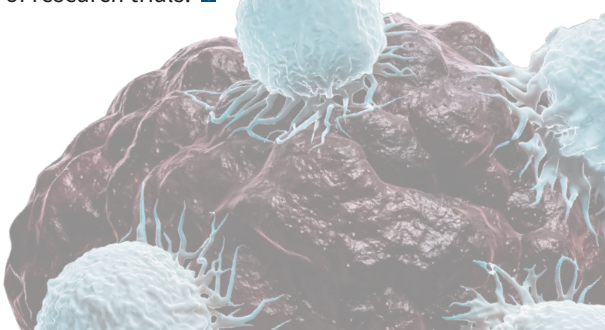
A: I have fairly strong opinions about that because patients can now anticipate living a long time. Because they will have many treatment choices available to them, they'll want to choose treatments that have an impact on something other than how long they're going to live. We need to hear from the patients about what's important there. Choices could include (that) they may prefer to have long periods of time where they're not taking treatment, or it may include other elements of quality of life that we as clinical researchers and doctors can only really speculate about because we're not the ones who are facing the decisions patients are. To the extent that patients want to have a role in shaping research moving forward, they should use patient-focused lymphoma societies such as the Lymphoma Research Foundation and advocacy groups to work with clinical researchers to develop quality-of-life outcomes in future research.

Q: What's an important message about MCL treatment that patients should know?

A: There is no one-size-fits-all in the upfront (setting), so patients will really want to be aware of that if they either seek multiple opinions from other doctors or if they seek other experiences from other patients.

(Also,) I want to emphasize that the choice of therapy that they make for first treatment is not as important as it used to be because there will undoubtedly be second treatments, third treatments and fourth treatments. We really don't know the impact of sequence.

The last point I want to make is several of these choices would involve different short-term and long-term impacts on their quality of life and daily life. They'll want to be aware of what their personal choices are when making these decisions and they'll want to work with advocacy groups to build measurements of quality of life into the next generation of research trials.



CANCER

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FOUR-LEGGED SUPPORT SYSTEMS DURING CANCER TREATMENT

We asked readers on *CURE*®'s Facebook and Twitter pages to share stories and photos of a major support system in their lives: **their pets. Here's what they told us.**

Meet **KONA**, my daughter's beautiful German Shepherd (who) comes to visit Grammy often. Kona is magical. I look at her pics when I'm in treatments, and she always brings a laugh or smile my way. She fills my heart with peace and joy! I forget cancer when we're together. – *J.D.*

When I was diagnosed with (acute promyelocytic leukemia) in 2010, I had a cat (named) **QUICKSILVER** and a dog named **ZOE**. When I came home from the hospital, they were both so glad to see me. For the longest time, they sat on or beside me. Their companionship was such a comfort to me. When I was in the hospital, I received stuffed animals as gifts to represent them. In 2013 when my bone marrow failed, I no longer had Quicksilver but a new dog, **HOWIE**, had joined my household. Howie and Zoe gave me a reason to get up every day and to keep fighting. I wanted so badly to be able to walk and play with them again. They are intrinsically linked to my cancer journey. Both Zoe and Howie died a year ago and I feel like a chapter in my life has closed. I now have **BIANCA** for the (next) part of my journey. – *M.I.*

DIVA was my earthly angel. While going through chemo, she was my shadow. I would sometimes get so cold and shiver, she would jump up on the couch and keep me warm, and she would not let me out of her sight. Diva also made sure I got some exercise. She crossed the rainbow bridge in April 2019 and I know she still watches over me. – *D.H.*

They keep me company and gave me a reason to fight it. – *E.L.P*

During chemo when I had a fever, my girls **AXEL** and **LUSSI** wrapped themselves around me like a neck pillow. They provided warmth and comfort. – *T.L.N.*

(BUTTERS &TORTELLINI) were only quiet when I let them sleep (with) me. – *M.I.*

My **JOEY** snuggles with me after every chemo treatment. – *A.B.*

HEIDI, the not-so-mini schnauzer. She got me outside and exercising even when I didn't feel like it. – *M.H.*

After my husband (died) from small cell lung cancer, my **MISSHER** kept me alive. She was there without her daddy, so I had to be there for her. – *S.R.N.*

INDIANA is a 15-year-old Maine Coon cat that has spent every bit of my cancer journey with me. It was April of 2016 when Indy forcibly stuck his nose in my mouth and sniffed and sniffed. I jokingly said he knows I'm not feeling well, I wonder if he knows what is wrong with me. The next month, I was diagnosed with ovarian cancer. I spent a week in the hospital after surgery. He was thrilled to have me back home and rarely left my side. He has been my nurse, my TV buddy, my lap and leg warmer, a companion and a true supportive friend. Today I am still fighting the side effects of cancer and chemo but happier having my furry friend nearby. – *J.O.*

Take an Active Role in Managing Polycythemia Vera (PV)

If you or a loved one is living with PV, you know that regular monitoring and medical care are important to help detect changes in your condition. Keeping your blood counts—particularly your hematocrit (a measure of red cells in the blood)—at the right levels is an important goal in managing PV. By tracking your symptoms and blood counts, you and your Healthcare Professional can work to control your disease and reduce the risk of complications.

Taking notice of any changes in symptoms can help you take an active role in your PV care! New or changing PV symptoms could be a sign that your disease is progressing. Be sure to discuss any changes in your PV symptoms with your Healthcare Professional. Together, you can determine the best approach for managing your PV.

Start the Conversation With Your Healthcare Professional

It is important to tell your Healthcare Professional about any symptoms you have, **even if you are not sure they are related to your PV**. This helps you both:

- Understand how PV is affecting you
- Follow how your PV is changing over time

Get more information about PV. Visit **PVSymptom.com** today.

Help Keep Your PV Under Control

Check off the information below that applies to you, and then share your answers with your Healthcare Professional.

COMMON PV SYMPTOMS

- ☐ Tiredness or fatigue
- ☐ Headaches or dizziness
- ☐ Itching, especially after a warm shower
- ☐ Sweating (at night or during the day)

SYMPTOMS RELATED TO ENLARGED SPLEEN IN PV

- ☐ Pain or discomfort under your left ribs
- ☐ Feeling full when you haven't eaten or have eaten very little

CHANGES TO SYMPTOMS AND DAILY ACTIVITIES

- ☐ Have you experienced any new symptoms?
- ☐ Have any of your symptoms become more frequent or severe?
- ☐ Are there activities you were able to do 3 months ago that you struggle with now?

OTHER CONSIDERATIONS

- ☐ Are your hematocrit, white blood cell, and platelet counts at the right levels?
- ☐ Any side effects from your current medications?
- ☐ Have you needed phlebotomy in addition to other treatments?

If you checked any of the boxes above, **take action and talk to your Healthcare Professional** to learn if your PV is under control.

Pet Companionship During the Cancer Journey

Having a pet to care for may motivate patients to exercise and be positive when undergoing cancer treatment. By DARLENE DOBKOWSKI, M.A.

PET COMPANIONSHIP — regardless of the animal — can mean a lot to people, especially during turbulent times in their lives such as receiving a cancer diagnosis and undergoing treatment. It is common for patients to show photos of their pets to nearly everyone and treat them similar to their children. Pets can play an integral role in patients' lives.

For patients with cancer, pets can also motivate them to exercise and bring positivity to their lives.

"Sometimes taking care of a pet offers certain demands, and sometimes they can be a challenge, but many patients do talk about the positive aspects (of pet companionship) and how having a pet pushes them to be more active and also brings some joy to their lives," said Dr. Aminah Jatoi, an oncologist and the Betty J. Foust, MD, and Parents' Professor of Oncology at Mayo Clinic College of Medicine and Science in Rochester, Minnesota, in an interview with *CURE*®.

The benefits of pet companionship during cancer treatment have been a focus of research for years, including one study reporting results of a survey completed by patients with cancer during chemotherapy published in the *Journal of Cancer Education* in 2010. Researchers aimed to assess the benefits and potential negative effects of pet ownership in these patients, such as who would care for a patient's pet if their cancer worsened, for example.

"It really surprised me and … surprised everybody else on our team. What we learned was that it wasn't a sense of worry," Jatoi said. "In fact, the majority of people who were part of that study said that they had contingency plans for their pets. They had plans in place (for) if (patients) didn't do well (from their) cancer … which made me think that if it is a source of stress, people have cared so much about their pets that they've made it so that their pets would be taken care of. … I think it really showed that pets mean an awful lot to people who have cancer."

The type of pet a person has — dog, cat, lizard, horse or other animal — may not indicate the benefit one may obtain from their companionship, and Jatoi noted that not every person will be suitable for a pet.

"It's probably very person-specific," she said. "There are probably some people for whom having a pet is just not the right thing to do. You certainly don't want to figure that out the hard way and then have to give up on that pet."

For patients who enjoy the companionship of a pet but cannot have one because of their living arrangement or other circumstances, some institutions including Mayo Clinic have pet therapy programs. Jatoi mentioned a former patient who was depressed from a prolonged hospital stay and wouldn't speak much to the staff. With the help of a dog named Jack, who also has a book written about him, Jatoi said this patient became a new person.

"I remember the first day after (Jack) entered that room, the whole ambiance … changed," Jatoi recalled. "The drapes were open. The patient was smiling. He was so much more interactive than he had been, and I know Jack made a huge difference."

Jatoi said oncologists don't typically ask about patients' pets during visits or treatment.

"I think the message there is that we, as cancer health care providers, maybe don't focus as much on pets and what they mean to patients as we probably should," Jatoi said.

That doesn't mean that all oncologists don't ask about pet ownership. Jatoi recalled a now-retired doctor who would make notes about things that were very meaningful to patients, which was often their pets. He would go as far as to include the pets' names so he would remember for the next visit.

"If it meant a lot to (patients), it meant a lot to him. We probably don't do that enough," Jatoi said. C

CURE Extraordinary HEALER 2021

MARIA LIM, B.S.N., RN, OCN, BMTCN,

Wins *CURE*®'s 2021 Extraordinary Healer® Award for Oncology Nursing

CURE Media Group also recognized **Jennifer E. Giovanni, Ph.D., M.S.N., M.P.H., RN**, as winner of The Finest Hour award, which highlights the dedication and selflessness exhibited in front-line workers during the COVID-19 pandemic. *By* DARLENE DOBKOWSKI, M.A.

CURE MEDIA GROUP recognized Maria Lim, B.S.N., RN, OCN, BMTCN, as the winner of its 2021 Extraordinary Healer® Award for Oncology Nursing, which honors the expertise, compassion, and helpfulness seen among nurses in the cancer community.

In addition, Jennifer E. Giovanni, Ph.D., M.S.N., M.P.H., RN, received The Finest Hour award, which recognizes the selfless achievements of a nurse caring for patients during the COVID-19 pandemic.

Essays were submitted by colleagues, patients, and family members that identified Lim, two finalists and nearly 100 other Extraordinary Healer® nominees, all detailing the noble acts of oncology nurses. These ranged from providing a shoulder to cry on or a blanket to keep warm to making accommodations above and beyond the call of duty so that patients' experiences during cancer treatment are a little more tolerable. For The Finest Hour award, Giovanni was one of over 20 nominations. Both awards were presented on April 29 during a virtual celebration held in conjunction with the 46th Annual Oncology Nursing Society Congress.

ARIELLE GALLIONE

MARIA LIM, B.S.N., RN, OCN, BMTCN, and nominator, **BRADFORD EVANS.**

Lim, a nurse since 1993, moved from the Philippines to the United States and serves as a hematology/oncology/infusion clinic nurse at the Captain James A. Lovell Federal Health Care Center in North Chicago, Illinois. She was nominated by one of her patients, who considers her the modern-day "angel of the battlefield." Lim aims to be not only a nurse but a support system for all her patients, some of whom have battles beyond cancer, with posttraumatic stress disorder, for example.

Giovanni, who was previously a travel nurse, started her life of serving others in 1995 when volunteering with the Peace Corps. Since then, she has worked for several agencies, including the Centers for Disease Control and Prevention and the U.S. Air Force. Most recently, she has worked in New York and New Jersey as a crisis response critical care nurse in areas severely affected by the COVID-19 pandemic.

Finalists for the Extraordinary Healer® award included Jessica Ellison, M.S.N., B.A., RN, a transplant coordinator at Rush University Medical Center in Chicago, Illinois, and Katherine Gacek, B.S.N., RN, OCN, a nurse navigator from the University of Chicago Medicine.

Mike Hennessy Jr., president and CEO of MJH Life Sciences™, the parent company of CURE Media Group, mentioned that he had experienced the impact oncology nurses have directly. His mother, Patti Hennessy, »

died in January 2020 after living with breast and ovarian cancers for nine years.

"The nominations come from your patients, your coworkers and loved ones, and it's just utterly remarkable," Hennessy said. "After reading through the different essays we received and seeing firsthand the care that my mother received during her battles with cancer, it is clear that oncology nurses are the most selfless, caring and truly inspiring individuals that you can be around. The way that you're all able to comfort patients in what is probably the most traumatic time of their lives is inspiring."

Angel of the Battlefield

Lim was nominated by her patient Bradford Evans, whom she has known for almost five years this coming August. In his interview, Evans said he can't imagine working with any other attending nurse and calls her the "helping hands" of the infusion unit.

"Myself or any of the other patients, we don't know what tomorrow is going to hold," Evans said. "It's by the grace of God that we're here. Ms. Maria, through her helping hands, she's the emissary of God, (who) keeps us alive and keeps us kicking. I will forever be indebted to her for her kindness, her professionalism. She listens to us, and not only me, but she listens to all the patients."

Evans mentioned that Lim had an important role in his life the moment he received his cancer diagnosis. "As soon as (my doctor) said, '(I'm referring you to) oncology,' my world stopped, and she brought the world back around," he said.

Lim aims to make chemotherapy a "somewhat enjoyable event," Evans said, by cheering patients up. She greets them with a warm smile and even places patients near each other so they can share stories about their active duty days.

Lim has always recognized the importance of patients with cancer, especially those who are on active duty or who are veterans. "When they're diagnosed, it's really like, OK, they're veterans, they have this experience," she said. "Some of them have PTSD, they have psych issues and all of that. And now they're diagnosed with cancer. It's like another battle for them."

Making the Impossible Possible

Ellison was nominated by Dr. Paul Kent from Rush University Medical Center, who credits her for establishing their institution as a national leader for patients with fibrolamellar carcinoma, a type of liver cancer that typically affects healthy adolescents and young adults.

"People come (to Rush University Medical Center) because they want to have a team that's going to take this rare disease really seriously and really do a deep dive," Kent said during the interview. "We have two of the best surgeons you could ever want, the best interventional radiologist you ever want, but not a single part of this, not from day one and not until today, would have been possible without Jessica."

LIFELONG SERVICE TOWARD OTHERS

GIOVANNI WAS NOMINATED by her aunt, Pam Malone, RN, APRN, who quoted a previous writing by Giovanni in her nominating essay and interview. Malone mentioned how, from the start, Giovanni's life has been one of serving others.

"Jennifer is someone who has done in her life all the things I wish I could have done," Malone said. "From the get-go, even before she became a nurse, hers was a life of service and trying to help others, starting out in the Peace Corps and progressing from there. Most recently with (COVID-19), she has been on those frontlines on more than one occasion. And I don't know how she does it, but she did and her experiences really meant a lot to her."

During the interview, Giovanni described a time she was there for a patient who had stage 4 lung cancer with metastases to his brain and liver before he was intubated, which required "one final call" with his wife and children. With an iPad in hand, Giovanni brought his family to his bedside virtually. The patient's family comforted him, saying "don't worry" and "we'll see you in a little bit," although he understood his outcome. The patient's son came to visit the day before he died.

"I was in there cleaning the room and doing those herculean nursing tasks that we all have to do somehow in 14 hours," Giovanni said. "The son was outside the room, and I just thought what it must be like to stand there and look at your father intubated, clearly in a bad way, and not be able to touch (him). … That was a heavy day, but that was also a heavy phone call, but also one that I walked away from with gratitude because I was that presence at that sacred space."

Giovanni took the opportunity to thank everyone for the award not only for herself, but also on behalf of all nurses on the frontlines. "There's something very special about the nurses that came forward to take care of patients with severe COVID-19, and also those that keep doing it day after day after day," she said. "The trauma of it is profound, and it doesn't come upon (a nurse) until one steps away, and then it is overwhelming. I worry about the nurses that are out there doing this day in and day out. They are the true heroes."

JENNIFER E. GIOVANNI, PH.D., M.S.N., M.P.H., RN and nominator, PAM MALONE, RN, APRN.

Kacy Meinecke

FINALISTS FOR THE EXTRAORDINARY HEALER® AWARD

included **JESSICA ELLISON, M.S.N., B.A., RN**, a transplant coordinator at Rush University Medical Center in Chicago, Illinois, and **KATHERINE GACEK, B.S.N., RN, OCN**, a nurse navigator from the University of Chicago Medicine in Illinois.

« FROM LEFT: **JESSICA ELLISON, M.S.N., B.A., RN** and **KATHERINE GACEK, B.S.N., RN, OCN,**

Arielle Gallione

Kent added that patients with fibrolamellar carcinoma represent a unique population especially since they are young; some are diagnosed in their teenage years and continue treatment into early adulthood. This leads to various questions such as whether patients should be seen by a pediatrician or an adult doctor, among other concerns. "It's really quite a diverse and confusing group, but the bottom line is these are all healthy patients who deserve a chance. Without Jessica, they wouldn't have this chance."

Ellison mentioned that she was at first caught off-guard when she received a phone call saying she was a finalist for the Extraordinary Healer® award, but then realized that Kent must have nominated her for it. "It has been a lot of work," she said about establishing the program at her institution. "There's been a lot of … tears from my eyes, tears from the patients' eyes. It's been a long journey for all of us, but in the end, I know that some of the work or all of the work that I have done has helped several patients, families and their caregivers."

Gacek was nominated by Rose Conti, M.S.N., RN, CNM, who described in her essay and interview about a time the nurse navigator made a storyboard to detail every treatment step for a nonverbal patient with autism who was being treated for Hodgkin lymphoma. The patient, who at first had disruptive behavior because he did not understand the severity of disease, was put at ease through Gacek's efforts.

"She does this for all of her patients, but this patient in particular was something that stood out," Conti said in the interview. "She really takes the time to make them feel comfortable. And this one was a very, very, very difficult patient for not only Katherine, but the nurses that were caring for him in the infusion suite. Her extra steps to care for this patient and make him feel comfortable did just so. It was a world of difference (between) what we saw in his actions and how he actually took his care while he was with us."

Gacek added some insight into that particular situation, which she practices with every patient she cares for.

"I could not believe that it worked so well," Gacek said. "And I just feel like I had such a small piece of the puzzle to get this done, but I think it just showed that sometimes we have to think outside of the box. That was one of those cases and nurses are doing all these things all the time. We're being very inventive, and it's not always straightforward, but we just have to find a way to get things done."

Gacek noted how recognition, such as being an Extraordinary Healer® award finalist, is a humbling experience.

"I'm just so, so thankful that nurses are being recognized because there are times that we are the unsung heroes," she said. "Especially in oncology, we wear so many hats and along with helping patients get through their treatment that means so many things. That could mean helping with side effects or helping someone get to and from their appointments or helping a mom explain to their school-aged child what it means to go through chemotherapy and what that is going to mean for them. It's just such a rewarding experience already, (and I feel) so appreciated to get recognized." C

cure Extraordinary HEALER 2021

CURE® Thanks You

for Being Part of an Extraordinary Evening!

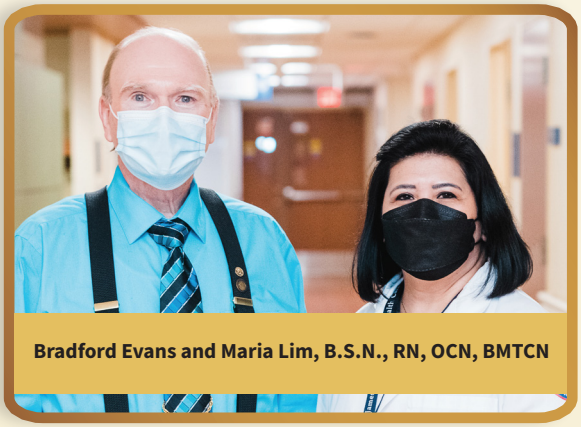
Congratulations to Maria Lim, B.S.N., RN, OCN, BMTCN, of the Captain James A. Lovell Federal Health Care Center in North Chicago, who received ***CURE***®**'s 2021 Extraordinary Healer® Award for Oncology Nursing** at a virtual celebration on April 29 before an audience of her nurse peers. Maria was nominated by one of her patients, *Bradford Evans*, who considered her the modern-day "angel of the battlefield." Maria aims to be not only a nurse but a support system for all of her patients.

CURE® **would also like to recognize our two finalists and the readers who nominated them:**

Jessica Kelley, M.S.N., B.A., RN, CNL — Rush University Medical Center in Chicago
Nominated by Paul Kent, MD

Katherine Gacek, B.S.N., RN, OCN — University of Chicago Medicine
Nominated by Rose Conti, M.S.N., RN, CNM

We also congratulate the winner of our Finest Hour Award, **Jennifer E. Giovanni, Ph.D., M.S.N., MPH, RN**, a travel nurse who, most recently, worked in New York and New Jersey as a crisis response critical care nurse in areas severely affected by the COVID-19 pandemic. Jennifer was nominated by her aunt, *Pam Malone, RN, APRN*.



Bradford Evans and Maria Lim, B.S.N., RN, OCN, BMTCN

Pam Malone, RN, APRN, and Jennifer E. Giovanni, PH.D., M.S.N., MPH, RN

Scan the QR code to see the video and special nurse shout outs from this year's event. In addition, *CURE*® is now accepting nominations for 2022. Get your submission in early!

Congratulations to This Year's Extraordinary Healer® Award Nominees:

Shiley Aguilar, M.S.N., APRN, FNP-C
Houston, Texas

Jessica Aguilera, RN
Casa Grande, Arizona

Wayne Allen
Silver Spring, Maryland

Lily Apfel, LVN
Ukiah, California

Rosaura R. Ascota
Edinburg, Texas

Emily Becker, B.S.N., RN, OCN
Columbia, Maryland

Brenda Biggins, B.S.N., RN, OCN
Boston, Massachusetts

Stephanie Bisignano, RN, RN-BC
Lakewood, New Jersey

Amy Brant, B.S.N., RN, BMTCN
Omaha, Nebraska

Christine Brooks, D.N.P., M.S.N., B.S.N., RN, OCN
Queens, New York

Maiken Burden, M.S.N., RN, OCN
Tacoma, Washington

Sandra Burns, B.S.N., RN, OCN
Madison, Wisconsin

Hayden Chae, B.S.N., ME, RN, OCN
Washington, D.C.

Kathryn Chambers, M.S.N., AOCNP
Palm Beach Gardens, Florida

Caitlin Chiado, M.S.N., CRNP, FNP-C
Pittsburgh, Pennsylvania

Sarah Choposko, RN
Dallas, Texas

Candace Churchwell, RN
Lexington, South Carolina

Cathy Coleman, D.N.P., M.S.N., RN, CNL, CPHQ
San Francisco, California

Lynn Cook, B.S.N., RN, OCN
Columbia, Maryland

Judy Davis
Annapolis, Maryland

Geary Lynn Delgado, M.S.N., RN, CPN
San Antonio, Texas

Yael Derman, M.S.N., RN, CPNP-AC CPHON
Chicago, Illinois

Maggie DeRosa, M.S.N., B.S.N., FNP-BC
Brandywine, Maryland

Sydney Desrosiers, RN
Boston, Massachusetts

Ruth Donelson Miller, RN, B.S.N., OCN
Daphne, Alabama

Joanne Downs, RN
Casa Grande, Arizona

MaryAnn Fragola, D.N.P., ANPc, ACHPN
Port Jefferson, New York

Victoria Frazier-Warmack, D.N.P., M.S.N., RN, OCN
Chicago, Illinois

Katherine Gacek, B.S.N., RN, OCN
Chicago, Illinois

Patty Garcia, B.S.N., RN
Silver Spring, Maryland

Jessica Garmon, D.N.P., RN, OCN
Charlotte, North Carolina

Donna Rebecca Garner, RN
Daphne, Alabama

Holly Gentry, RN
Lanham, Maryland

Sharolyn Gonzalez, B.S.N., RN, OCN, B.C.N.
Lansig, Michigan

Beth Henderson, M.S.N., NP, AOCNP
Silver Spring, Maryland

Mary Ellen Husted, OCN
Washington, D.C.

Katie Johnson, RN
Baltimore, Maryland

Jessica Kelley, M.S.N., B.A., RN, CNL
Chicago, Illinois

Kari Lahmon, B.S.N., RN, CNP, CAPA, CPAN
Memphis, Tennessee

Bethany Larkin, M.S.H.A., RN-BC, OCN, CT
New Haven, Connecticut

Maria Lim, B.S.N., RN, OCN, BMTCN
North Chicago, Illinois

Mary Lovely, Ph.D., RN, CNRN
Newton, Massachusetts

Kathleen Lutz, M.S.N., RN, OGNP
New York, New York

Ashley Marston, M.S.N., B.S., RN
Memphis, Tennessee

Jeannette Mazzola, M.S.N., APRN-CNP, AOCNP, AGPCNP-BC
Beachwood, Ohio

Ann McCue, M.S.N., RN, OCN
Denver, Colorado

Jonlyn McGettigan, M.S.N., RN, NP-C
Tuscon, Arizona

Glee McGinley, RN
Frederick, Maryland

Hanh Miller, RN
Casa Grande, Arizona

Linda Moors, PA-C
Tuscon, Arizona

Megan Moquin, B.S.N., RN, OCN
Appleton, Wisconsin

Mary Leslie Morgan, B.S.N., RN, OCN
Annapolis, Maryland

Kristy Myers, RN
Mobile, Alabama

Judith Newcomb, B.S.N., RN, OCN
Annapolis, Maryland

Amy Nibaur, B.S.N., RN, CMSRN
Iowa City, Iowa

Joann Nugent, B.S.N., RN
Baltimore, Maryland

Jamie O'Connor, B.S.N., RN, OCN
Washington, D.C.

Regina O'Connor, B.S.N., RN
West Harrison, New York

Elly Palmer, M.S.N., RN, CNL, OCN
Washington, D.C.

Sheryl Passino, RN, OCN
Wellington, Florida

Leslie A. Pillar, B.S.N., RN
Fort Myers, Florida

Alice Pons, B.S.N., B.S., RN
Baltimore, Maryland

Michelle Radke, RN
Stevens Point, Wisconsin

Patricia Schwickerath, ARNP
Des Moines, Iowa

Megha Shah, B.S.N., RN, OCT
Geneva, Illinois

Jackie Shanahan, RN, OCN
Annapolis, Maryland

Angela Snyder, D.N.P., PNP-BC,CHPPN
Memphis, Tennessee

Christa Spinelli, B.S.N., RN
Middletown, New Jersey

Joyce Spitz, RN
Columbia, Maryland

Kristina Trafelet, NP
Casa Grande, Arizona

Trish Traylor, RN, OCN
Bethesda, Maryland

Allison Vallance, M.A., B.S.N., RN, CBCN
New Haven, Connecticut

Marissa Victor, B.S.N., RN
Overland Park, Kansas

Timra Walsh, B.S.N., RN, OCN
Lake Success, New York

Brenda Wilbanks, RN, OCN
Atlanta, Georgia

Anne Wiltshire, B.S.N., RN, OCN
Annapolis, Maryland

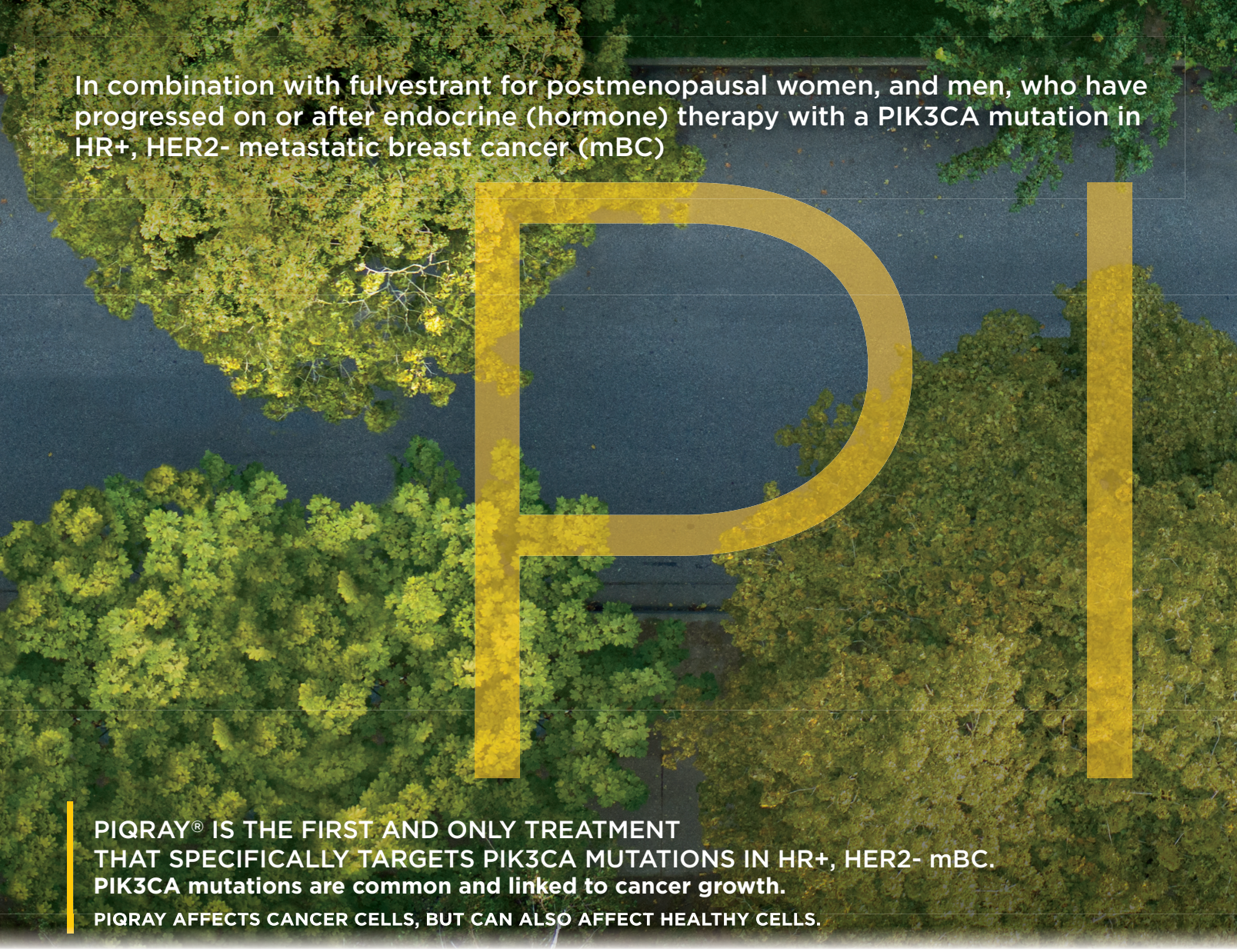
Karina Wischhusen, RN
Casa Grande, Arizona

Ron Zapata, RN
Washington, D.C.

Nurses at Aquilino Cancer Center
Rockville, Maryland

The Entire Clinical Team
(NP, PA, RN's, LVN and MA's)
Los Angeles, California

The St. Francis Cancer Institute
Infusion Unit Nursing Staff,
Team of 17 RNs, OCNs
Roslyn, New York



INDICATION

PIQRAY® (alpelisib) tablets is a prescription medicine used in combination with the medicine fulvestrant to treat women who have gone through menopause, and men:

- who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), with an abnormal phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA) gene, **and**
- whose disease has progressed on or after endocrine therapy

Your health care provider will test your cancer for an abnormal "PIK3CA" gene to make sure that PIQRAY is right for you.

It is not known if PIQRAY is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not take PIQRAY if you have had a severe allergic reaction to PIQRAY or are allergic to any of the ingredients in PIQRAY.

PIQRAY may cause serious side effects, including:

- **Severe allergic reactions:** Tell your health care provider or get medical help right away if you have trouble breathing, flushing, rash, fever, or fast heart rate during treatment with PIQRAY
- **Severe skin reactions:** Tell your health care provider or get medical help right away if you get severe rash or rash that keeps getting worse, reddened skin, flu-like symptoms, blistering of the lips, eyes or mouth, blisters on the skin or skin peeling, with or without fever
- **High blood sugar levels (hyperglycemia):** Hyperglycemia is common with PIQRAY and can be severe. Your health care provider will monitor your blood sugar levels before you start and during treatment with PIQRAY. Your health care provider may monitor your blood sugar levels more often if you have a history of Type 2 diabetes. Tell your health care provider right away if you develop symptoms of hyperglycemia, including excessive thirst, dry mouth, urinate more often than usual or have a higher amount of urine than normal, or increased appetite with weight loss
- **Lung problems (pneumonitis):** Tell your health care provider right away if you develop new or worsening symptoms of lung problems, including shortness of breath or trouble breathing, cough, or chest pain
- **Diarrhea:** Diarrhea is common with PIQRAY and can be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney problems. If you develop diarrhea during treatment with PIQRAY, tell your health care provider right away. Your health care provider may tell you to drink more fluids or take medicines to treat diarrhea

Your health care provider may tell you to decrease your dose, temporarily stop your treatment, or completely stop your treatment with PIQRAY if you get certain serious side effects.

Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you:

- have a history of diabetes
- have a history of skin rash, redness of skin, blistering of the lips, eyes or mouth, or skin peeling
- are pregnant or plan to become pregnant. PIQRAY can harm your unborn baby

  Females who are able to become pregnant:
  - Your health care provider will check to see if you are pregnant before you start treatment with PIQRAY
  - You should use effective birth control during treatment with PIQRAY and for 1 week after the last dose. Talk to your health care provider about birth control methods that may be right for you during this time
  - If you become pregnant or think you are pregnant, tell your health care provider right away

  Males with female partners who are able to become pregnant should use condoms and effective birth control during treatment with PIQRAY and for 1 week after the last dose. If your female partner becomes pregnant, tell your health care provider right away.
- are breastfeeding or plan to breastfeed. It is not known if PIQRAY passes into your breast milk. Do not breastfeed during treatment with PIQRAY and for 1 week after the last dose

You should also read the Full Prescribing Information of fulvestrant for important pregnancy, contraception, infertility, and lactation information

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PIQRAY and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

The most common side effects of PIQRAY when used with fulvestrant include:

- rash
- nausea
- tiredness and weakness
- decreased appetite
- mouth sores
- vomiting
- weight loss
- hair loss
- changes in certain blood tests

PIQRAY may affect fertility in males and in females who are able to become pregnant. Talk to your health care provider if this is a concern for you.

These are not all of the possible side effects of PIQRAY. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Summary of Important Information on the following page.

SUMMARY OF IMPORTANT INFORMATION

WHAT IS PIQRAY USED FOR?

PIQRAY® (alpelisib) tablets is a prescription medicine used in combination with the medicine fulvestrant to treat women who have gone through menopause, and men:

- who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), with an abnormal phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA) gene, **and**
- whose disease has progressed on or after endocrine therapy

Your health care provider will test your cancer for an abnormal "PIK3CA" gene to make sure that PIQRAY is right for you.

It is not known if PIQRAY is safe and effective in children.

WHO SHOULD NOT TAKE PIQRAY?

Do not take PIQRAY if you have had a severe allergic reaction to PIQRAY or are allergic to any of the ingredients in PIQRAY.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE TAKING PIQRAY?

Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you:

- have a history of diabetes
- have a history of skin rash, redness of skin, blistering of the lips, eyes or mouth, or skin peeling
- are pregnant or plan to become pregnant. PIQRAY can harm your unborn baby

  Females who are able to become pregnant:
  - Your health care provider will check to see if you are pregnant before you start treatment with PIQRAY
  - You should use effective birth control during treatment with PIQRAY and for 1 week after the last dose. Talk to your health care provider about birth control methods that may be right for you during this time
  - If you become pregnant or think you are pregnant, tell your health care provider right away

  Males with female partners who are able to become pregnant should use condoms and effective birth control during treatment with PIQRAY and for 1 week after the last dose. If your female partner becomes pregnant, tell your health care provider right away.

  You should also read the fulvestrant Prescribing Information for important pregnancy, contraception, and infertility information.
- are breastfeeding or plan to breastfeed. It is not known if PIQRAY passes into your breast milk. Do not breastfeed during treatment with PIQRAY and for 1 week after the last dose.

WHAT OTHER MEDICATIONS MIGHT INTERACT WITH PIQRAY?

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PIQRAY and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF PIQRAY?

PIQRAY may cause serious side effects, including:

- **Severe allergic reactions:** Tell your health care provider or get medical help right away if you have trouble breathing, flushing, rash, fever, or fast heart rate during treatment with PIQRAY
- **Severe skin reactions:** Tell your health care provider or get medical help right away if you get severe rash or rash that keeps getting worse, reddened skin, flu-like symptoms, blistering of the lips, eyes or mouth, blisters on the skin or skin peeling, with or without fever
- **High blood sugar levels (hyperglycemia):** Hyperglycemia is common with PIQRAY and can be severe. Patients with a history of type 2 diabetes may require closer monitoring by their health care professional. Your health care provider will check your blood sugar levels before you start and during treatment with PIQRAY. Tell your health care provider right away if you develop symptoms of hyperglycemia, including excessive thirst, dry mouth, urinate more often than usual or have a higher amount of urine than normal, or increased appetite with weight loss
- **Lung problems (pneumonitis):** Tell your health care provider right away if you develop new or worsening symptoms of lung problems, including shortness of breath or trouble breathing, cough, or chest pain
- **Diarrhea:** Diarrhea is common with PIQRAY and can be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney problems. If you develop diarrhea during treatment with PIQRAY, tell your health care provider right away. Your health care provider may tell you to drink more fluids or take medicines to treat diarrhea

Your health care provider may tell you to decrease your dose, temporarily stop your treatment, or completely stop your treatment with PIQRAY if you get certain serious side effects.

The most common side effects of PIQRAY when used with fulvestrant include:

- rash
- nausea
- tiredness and weakness
- decreased appetite
- mouth sores
- vomiting
- weight loss
- hair loss
- changes in certain blood tests

PIQRAY may affect fertility in males and in females who are able to become pregnant. Talk to your health care provider if this is a concern for you.

These are not all of the possible side effects of PIQRAY. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

WHAT LABORATORY MONITORING TESTS DO I NEED WHEN TAKING PIQRAY?

Your health care provider will check your blood sugar levels before you start and during treatment with PIQRAY. Your health care provider may monitor your blood sugar levels more often if you have a history of Type 2 diabetes.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF PIQRAY

Medicines are sometimes prescribed for purposes other than those listed. Do not use PIQRAY for a condition for which it was not prescribed. Do not give PIQRAY to other people, even if they have the same symptoms you have. It may harm them. You can ask your health care provider or pharmacist for more information about PIQRAY that is written for health professionals.

For more information about PIQRAY, talk with your doctor or pharmacist or call 1-833-4-PIQRAY (1-833-474-7729). The FDA-approved product labeling or prescribing information can be found at PIQRAY.com.

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LUNGEVITY
Find it. Treat it. Live.

KATIE BROWN, senior vice president of survivorship and support for LUNGevity Foundation, wrote about a program for patients to gain knowledge from survivors.

JARED REY HERNANDEZ

Peer Support Helps Patients Navigate Their Cancer Journey

A CANCER DIAGNOSIS CAN BE overwhelming, leaving individuals with a flurry of emotions, concerns or even shock in the attempt to process the new direction their lives have taken. Support from family and friends becomes a crucial part of navigating the disease, though an equally important but overlooked need for many is the support and understanding from someone who has already walked the cancer path.

Finding someone who understands this experience firsthand, however, is not always easy. That's why LUNGevity Foundation created the LifeLine Support Program.

The LifeLine Support Program is a free service that matches patients with lung cancer or caregivers with LifeLine Support Partners. The Support Partners volunteer to mentor and offer encouragement, advice, experience and hope to those newly diagnosed and anyone needing additional support through a one-on-one personal connection by email or telephone. Partners are matched based on factors such as type of lung cancer, age group or other similarities.

According to the National Cancer Institute, one in three people with cancer experiences mental or emotional distress, with a staggering 25% of cancer survivors experiencing symptoms of depression and 45% experiencing anxiety. LifeLine Partners can be a vital part of a newly diagnosed patient's support system and can help navigate through the logistics and emotions of a lung cancer diagnosis.

"It's like having a wingman who not only helps you in the beginning, but also helps you adjust to living with the disease," says Michelle, a LifeLine Support Partner mentee. "You need that added support before the next round of labs or the next scan. You need to expect the unexpected and have the safety net. A LifeLine partner gives you that."

It is LUNGevity's goal to help mitigate the tremendous emotional pressure one faces upon and through their diagnosis. No one can understand the concerns of a patient with cancer on quite the same level as someone who has already had those same thoughts, feelings and experiences. LifeLine partners can offer help with the practical aspects of self-advocacy, communicating with your medical provider, how to share your diagnosis with your loved ones and what symptoms to expect. This peer-to-peer support can also address the emotional aspects of a lung cancer diagnosis; for example, how to use mindfulness practices to battle fearful or negative thoughts.

LUNGevity offers the largest online network of support and survivorship programs for all people affected by lung cancer. Our annual International Lung Cancer Survivorship Conference is composed of three summits that provide an opportunity for local communities to come together to find the latest information on treatments and living with lung cancer, as well as to be surrounded by other people impacted by this disease: the HOPE Summit for patients, the COPE Summit for caregivers and the »

A 'Turning Point' for Metastatic NSCLC Treatment

Patients with metastatic KRAS G12C mutated non-small cell lung cancer now have another treatment option if they previously failed at least one line of therapy. *By* DARLENE DOBKOWSKI, M.A.

THE FOOD AND DRUG ADMINISTRATION (FDA) recently approved Lumakras (sotorasib), a KRAS inhibitor for patients with metastatic KRAS G12C mutated non-small cell lung cancer who previously received at least one line of systemic therapy.

"The FDA approval of (Lumakras) … truly represents a turning point, an inflection point," said Dr. Ferdinandos Skoulidis, assistant professor in the department of thoracic/head and neck medical oncology at The University of Texas MD Anderson Cancer Center in Houston and lead author of the phase 2 CodeBreaK 100 trial on which the FDA approval was based, in an interview with *CURE®*. "There is now an approved and accessible oral therapy that can shrink tumors and prolong survival without compromising quality of life."

According to the FDA, KRAS mutations are identified in 25% of patients with non-squamous non-small cell lung cancer, and the specific KRAS G12C mutation that is targeted by Lumakras accounts for an estimated 13% of all patients — approximately 1 in 8 patients. KRAS is a gene that regulates cell division and growth, and when it is mutated, it can lead to the development of cancer.

Before Lumakras was approved by the FDA, patients with KRAS-mutated lung cancer who progressed after first-line systemic therapy involving immunotherapy alone or in combination with platinum-based chemotherapy were typically treated with cytotoxic chemotherapy. Treatments were administered intravenously, required patients to visit the hospital once every three weeks and were associated with significant side effects such as the risk of infections, nausea, vomiting and hair loss, "which has a big impact on their quality of life," Skoulidis said.

In contrast, Lumakras is an oral therapy given at a 960-milligram dose once per day.

"The ability to take (Lumakras) orally as a pill will definitely improve the patient experience compared to the need to have a drug administered intravenously every three weeks with all the associated problems," Skoulidis said. "The convenience of oral therapy is an important plus for patients."

Side effects related to Lumakras, Skoulidis said, are mostly mild, reversible and manageable with standard-of-care supportive measures. The most common treatment-related side effects included diarrhea, nausea, elevated liver enzymes and fatigue. The label for Lumakras includes two specific FDA warnings related to liver-related toxicity, requiring regular monitoring of liver function tests, and pneumonitis (inflammation of lung tissue).

"Patients should be carefully followed, and if they develop any symptoms suggesting worsening respiratory status, (Lumakras) should be withheld and appropriate diagnostic evaluation should be initiated promptly," Skoulidis said. "But overall, the drug was safe and certainly far better tolerated than what we're used to with the standard-of-care cytotoxic chemotherapy in this setting."

Skoulidis said future clinical development of Lumakras will focus on therapeutic combinations aimed at maximizing clinical benefit, efficacy as well as elucidation of molecular determinants of therapy response and mechanisms of innate and acquired resistance.

"The hope … is that once we have a deeper understanding of possible mechanisms of resistance to (Lumakras) this will lead to rational, effective and tailored combination regimens in order to either prevent the emergence of resistance or tackle it in the event that it has occurred."

The approval of Lumakras may also be a call to action to perform more molecular testing for patients with metastatic non-small cell lung cancer.

"Access to broad molecular profiling is not equitable across the U.S.," Skoulidis said. "Hopefully the first approval of a KRAS G12C inhibitor (Lumakras) will also increase the uptake of broad genomic profiling in community oncology practices to make (Lumakras) accessible to the broadest possible population of patients that it may benefit."

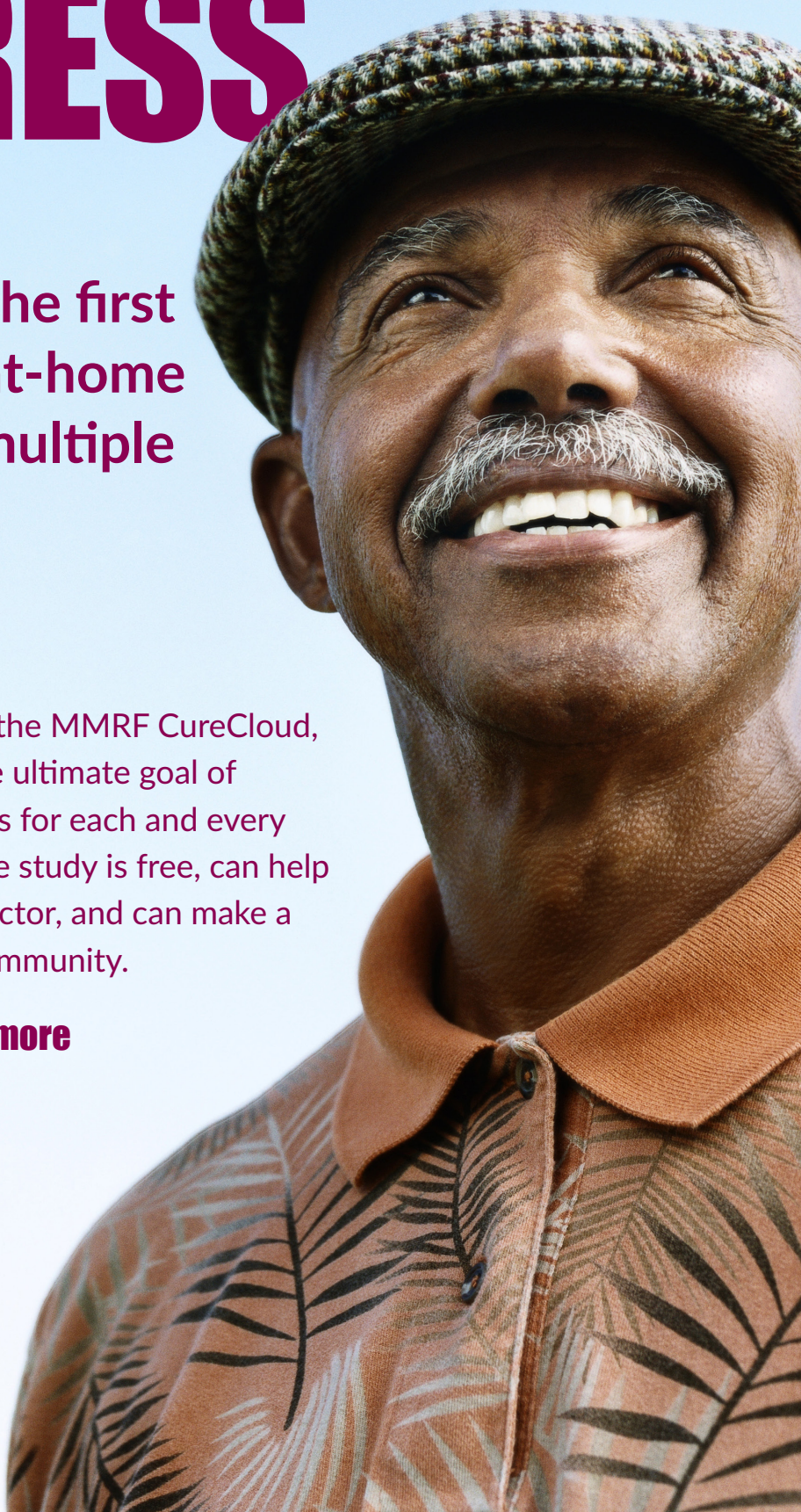
Survivorship Summit for advocates and survivors who are interested in more advanced topics.

Patients and caregivers can receive additional peer-to-peer support and information from LUNGevity's social media platforms as well as the online Lung Cancer Support Community, an extensive message board that includes the latest lung cancer information and notices of lung cancer events and advocacy opportunities. The Lung Cancer HELPLine also offers toll-free, personalized support for patients and caregivers at any time during their lung cancer experience. LUNGevity's oncology social workers are available to individuals to manage their emotional, financial and support challenges. Also provided are referrals to financial assistance resources for needs including pain medication, home care, child care, medical supplies, transportation for treatment and copayment assistance.

More than 235,000 people in the U.S. will be diagnosed with lung cancer this year, with a new diagnosis every 2.2 minutes, according to the National Cancer Institute. The road after a lung cancer diagnosis is often troubling, uncertain and difficult to navigate, and it is not uncommon to feel lost on the journey. But the road isn't one that needs to be traveled alone. Support is always just a step — or a phone call — away.

EXPECT PROGRESS

Introducing the MMRF CureCloud®, the first research study with at-home genomic testing for multiple myeloma patients.



Our groundbreaking research study, the MMRF CureCloud, will help accelerate research with the ultimate goal of identifying smarter treatment options for each and every multiple myeloma patient. Joining the study is free, can help inform your discussions with your doctor, and can make a difference for the entire myeloma community.

Visit MMRFCureCloud.org to learn more

MMRF® CureCloud®

GEORGE and **PAULA SHEEHAN** celebrated his improved health with a cross-country motorcycle trip.

Treating Cancer as PATIENTS AGE

As patients aged 65 or older receive a diagnosis of cancer, their treatment course and priorities may differ from their younger counterparts.

By DON VAUGHAN

George Sheehan, 77, of Diamond Springs, California, enjoyed excellent health until he was stricken with a persistent sore throat in 2016. His ear, nose and throat specialist diagnosed the problem as acid reflux, but after months of treatment with traditional therapies brought no relief, Sheehan sought a second opinion from his gastroenterologist. Sheehan was referred to the University of California, Davis, where a biopsy confirmed that the retired manager had stage 4 squamous cell carcinoma of the larynx.

"They sat me down, explained I had cancer and said it would be best if they removed my larynx," Sheehan recalls. "The cancer was isolated so I didn't need chemotherapy or radiation. I was very fortunate."

Sheehan received a voice prosthesis and met regularly with a speech therapist. At the same time, Sheehan's wife, Paula, also a cancer survivor, learned from visiting nurses and instructional videos how to help her husband keep his stoma clean and regain his ability to speak. When Sheehan was well again, the couple celebrated with a cross-country motorcycle trip. »

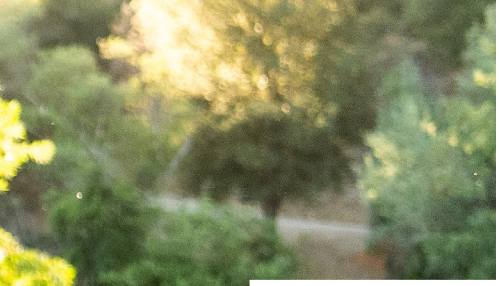
JENNIFER POPE

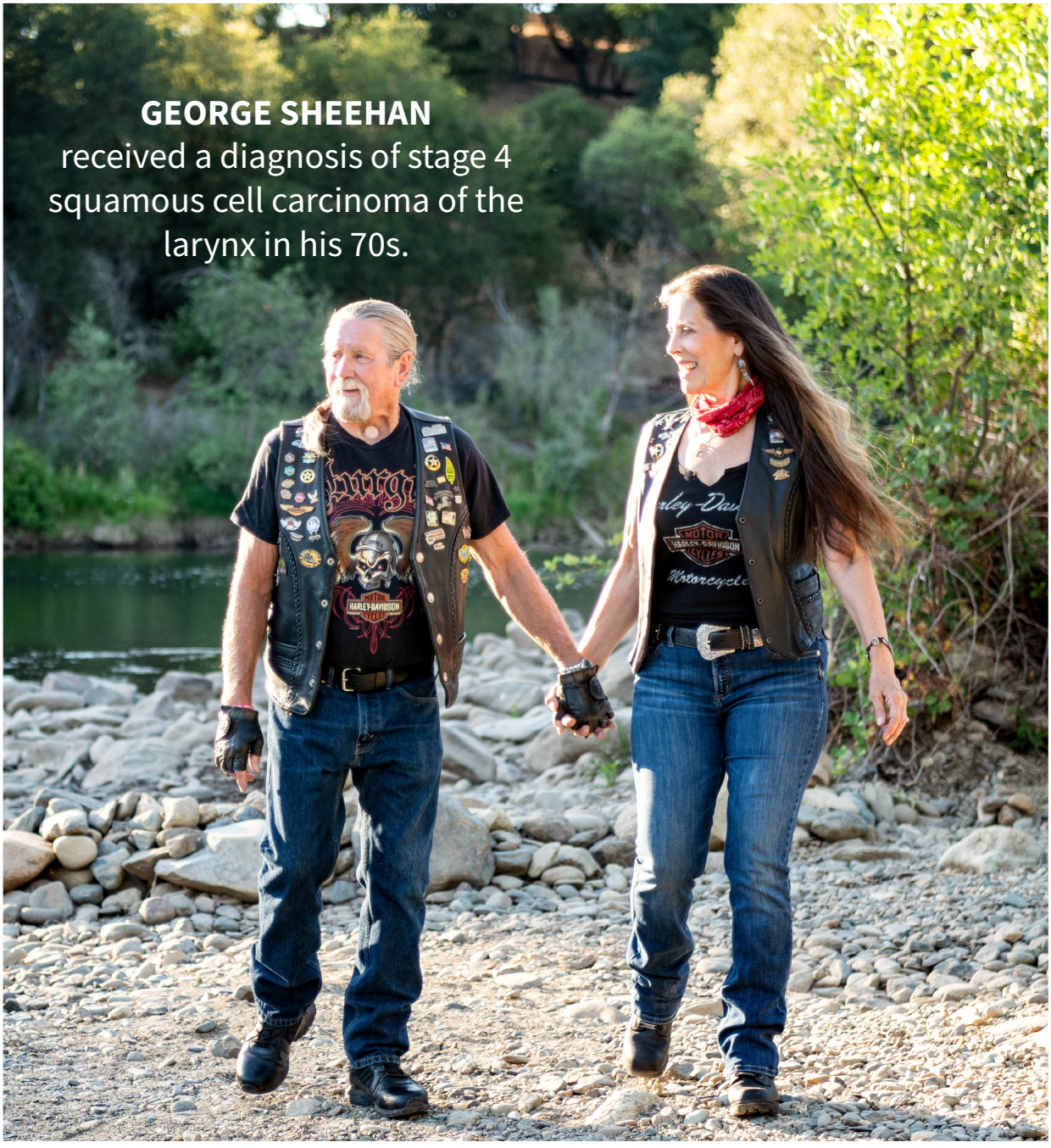
Despite losing his larynx, Sheehan was luckier than many patients with cancer his age. Geriatric patients with cancer, defined as those 65 and older, often have health and other issues that can make cancer treatment difficult. Caring for this population has always been a challenge, but cancer care specialists are making strides to ensure that they receive the same level of support provided to younger patients.

CANCER RISK AND AGE

Cancer can strike at any age but is most prevalent among adults as they age. According to a 2008 study published in the journal *Cancer*, about 60% of cancer incidence and 70% of cancer mortality occurs among adults aged 65 and older. This also happens to be the fastest-growing population in the United States, notes the National Cancer Institute, with a projected population of 84 million by 2050.

As patients age, they can be divided into three groups, says Dr. Stuart Lichtman, a medical oncologist at Memorial Sloan Kettering Cancer Center in New York. The first is the well elderly, who tend to be the minority. This is followed by the vulnerable elderly, who can be well functioning and independent but have other medical issues that make them vulnerable to side effects of cancer treatment. The third group is the frail elderly, such as patients in nursing homes. Some frail elderly patients are strong enough to receive treatment for their cancer, Lichtman says, but others may be so vulnerable that treatment is not even a consideration.





SHEEHAN'S wife, **PAULA,** took care of him when he came home from the hospital, which she says was challenging at times.

"Medicine is never black and white," Lichtman notes. "You can't just look at age. You have to look at the whole patient. Geriatric oncology is 'the ultimate in personalized medicine' because everyone is a little different. Everyone at that point in their life has had issues in the past and it affects treatment decisions as well as wishes and goals."

AGING PATIENTS EXCLUDED

Only within the past few decades has a greater focus been placed on the unique needs of aging patients with cancer, thanks to the efforts of advocates such as medical sociologist Rosemary Yancik, who served many years at the National Institutes of Health and was instrumental in founding the

continued on page 48 »

For certain adults with **newly diagnosed metastatic non-small cell lung cancer (NSCLC)** that **tests positive for PD-L1**

OPDIVO® (nivolumab) + YERVOY® (ipilimumab) = **A CHANCE FOR MORE BIG HORIZONS**

A Chance to Live Longer™

THE ONLY FDA-APPROVED **CHEMO-FREE COMBINATION** OF **2 IMMUNOTHERAPIES** THAT WORKS DIFFERENTLY

In a study of newly diagnosed advanced NSCLC patients, half of those on OPDIVO + YERVOY were alive at 17.1 months versus 14.9 months on platinum-based chemotherapy.

Thank you to all the patients, nurses, and physicians in our clinical trials.

Results may vary. OPDIVO® + YERVOY® is not approved for patients younger than 18 years of age.

Indication & Important Safety Information for OPDIVO (nivolumab) + YERVOY (ipilimumab)

Only your healthcare professional knows the specifics of your condition and how OPDIVO in combination with YERVOY may fit into your overall therapy. The information below does not take the place of talking with your healthcare professional, so talk to them if you have any questions.

What are OPDIVO and YERVOY?

OPDIVO and YERVOY are prescription medicines used to treat people with a type of advanced stage lung cancer called non-small cell lung cancer (NSCLC). OPDIVO may be used in combination with YERVOY as your first treatment for NSCLC when your lung cancer has spread to other parts of your body (metastatic) **and** your tumors are positive for PD-L1, but do not have an abnormal EGFR or ALK gene.

It is not known if OPDIVO and YERVOY are safe and effective when used in children younger than 18 years of age.

What is the most important information I should know about OPDIVO and YERVOY?

OPDIVO and YERVOY are medicines that may treat certain cancers by working with your immune system. OPDIVO and YERVOY can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death and may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time. Some of these problems may happen more often when OPDIVO is used in combination with YERVOY.

Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including

- **Lung problems:** new or worsening cough; shortness of breath; chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; severe stomach-area (abdominal) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen); dark urine (tea colored); bleeding or bruising more easily than normal
- **Hormone gland problems:** headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in the amount of urine; blood in your urine; swelling in your ankles; loss of appetite
- **Skin problems:** rash; itching; skin blistering or peeling; painful sores or ulcers in mouth or nose, throat, or genital area
- **Eye problems:** blurry vision, double vision, or other vision problems; eye pain or redness

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with OPDIVO and YERVOY. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- Chest pain; irregular heartbeat; shortness of breath; swelling of ankles
- Confusion; sleepiness; memory problems; changes in mood or behavior; stiff neck; balance problems; tingling or numbness of the arms or legs
- Double vision; blurry vision; sensitivity to light; eye pain; changes in eye sight
- Persistent or severe muscle pain or weakness; muscle cramps
- Low red blood cells; bruising

Getting medical help right away may help keep these problems from becoming more serious. Your healthcare team will check you for these problems during treatment and may treat you with corticosteroid or hormone replacement medicines. Your healthcare team may also need to delay or completely stop your treatment if you have severe side effects.

What should I tell my healthcare provider before receiving OPDIVO and YERVOY? Before you receive OPDIVO and YERVOY, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant

- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area in the past and have received other medicines that are like OPDIVO
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. OPDIVO and YERVOY can harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO or YERVOY passes into your breast milk. Do not breastfeed during treatment with OPDIVO or YERVOY and for 5 months after the last dose of OPDIVO or YERVOY

Females who are able to become pregnant: Your healthcare provider should do a pregnancy test before you start receiving OPDIVO or YERVOY.

- You should use an effective method of birth control during your treatment and for at least 5 months after your last dose of OPDIVO or YERVOY. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with OPDIVO or YERVOY. You or your healthcare provider should contact Bristol Myers Squibb at 1-844-593-7869 as soon as you become aware of the pregnancy.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare providers and pharmacist when you get a new medicine.

What are the possible side effects of OPDIVO and YERVOY?

OPDIVO and YERVOY can cause serious side effects, including:

- **See "What is the most important information I should know about OPDIVO + YERVOY?"**
- **Severe infusion reactions.** Tell your healthcare team or nurse right away if you get these symptoms during an infusion of OPDIVO or YERVOY: chills or shaking; itching or rash; flushing; shortness of breath or wheezing; dizziness; feel like passing out; fever; back or neck pain
- **Complications, including graft-versus-host disease (GVHD), of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO or YERVOY. Your healthcare provider will monitor you for these complications.

The most common side effects of OPDIVO when used in combination with YERVOY include: feeling tired; diarrhea; rash; itching; nausea; pain in muscles, bones, and joints; fever; cough; decreased appetite; vomiting; stomach-area (abdominal) pain; shortness of breath; upper respiratory tract infection; headache; low thyroid hormone levels (hypothyroidism); decreased weight; and dizziness.

These are not all the possible side effects of OPDIVO and YERVOY. Call your doctor for medical advice about side effects.

You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

OPDIVO (10 mg/mL) and YERVOY (5 mg/mL) are injections for intravenous (IV) use.

This is a brief summary of the most important information about OPDIVO and YERVOY. For more information, talk with your healthcare providers, call 1-855-673-4861, or go to www.OPDIVO.com.

Bristol Myers Squibb™

« *continued from page 45*

International Society of Geriatric Oncology in 2000. One of the most important concerns for advocates such as Yancik has been the lack of patients 65 and older enlisted in clinical drug trials because of safety concerns.

"In the early days of cancer treatment, the thinking was that people above the age of 65 would not be able to tolerate treatment, so the upper age was 65 for clinical trials," notes Dr. Martine Extermann, program leader in the senior adult oncology program at H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida. "Dr. Yancik pushed for programs designed to help older cancer patients, and one of the first in the United States was here at Moffitt."

A lack of aging trial participants can have serious consequences in cancer treatment, says Dr. Supriya Mohile, a geriatric oncologist at the University of Rochester Cancer Center in New York. "The challenge for us as oncologists is that data regarding the safety and efficacy of therapeutics comes from clinical trials that do not include older adults to the prevalence they have in the community," she explains. "The therapies we have are tested on patients who are younger and in better health. When we see older adults who may have other health problems, we often don't know how to appropriately manage that patient because we don't have the data."

> "You have a lot on your shoulders. It was difficult, but we got through it together. I'm really proud of him."
>
> —PAULA SHEEHAN

Thankfully, attitudes regarding the inclusion of aging patients in clinical trials are starting to shift. The Cancer and Aging Research Group, in collaboration with the National Institute on Aging and the National Cancer Institute, reviewed gaps in knowledge about the care of patients age 65 and older with cancer and developed a series of recommendations to improve their participation. They include the following:

- design trials specific to this patient population;
- modify trial designs to collect more data on aging patients;
- leverage population cohort studies to answer commonly posed questions in geriatric oncology regarding the feasibility, dosing and toxicity of a selected regimen;
- conduct concurrent differential dosing trials for these patients; and
- broaden further eligibility criteria.

Ed Cutler, 75, of Tampa, Florida, after standard-of-care chemotherapy for 16 months, participated in two separate phase 1 immunotherapy trials as part of his treatment for lung cancer with metastases to the liver. The first drug combo — Imfinzi (durvalumab) and tremelimumab, two drugs known as checkpoint inhibitors, beginning in 2015 — reduced the size of the tumor in Cutler's lung by 70% but side effects including severe colitis forced him to stop after seven months. A year later, Cutler began receiving taminadenant, another immunotherapy drug known as an adenosine receptor antagonist, in a phase 1 trial conducted at the Moffitt Cancer Center, again with positive results.

"I'm still an active participant of the trial and have been stable since early 2017," Cutler says. "I am not cancer free. There is still something there, but it is not growing and it's not getting any smaller. The treatment appears to be keeping my cancer stable."

COMORBIDITIES AND TREATMENT

Cutler says that, to the best of his knowledge, his age was never considered a factor by his care team, likely because he was in relatively good physical health at the time with no comorbidities.

But that's not the case for the majority of aging patients with cancer. Comorbidities tend to become more common with age and are a very important factor when developing a treatment plan. Especially concerning are illnesses that can negatively affect treatment and recovery such as obesity, diabetes, kidney disease, liver disease and heart issues.

"From a physiologic point of view, 20-year-olds are essentially the same. Everyone is healthy with no other diseases," Extermann explains. "That changes as we get into our 70s and 80s. We need to understand the disease, but in addition, we need a knowledge of the patient that is much deeper than you would have for younger patients. We need to evaluate which diseases they have as well as their function and reserve, which is their capacity to rebound."

One of the most useful tools available to geriatric oncologists is the comprehensive geriatric assessment (CGA), which helps determine if a patient will benefit from treatment or would be better off with palliative care. The CGA evaluates physical functioning, comorbid conditions, cognitive performance, psychological and nutritional

JEN BRAVO

status, social support, current medications and the presence of geriatric syndromes.

"With some patients, the screening may tell us that the patient is really very fit and should receive a full treatment," Lichtman notes. "Another person may look pretty good, but when you start looking at their function, you discover all kinds of vulnerabilities, and if you start treatment with a full-dose regimen, you are going to harm that patient. We have to modify the dose and use a lighter treatment for the patient to get the best benefit."

In a trial conducted by the University of Rochester Cancer Center, the CGA was found to improve care delivery and patient/caregiver satisfaction, Mohile reports. A second trial found that the tool also improves decision-making and reduces cancer treatment toxicity.

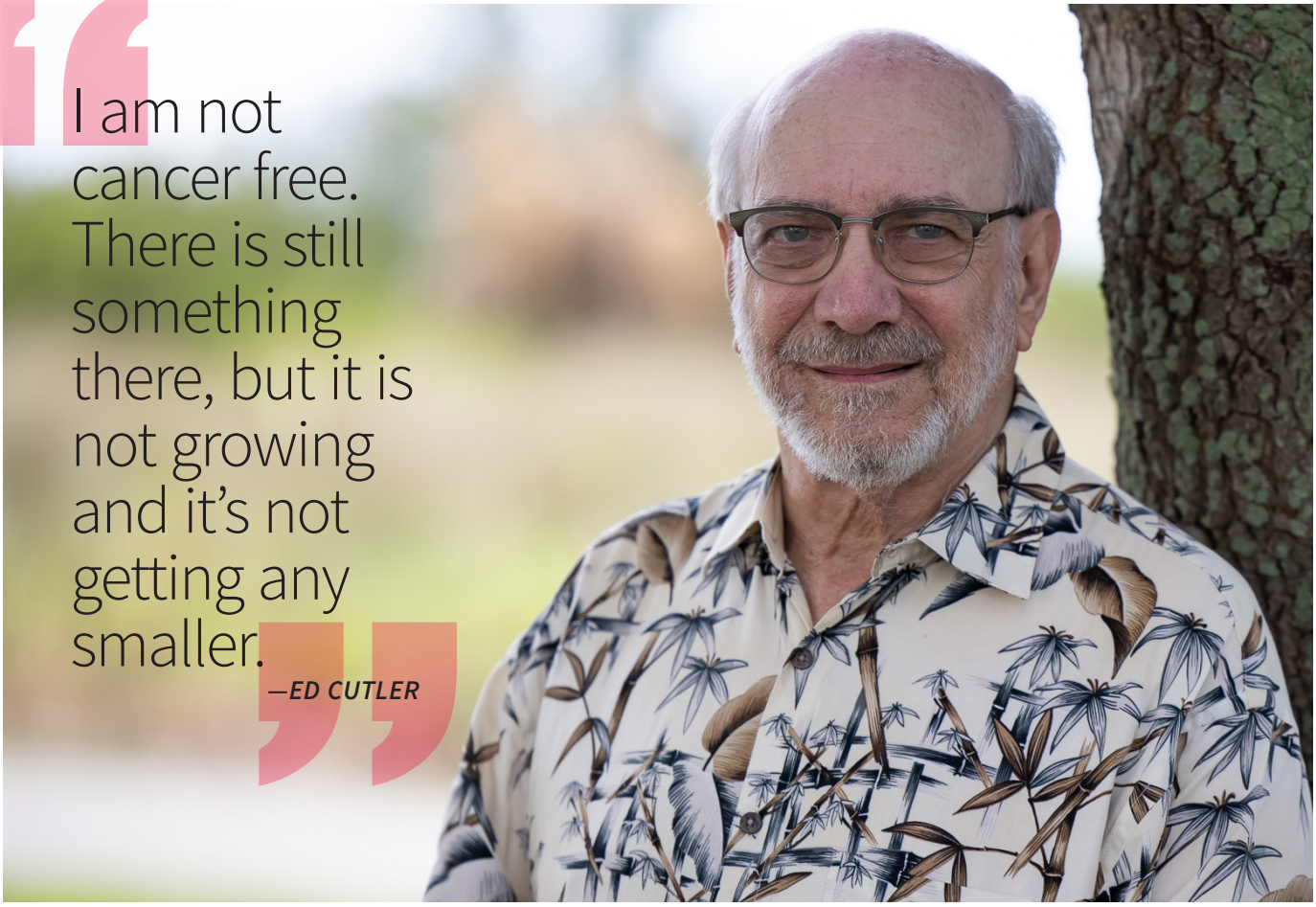
"We need to learn how to implement the comprehensive geriatric assessment better and make patients and caregivers aware of it," says Mohile. "If patients demand this evidence-based practice of their doctors, practices will adopt it more."

CHALLENGES AT HOME

Home care — both during and after treatment — can present its own challenges for aging patients with cancer. Many require continued support from their medical team, which may include a home nurse, speech therapist, physical therapist, nutritionist, wound care specialist, social worker and others. However, daily assistance typically is provided by family and friends, which can result in caregiver burnout.

"Just because a patient is married, oncologists shouldn't assume they have a caregiver because the spouse may be in worse condition than the patient," Extermann says. "You have to ask patients about their arrangements."

"Our system is not a good one for caregivers," Mohile acknowledges. "We barely address caregiver needs in our clinical encounters, and there is not a lot of support for caregivers in general. This can affect the patient. If the caregiver is stressed or has their own health needs that are being affected by caregiving, the patient is not going to do well. We need to think about them as a team." »



Paula Sheehan did all she could to meet her husband's care needs when he returned home from the hospital. Yet despite the support she received from nurses and others, she found the experience emotionally stressful. "I took it upon myself," she says. "You have to learn how to care for your spouse when they get home, and it's a shock, really. You have a lot on your shoulders. It was difficult, but we got through it together. I'm really proud of him."

Numerous organizations provide resources for home caregivers including the American Cancer Society, the Cancer and Aging Research Group, the American Society of Clinical Oncology, Susan G. Komen for the Cure, the LUNGevity Foundation, the GO_2 Foundation for Lung Cancer and the National Cancer Institute.

IMPORTANCE OF SELF-ADVOCACY

Aging patients are encouraged to be their own advocates and not hesitate to ask questions about their treatment options, goals and more. "One important question patients should ask is, what is the evidence for this treatment plan for patients like me? The doctor should be honest regarding the available data," says Mohile.

Another essential question is how a particular treatment will affect the patient's ability to function, Extermann adds. "Function matters a lot to older patients," she notes. "Everyone wants to live longer but no one wants to grow old."

Before surgery, patients and caregivers should look into appropriate support groups at their local hospital or cancer organization, Paula Sheehan suggests. "That was very helpful to us both," she says. "Speaking with other laryngectomy patients before and after surgery helped us know what to expect."

Cutler also encourages patients 65 years and older to talk not only to their medical care team but also to other patients with cancer who have been through it. "I think they are more valuable than anybody," he notes. "A connection to other patients through the LUNGevity Foundation helped me personally and really began my journey of advocacy."

While aging patients with cancer face unique challenges, it's important to understand that treatment options are broad and the prognosis is good for most. "Nowadays, most cancers are either curable or manageable so that you can live several years with it," says Extermann. "It's not necessarily a death sentence."

JEN BRAVO

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TOO MUCH MONEY FOR THE MEDICINE

NEWER CANCER THERAPIES EASILY COST UPWARD OF $100,000. WHY SO MUCH? WHO SETS THE PRICES AND WHAT CAN PATIENTS DO IF THEY CAN'T AFFORD THEM?

By KATHERINE MALMO

On Halloween of 2010, David Mitchell got out of bed and immediately fell to the floor with pain so excruciating he was unable to move. A few days later, the results of his MRI showed malignant-appearing lesions up and down his spine and ribs, and he was diagnosed with multiple myeloma.

Multiple myeloma is incurable but treatable, and Mitchell had surgery to stabilize his spine and started an expensive drug therapy. For over five years, he took Revlimid (lenalidomide) manufactured by Bristol Myers Squibb (BMS). Each capsule currently sells for $833 — and cost less than $1 to make. Now he's on a four-drug combination that costs $900,000 per year. When the three classes of recommended drugs stop working, Mitchell says some oncologists say the outlook might appear to be "dismal." »

> **DAVID MITCHELL**'s current treatment is a four-drug combination that costs $900,000 per year.

BOB RIVES

"But I don't look at it that way," he says. "There are new drugs in development and coming on the market all the time. With each drug, I'm going to get enough additional time to get to the next new drug. So innovation and drug development are vitally important to me — literally life and death."

Mitchell is not the only patient with cancer whose drugs are expensive. According to Dr. Vincent Rajkumar, hematologist and professor of medicine at Mayo Clinic in Rochester, Minnesota, every single type of cancer is expensive to treat.

"Almost every new cancer drug introduced in the last three years has been priced at more than $100,000 per year," Rajkumar says. "The median price was approximately $150,000 in 2018."

WHY ARE PRICES SO HIGH?

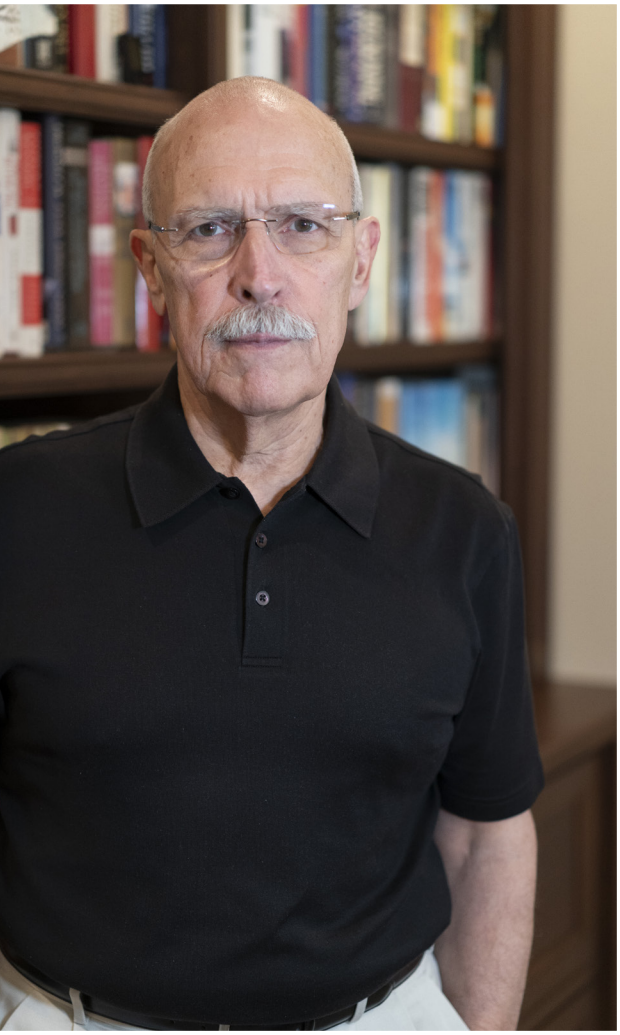
Medications aren't the only cost in cancer treatment. Depending on the patient and their diagnosis, therapy can involve surgery, radiation and pharmacological therapy, as well as indirect costs like lodging, transportation, child care, lost wages, special food, fertility treatment or adoption fees. But medications are one of the biggest costs and among the fastest rising. While research and development do take a significant investment, why do they require such aggressive pricing? Or is too much money spent on marketing and advertising, or perhaps on high salaries for executives? These questions are receiving more scrutiny than ever before.

The American Cancer Society (ACS) reports that Americans with cancer paid nearly $4 billion out of pocket in 2014. Employers, insurance companies and taxpayer-funded programs paid roughly $87.8 billion that same year. For patients with multiple myeloma like Mitchell, drugs account for approximately 60% of the cost of care, according to a study published in *Blood* in 2019.

Rajkumar warns that programs that lower out-of-pocket costs for patients can be helpful but offer only "Band-Aid" solutions that don't fix the larger problem (see breakout box).

MONOPOLY

"The reason drug prices in America are so high is because most other countries have governments that negotiate directly with drug companies," Mitchell says.



MITCHELL founded a patient organization focused on lowering drug prices through policy changes.

"And we have laws and policies in the United States that literally prohibit the government from using its purchasing power through Medicare (the largest payer of medications) to lower drug prices. Consequently, we have a system in which the drug companies have all of the pricing power, and we have none of the purchasing power."

Mitchell, who is the CEO and founder of Patients for Affordable Drugs, points out that the U.S. government negotiates prices for nearly everything from aircraft carriers to copy paper. Why not for the cost of lifesaving drugs for millions of Americans?

Because of the Medicare Modernization Act. Passed in 2003, this act includes a noninterference clause that states that the secretary of health and human services cannot intervene in negotiations between drug companies and insurance companies' pharmacy benefit managers. According to Mitchell, Billy Tauzin, who represented Louisiana then as a Republican in the U.S. House of Representatives, and was a primary advocate for the bill, became CEO of a trade association for the pharmaceutical industry earning an annual salary of $2 million in January 2005.

"Basically, Medicare needs to buy the drug for all beneficiaries who need it and pay whatever price pharmaceutical companies set," Rajkumar says. "That's the recipe for the problem we have right now."

For many new drugs, there are no alternatives. These monopolies should be temporary and only until generic competition enters the market when patents expire. However, this often does not happen because by the time the patent ends the drug has already been replaced by a "new and improved" version with a new patent that is now the standard of care.

Stacie Dusetzina, associate professor of health policy and Ingram Associate Professor of Cancer Research at Vanderbilt Medical Center in Nashville, Tennessee, says BMS has been criticized by the Food and Drug Administration (FDA) for withholding samples of Revlimid from generic manufacturers.

"This makes it hard for companies to do the tests they need to do to get a generic on the market," Dusetzina says. "Other companies do things like create slightly different formulations or use something like an auto-injector or device that can be patented. There's a whole bag of tricks."

continued on page 58 »

H.R.3 – Elijah E. Cummings Lower Drug Costs Now Act

DAVID MITCHELL IS optimistic that this bill that would allow Medicare to negotiate drug prices can pass the House and the Senate because of high bipartisan support from the electorate (92% of Americans approve, according to a 2017 brief from The Commonwealth Fund).

"H.R.3 would allow Medicare to negotiate directly with drug companies for lower prices," Mitchell says. "It would also cap annual price increases at no more than the rate of inflation. It would extend the lower prices to the commercial sector. It would lower the out-of-pocket maximum and Medicare Part D from no maximum and, importantly, it would direct a large portion of the savings to the NIH to help ensure we are feeding innovation.

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To all of you, as well as the clinical trial investigators, nurses and cancer care teams, thank you for making this advancement possible.

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Oncology

What is LUMAKRAS™?

LUMAKRAS™ is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):
- that has spread to other parts of the body or cannot be removed by surgery, **and**
- whose tumor has an abnormal *KRAS* G12C gene, **and**
- who have received at least one prior treatment for their cancer.

Your healthcare provider will perform a test to make sure that LUMAKRAS™ is right for you.

It is not known if LUMAKRAS™ is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What should I tell my healthcare provider before taking LUMAKRAS™?

- Before taking LUMAKRAS™, tell your healthcare provider about all your medical conditions, including if you:
  - have liver problems
  - have lung or breathing problems other than lung cancer
  - are pregnant or plan to become pregnant. It is not known if LUMAKRAS™ will harmyour unborn baby.
  - are breastfeeding or plan to breastfeed. It is not known if LUMAKRAS™ passes into your breast milk. Do not breastfeed during treatment with LUMAKRAS™ and for 1 week after the final dose.
- Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, dietary and herbal supplements. LUMAKRAS™ can affect the way some other medicines work, and some other medicines can affect the way LUMAKRAS™ works.
- Especially tell your healthcare provider if you take antacid medicines, including Proton Pump Inhibitor (PPI) medicines or H_2 blockers during treatment with LUMAKRAS™. Ask your healthcare provider if you are not sure.

LUMAKRAS™ may cause serious side effects, including:

- Liver problems: LUMAKRAS™ may cause abnormal liver blood test results. Your healthcare provider should do blood tests before starting and during treatment with LUMAKRAS™ to check your liver function. Tell your healthcare provider right away if you get any signs or symptoms of liver problems, including: your skin or the white part of your eyes turns yellow (jaundice), dark or "tea-colored" urine, light-colored stools (bowel movements), tiredness or weakness, nausea or vomiting, bleeding or bruising, loss of appetite, and pain, aching, or tenderness on the right side of your stomach-area (abdomen).
- Lung or breathing problems: LUMAKRAS™ may cause inflammation of the lungs that can lead to death. Tell your healthcare provider or get emergency medical help right away if you have new or worsening shortness of breath, cough or fever.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with LUMAKRAS™ if you develop side effects.

The most common side effects

- The most common side effects of LUMAKRAS™ include diarrhea, muscle or bone pain, nausea, tiredness, liver problems, cough, changes in liver function tests, and changes in certain blood tests.
- These are not all the possible side effects of LUMAKRAS™. Call your doctor for medical advice about side effects.

Please see Brief Summary of Patient Information on the following page

ONCE-DAILY ORAL
LUMAKRAS™
(sotorasib) 120 mg tablets

LUMAKRAS™

(sotorasib) 120 mg tablets

BRIEF SUMMARY OF PATIENT INFORMATION
LUMAKRAS™ (loo-ma-krass) (sotorasib) tablets

What is LUMAKRAS?

LUMAKRAS is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):

- that has spread to other parts of the body or cannot be removed by surgery, **and**
- whose tumor has an abnormal KRAS G12C gene, **and**
- who have received at least one prior treatment for their cancer.

Your healthcare provider will perform a test to make sure that LUMAKRAS is right for you.

It is not known if LUMAKRAS is safe and effective in children.

What should I tell my healthcare provider before taking LUMAKRAS?

Before taking LUMAKRAS, tell your healthcare provider about all your medical conditions, including if you:

- have liver problems
- have lung or breathing problems other than lung cancer
- are pregnant or plan to become pregnant. It is not known if LUMAKRAS will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LUMAKRAS passes into your breast milk. Do not breastfeed during treatment with LUMAKRAS and for 1 week after the final dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, dietary and herbal supplements. LUMAKRAS can affect the way some other medicines work, and some other medicines can affect the way LUMAKRAS works.

Especially tell your healthcare provider if you take antacid medicines, including Proton Pump Inhibitor (PPI) medicines or H_2 blockers during treatment with LUMAKRAS. Ask your healthcare provider if you are not sure.

How should I take LUMAKRAS?

- Take LUMAKRAS exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking LUMAKRAS unless your healthcare provider tells you to.
- Take LUMAKRAS 1 time each day, at about the same time each day.
- Take LUMAKRAS with or without food.
- Swallow LUMAKRAS tablets whole. Do not chew, crush, or split tablets.
- If you cannot swallow LUMAKRAS tablets whole:
  - Place your daily dose of LUMAKRAS in a glass of 4 ounces (120 mL) of non-carbonated, room temperature water without crushing the tablets. Do not use any other liquids.
  - Stir until the tablets are in small pieces (the tablets will not completely dissolve). The color of the mixture may be pale yellow to bright yellow.
  - Drink the LUMAKRAS and water mixture right away or within 2 hours of preparing. Do not chew pieces of the tablet.
  - Rinse the glass with an additional 4 ounces (120 mL) of water and drink to make sure that you have taken the full dose of LUMAKRAS.
  - If you do not drink the mixture right away, stir the mixture again before drinking.
- If you take an antacid medicine, take LUMAKRAS either 4 hours before or 10 hours after the antacid.
- If you miss a dose of LUMAKRAS, take the dose as soon as you remember. If it has been more than 6 hours, do not take the dose. Take your next dose at your regularly scheduled time the next day. Do not take 2 doses at the same time to make up for a missed dose.
- If you vomit after taking a dose of LUMAKRAS, do not take an extra dose. Take your next dose at your regularly scheduled time the next day.

What are possible side effects of LUMAKRAS?

LUMAKRAS may cause serious side effects, including:

- **Liver problems.** LUMAKRAS may cause abnormal liver blood test results. Your healthcare provider should do blood tests before starting and during treatment with LUMAKRAS to check your liver function. Tell your healthcare provider right away if you get any signs or symptoms of liver problems, including:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or "tea-colored" urine
  - light-colored stools (bowel movements)
  - tiredness or weakness
  - nausea or vomiting
  - bleeding or bruising
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach-area (abdomen)
- **Lung or breathing problems.** LUMAKRAS may cause inflammation of the lungs that can lead to death. Tell your healthcare provider or get emergency medical help right away if you have new or worsening shortness of breath, cough or fever.

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with LUMAKRAS if you develop side effects.

The most common side effects of LUMAKRAS include:

- diarrhea
- muscle or bone pain
- nausea
- tiredness
- liver problems
- cough
- changes in liver function tests
- changes in certain other blood tests

These are not all the possible side effects of LUMAKRAS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Amgen at 1-800-772-6436 (1-800-77-AMGEN).

How should I store LUMAKRAS?

- Store LUMAKRAS at room temperature between 68°F to 77°F (20°C to 25°C).
- The bottle has a child-resistant closure.

Keep LUMAKRAS and all medicines out of the reach of children.

General information about the safe and effective use of LUMAKRAS.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LUMAKRAS for a condition for which it was not prescribed. Do not give LUMAKRAS to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about LUMAKRAS that is written for healthcare professionals.

What are the ingredients in LUMAKRAS?

Active Ingredient: sotorasib

Inactive Ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, and magnesium stearate. Tablet film coating material contains polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and iron oxide yellow.

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For more information, go to www.LUMAKRAS.com or call 1-800-772-6436 (1-800-77-AMGEN).

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 05/2021

v1

> I had cost-of-living debt because I chose to pay my medical bills. I put other things, like food, on my credit card.
>
> —GWEN DARIEN

BEN HIDER

« *continued from page 55*

Even when generics are available, Dusetzina says, people on Medicare can have higher out-of-pocket costs for generics than for brand names because of a loophole in the Medicare Part D benefit.

"This monopoly is completely a function of our laws and the policies that have been purchased with billions of dollars in lobbying and campaign contributions by the drug companies through the years," Mitchell says.

Rajkumar agrees and noted that pharmaceutical companies and their trade organizations spent $220 million on lobbying in the U.S. in 2018.

SERIOUSNESS OF THE DISEASE

Patients' lives are dependent on new innovation of these drugs. Maybe the high costs are necessary to drive development. It takes about 12 years for a drug to go from testing to approval, and only about 10% to 20% ever reach the market.

But this still doesn't explain why Americans pay at least twice as much for medications as patients do in other countries.

"Some would argue that we can't make this comparison because not all drugs are available in those countries," Dusetzina says. "However, you could ask why a certain

drug isn't available in another country; probably because it doesn't have good value."

Mitchell agrees that the argument for innovation doesn't hold up. U.S. drug prices are still drastically inflated.

"A recent study showed that every single one of the drugs approved by the FDA from 2010 to 2019 was based on science paid for by taxpayers through the National Institutes of Health (NIH)," Mitchell points out. "In other words, taxpayers are paying for the early high-risk basic foundational science. When something shows promise, the NIH hands it off to the drug companies."

HOW WE FIX THE PROBLEM

Gwen Darien, who is the executive vice president for patient advocacy and engagement at the National Patient Advocate Foundation, has been diagnosed with cancer three times — in 1993 with non-Hodgkin lymphoma, in 2014 with breast cancer and in 2018 with endometrial cancer. She still remembers the moment in 1994 when she found out the Epogen (epoetin alfa) injections that boost her white blood cells cost $2,000 per shot. She didn't have to pay the full amount, but her portion was significant. »

"I was shocked because it was an integrated part of my care that helped me stay on my chemotherapy schedule," Darien says. "I had to decide where I was going to take on debt. I didn't have any medical debt, but I had cost-of-living debt because I chose to pay my medical bills. I put other things, like food, on my credit card."

The truth of the problem, Mitchell points out, is that drugs don't work if people can't afford them.

So what do we do now?

VALUE-BASED PRICING

Most other developed countries have health technology assessment evaluations that look at a new treatment and compare it to the standard of care, then negotiate a fair price based on the benefit it brings over existing treatments. Dusetzina says the U.S. does not do this and coverage is mandatory if a medication is FDA approved. This makes for a lack of fair pricing.

"We have a lot of drugs that don't improve the quality or length of a patient's life more than the current standard of care," Dusetzina says. "So we should think about either not paying as much or not offering them at all. And that's important: The most powerful negotiations are the ones you can walk away from. As a country, we have a really hard time walking away from the table when it comes to a treatment, even if it doesn't look like it works."

The solution is pretty straightforward, according to Rajkumar. "The price of the drug is negotiated and proportional to the value it provides," he says. "So the drug that works for one month will not be the same price as a drug that works for one or two years."

MEDICARE NEGOTIATION

To have a value-based pricing system, Medicare must have the ability to negotiate. These solutions go hand-in-hand.

One study found that if Medicare negotiated prices to those secured by the Veterans Administration hospital system, there would be savings of $14.4 billion on just the top 50 dispensed oral drugs.

Beyond these two big changes, Rajkumar outlines others, including allowing more generics and biosimilars to enter the market and reforming the patent system to stop manufacturers from maintaining monopolies.

"The first step is to curb the drug companies' unilateral pricing power," Mitchell says. "And then to ensure that we make adjustments downstream, like with the pharmacy benefits managers (PBMs) who work for insurance companies and do all of their work in secret. There's no transparency

JENNY SIEGWART

whatsoever. It's wrong that I can't know if the preferred drug on a pharmacy plan formulary is the best drug for me, or if it's the least expensive drug among equally effective options, or if it's simply there because the PBM got a big rebate from the drug company."

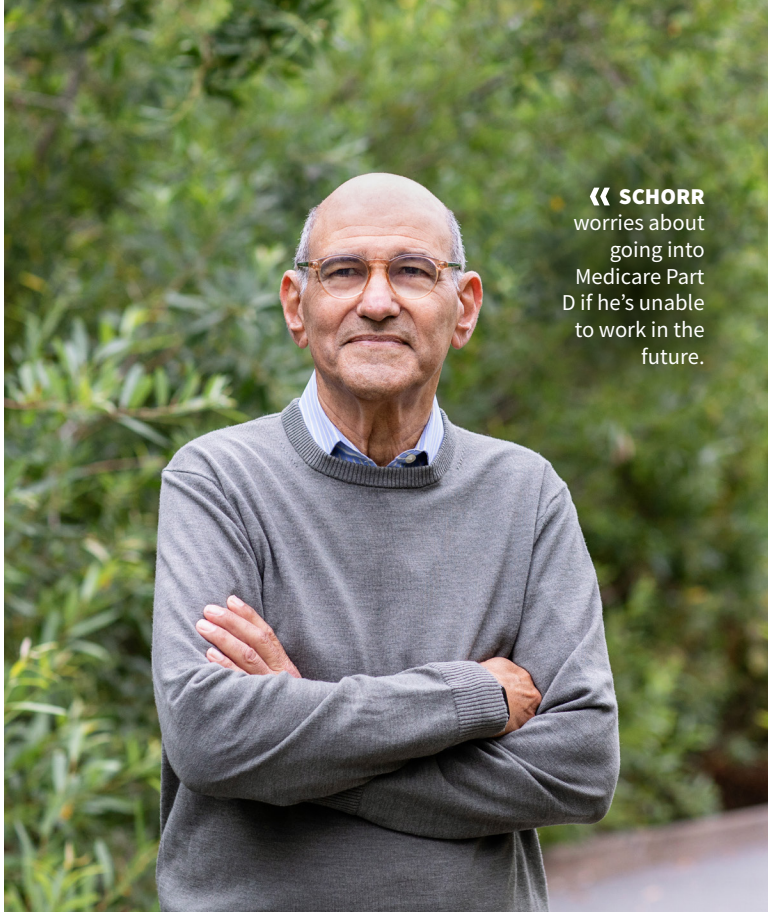
Robin Yabroff, the scientific vice president of health services research at ACS, says their research shows that when patients have health insurance coverage, they are more likely to receive recommended cancer screening and be diagnosed with earlier-stage disease when the cancer is more treatable. Treating early-stage cancer tends to be much less expensive for patients as well as for payers.

Additionally, people with health insurance coverage who smoke are also more likely to receive support for smoking cessation, which can reduce the risk of developing multiple types of cancer.

"So that is another solution to keeping costs of cancer care down," Yabroff says. "Ensuring people get access to high-quality, primary care, cancer prevention and screening."

'HOUSE OF CARDS'

Andrew Schorr received a diagnosis of chronic lymphocytic leukemia in 1996 and myelofibrosis in 2011. Currently, he gets immunoglobulin infusions once a month. When he went on Medicare at 65, his treatment cost him $700 a month, and because he still worked, he did not qualify for patient assistance programs. He had no choice but to struggle through. When his doctor switched drugs, his payment went up to $980 a month. So he took a new job and went back on private insurance with Medicare as secondary. His copay went down to $25 a month. Schorr, who is the executive vice president of Patient Power, says he loves his work and sees it as his calling, but what if he isn't able to work anymore?



« SCHORR worries about going into Medicare Part D if he's unable to work in the future.

"I would be really concerned about my health," Schorr says. "Because that would throw me back into Medicare Part D, and Medicare doesn't negotiate prices. And there's not anywhere I can get assistance from."

Because, as Darien says, "If you're in a house of cards, you can pull out any one of the cards and the rest will come tumbling down." C

Patient Assistance Programs

"THERE ARE PEOPLE WHO CAN HELP," Gwen Darien says. "In hospitals, outpatient centers and even in small doctors' offices there are social workers and patient navigators who can help you negotiate a payment plan. Our organization, Patient Advocate Foundation, provides case management services and financial aid to patients with chronic and complex illnesses. There are other organizations like the Leukemia & Lymphoma Society that also have copay relief."

Andrew Schorr agrees that patient navigators are a great resource. "My best advice is to not be embarrassed to seek out an oncology financial navigator that's accessible to you either through your clinic, hospital or patient advocacy group."

However, it's important to keep in mind that patient assistance programs, like copay cards and coupons, are usually geared toward people with private insurance and are not a solution to the problem.

"Furthermore, these programs are not infinitely funded," Dusetzina says. "Often funds run dry towards the later part of the year when they've exhausted the support they can give."

Rajkumar points out that if we continue to focus on the out-of-pocket cost to the patient, overall costs will continue going up.

"That's what pharma is doing," he says. "Telling patients they should advocate for lower out-of-pocket costs. This means the manufacturers can keep increasing prices because they pass that expense on to someone else. And that someone else is the whole of society, which pays higher insurance premiums and taxes."

The idea that people have to start GoFundMe campaigns or ask multinational corporations for help is wrong to David Mitchell.

"It's offensive," he says. "These drugs should be affordable and they should be able to get them."

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Matchmakers

How basket trials match patients with drugs based on the genetic makeup of their tumors

By SONYA COLLINS

Drew Huggins was running out of options. After his diagnosis of metastatic pancreatic cancer two years ago, at age 47, he hadn't had any luck with the treatments he'd tried so far.

His tumors didn't respond to 13 cycles of FOLFIRINOX, an arduous four-drug chemotherapy combination. The chemotherapy combination of gemcitabine and paclitaxel didn't work either. They only left him with severe neuropathy, which causes debilitating pain, weakness and numbness in his hands and feet, from which he is still trying to recover. Next, he enrolled in a clinical trial at The University of Texas MD Anderson Cancer Center in Houston that used an antibody-drug conjugate to try to attack the tumor. But while Huggins was on this drug, the tumor grew by 25%.

"After that, I pushed and said, 'There's got to be something else that can be done here,'" Huggins recalls.

PHOTO PROVIDED BY DREW HUGGINS

DREW HUGGINS participated in a basket trial, where he was introduced to a successful treatment option for metastatic pancreatic cancer.

It's rare for pancreatic tumors to have a genetic mutation that drugs can target. But Huggins' oncologist took a "we'll never know till we try" approach, and it paid off. The doctor sent tissue from one of Huggins' tumors to a lab to see if it had any gene mutations that might be vulnerable to existing targeted drugs. »

SHYREECE POMPEY'S tumors shrank with the help of a targeted therapy suggested to her at a second opinion appointment.

MARITA MADELONI

"And that's when it came back with the match," Huggins says.

Huggins' tumor had a rare mutation called an NRG1 fusion. This genetic change happens in only about 1.5% of pancreatic cancers, according to some estimates. That gives NRG1-driven pancreatic cancers the distinction of being a "rare disease." The gene fusion made Huggins eligible for a phase 1 clinical trial in MD Anderson's Department of Investigational Cancer Therapeutics. The trial tests a targeted drug called Zeno (zenocutuzumab) in any type of cancer driven by NRG1 fusions.

Huggins travels the 200-plus miles from his home in San Antonio, Texas, to MD Anderson for two-hour infusions every two weeks. His first scan six weeks into the experimental treatment showed a significant reduction in tumor size.

"It was dramatic. On the scans, you could see the difference in the dark areas and the areas where it was cleared up," Huggins says.

Now, nine months later and still on the treatment, his cancer is stable.

Increasingly, researchers are playing matchmaker between patients with metastatic cancer and targeted drugs. In studies called basket trials, researchers focus less on the cancer site — such as the breast, lung or colon — and more on the genetic makeup of the tumor no matter where it first appeared. They perform comprehensive genetic analysis of the tumor tissue to see if it carries any tumor-driving mutations for which targeted drugs already exist. The existing drug may not be approved by the Food and Drug Administration (FDA) or may have approval to treat only a certain type of cancer with that particular mutation. But in the trial, anyone with that mutation, regardless of the type of cancer, receives treatment with that drug to see if it might work for them.

"Is treatment response guided more by the mutation or more by the tumor type? We are looking for the answer to that. The results may be complicated," says Dr. Peter O'Dwyer, who co-chairs the NCI-MATCH trial, the largest-ever basket trial. The publicly funded trial is co-led by the ECOG-ACRIN Cancer Research Group and the NCI.

> I learned about targeted therapy for my specific biomarker. They never mentioned that at the other hospital.
>
> — *SHYREECE POMPEY*

While basket trials won't lead to effective new treatment options for everyone, the study design is bringing hope as well as life-prolonging treatment to many people who previously had none.

WHAT ARE TARGETED DRUGS?

Targeted drugs, also known as precision treatments, attack a specific genetic characteristic of the tumor that is helping it grow. The drugs act more specifically on cancer cells, unlike chemotherapy, which attacks cancerous and normal cells. Typically, a specific genetic alteration or presence of a protein in the tumor would be necessary to be eligible for treatment.

Among FDA-approved targeted drugs are treatments for breast, colorectal, skin and lung cancers and many others. Typically, the FDA approves these drugs to treat a specific type of cancer, such as lung. Sometimes drugs earn approval for another type of cancer later, after additional studies prove it is beneficial for that other type.

Non-small cell lung cancer is one in which targeted drugs have been a major advance. There are nearly a dozen targetable gene mutations that arise in this type of cancer. Comprehensive biomarker testing matches patients or the genetic makeup of their unique tumor with treatments.

This type of genetic matchmaking is why Shyreece Pompey, 50, who now lives in Woodland, California, »

believes she's alive today. She has been living with stage 4 non-small cell lung cancer for seven years.

When she was diagnosed with advanced cancer at a local community hospital in St. Joseph, Michigan, the oncologist wanted to start her on a highly potent combination of chemotherapy drugs that night, and Pompey agreed. But she also sought a second opinion on her treatment options at the University of Michigan.

"That's where I learned about targeted therapy for my specific biomarker," she recalled. "They never mentioned that at the other hospital."

Pompey had ALK-positive lung cancer, so she received Xalkori (crizotinib), which targets ALK and ROS1 fusions. Her cancer didn't progress for three-and-a-half years. But eventually, it spread to her brain. That's when her oncologist switched her to a different ALK inhibitor called Alecensa (alectinib).

The drug shrank all her tumors. They are still visible but static. Today, her lungs, which were filled with fluid and caused her great difficulty breathing when she was diagnosed, have recovered their full capacity.

"My voice is hoarse this morning but that's not because of the cancer," she says. "I sang with the worship team at church yesterday. They like to have me rock out on this one rock-gospel song."

Pompey's story is not unusual. Though many life-prolonging targeted drugs are available to treat non-small cell lung cancer, comprehensive biomarker testing to match patients with those drugs is not a foregone conclusion at every health care facility. Some organizations, such as the American Society for Clinical Oncology, recommend that everyone with this type of cancer get tested for at least the most common drug targets. Some patient advocacy groups, such as the American Lung Association and LUNGevity, urge anyone with non-small cell lung cancer to ask their health care provider about comprehensive biomarker testing.

PARADIGM SHIFT

Non-small cell lung cancer is just one cancer type for which medical societies are pushing for doctors to let genetic mutations be their guide. But basket trials could prompt this type

ATHENA BLUDÉ

RERAT matched for a drug combination that was tested in patients with advanced solid tumors and a specific genetic mutation.

of paradigm shift across many cancer types and lead to more "tumor-agnostic" drug approvals from the FDA. That means the drug would be approved to treat any type of cancer, regardless of where it originated, as long as it has a particular genetic mutation.

"We have a few drugs that have tumor-agnostic approval, but so many other targeted drugs do not," says Dr. Monica Mita, a hematologist-oncologist and co-director of experimental therapeutics at Cedars-Sinai Medical Center in Los Angeles. "That's one of the most interesting opportunities of tumor-agnostic studies."

Basket trials also give researchers the opportunity to learn the role that certain tumor-driving gene mutations play in the overall behavior of the cancer. "It's an opportunity to go beyond just seeing the cancer as a breast cancer or a colon cancer and to see it instead, for example, as a PI3K-mutated cancer," Mita says.

The greatest beneficiaries of this study design may be people with rare cancers.

CANCERS TOO RARE TO STUDY

Ann Rerat of Trumbull, Connecticut, learned she had leiomyosarcoma (LMS) of the uterus in 2017 when she was 60 years old. This rare but very malignant cancer can develop in any smooth muscle tissue, such as the digestive system, urinary system, blood vessels and uterus. Uterine LMS affects fewer than 1 in 100,000 women.

In cancers as rare as these, clinical trials are pretty uncommon. Researchers simply cannot enroll enough patients with the disease to study it properly. That's why basket trials can be such a boon for people with these rare conditions. When researchers build study cohorts based on the genetic makeup of the tumor, rather than the tumor type, they may be able to enroll enough people with many different tumor types for a viable clinical trial.

After a hysterectomy, a targeted drug, an additional surgery and chemotherapy with docetaxel and gemcitabine, Rerat's cancer continued to advance. She was at stage 4 and had a life expectancy of less than five years when Dr. David Hyman, a medical oncologist at Memorial Sloan Kettering Cancer Center in New York, invited her to participate in a basket trial. The JAVELIN BRCA/ATM trial tested the drug combo of the PD-L1 inhibitor Bavencio (avelumab) and PARP inhibitor Talzenna (talazoparib) in people with advanced solid tumors that had either a BRCA1 or 2 gene mutation or an ATM mutation. Rerat was a match.

Talzenna is a daily pill and Bavencio is administered by IV infusion every two weeks. When Rerat started the drug combination in August 2018, she had tumors throughout her pelvic area. She went for scans every three months to monitor the drug's efficacy.

On the first scan, the tumors were smaller. By the sixth, Rerat had no evidence of disease. Her scans have been clean ever since. »

"I still don't have the words to express what it was like to get those results," she says. "Incredible. Grateful. It has changed my whole world."

Basket trials may make this world-changing impact on many people with rare cancers.

"People with very rare tumors are an underserved population," Mita says.

The DART trial aims to serve these patients. This trial tests the immune checkpoint inhibitor combination of Opdivo (nivolumab) and Yervoy (ipilimumab) in patients with any of a long list of rare solid tumors. A recent publication of the nonpancreatic high-grade neuroendocrine carcinoma group showed that 44% of patients with this type of tumor responded to the drug combo. In the angiosarcoma patient group, 25% responded.

As of June 20, 2021, about 60% of the 1,172 patients enrolled in the NCI-MATCH had rare or less common cancers. The trial defines "less common" as any cancers other than breast, colorectal, non-small cell lung or prostate. Among the less common cancers included in the trial are cancers of the central nervous system, kidney, liver and biliary tract, and neuroendocrine cells, among others.

"But you can also think of rare cancers as being defined by molecular aberration," O'Dwyer says. "Some of these mutations occur in fewer than 1% or 2% of cancers, so in many regards each of these tumors is a rare tumor."

That's the case with the NRG1 fusions — the kind that Huggins has.

"NRG1 fusions are extremely rare; however, they are rare across many different disease types, so when you group them all together in a basket trial, you can study the effects of targeting this genetic alteration," says Dr. Alison Schram, a medical oncologist at Memorial Sloan Kettering Cancer Center and principal investigator on the Zeno trial in which Huggins is enrolled. Schram and her colleagues recently reported that 42% of patients with NRG1 fusion-positive pancreatic cancer responded to the drug.

> I still don't have the words to express what it was like to get those results. Incredible. Grateful.
>
> —ANN RERAT

TUMOR TYPE OR GENE MUTATION: WHICH MATTERS MORE?

For some, but certainly not all tumor types, basket trials have shown that mutations could be more important than tumor type in treatment decisions. Basket trials that studied the effects of Vitrakvi (larotrectinib) and Rozlytrek (entrectinib) in tumors with a genetic alteration called an NTRK fusion led to tumor-agnostic FDA approvals for these drugs.

Research has also found that tumors with RET fusions tend to respond to RET inhibitors regardless of the tumor type. The RET inhibitor Retevmo (selpercatinib) is approved to treat lung and thyroid cancers with this mutation. But investigators on the LIBRETTO-001 trial recently reported that 47% of patients with RET fusions across numerous cancer types responded to Retevmo.

"Basket trials enrolling patients on the basis of NTRK and RET fusions have yielded incredible results. These drugs benefit the majority of patients with the relevant biomarkers," says Schram, who has been an investigator on trials of those drugs.

The massive NCI-MATCH trial's 39 treatment groups, enrolling at nearly 1,100 cancer centers in all 50 states, Washington, D.C., and Puerto Rico, explore the efficacy of a number of drugs to treat tumors with various genetic abnormalities. The researchers have published the findings of 19 of those groups.

Among the findings, 38% of patients with $BRAF^{v600E}$ mutations responded to the drug combination of the BRAF inhibitor Tafinlar (dabrafenib) and MEK inhibitor Mekinist (trametinib). In patients without colorectal cancer whose tumors had what's called a mismatch repair deficiency, 36% responded to Opdivo, an immunotherapy

drug that targets PD-1. That data helped earn the drug tumor-agnostic approval from the FDA. Just over 28% of those with AKT1 E17K mutations responded to the AKT kinase inhibitor capivasertib.

But not all gene mutations trump cancer type. Research indicates, for example, that colorectal cancers tend to be harder to attack with gene-targeted therapies, as they are sometimes better suited for other cancers such as melanoma but not for gastrointestinal cancer.

"In these cancers, if you inhibit one pathway, another pathway can sometimes compensate, leading to continued cancer growth despite inhibiting the specific gene alteration," Schram says.

For that reason, researchers are testing drug combinations to target multiple pathways simultaneously and will continue to design both the trials that group cancers by site or tumor type and basket trials that group cancers by their genetic makeup.

Because not all tumors have a strong response to targeted drugs, the jury is still out on whether everyone with metastatic cancer of any type should get genetic analysis of their tumor. "There's a lot of controversy," Schram says, "about the cost-benefit ratio of doing genomic sequencing on every tumor." Some say the tests are too expensive to justify in people who have cancers for which there are no proven-effective targeted drugs. But on the other hand, with the advent of basket trials as well as the continually dropping price of DNA sequencing, genetic analysis could open the door to experimental treatments for people who may believe they are out of options.

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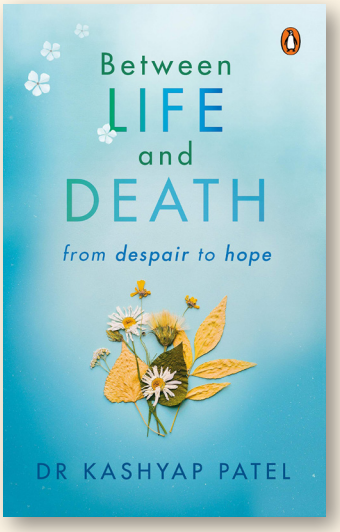
Recognizing Fate Without Losing Control

Patients and their caregivers can navigate a terminal cancer diagnosis while keeping dignity intact. *By* DARLENE DOBKOWSKI, M.A.



"BETWEEN LIFE AND DEATH: FROM DESPAIR TO HOPE" can be purchased on Amazon.

AS MUCH AS PATIENTS, their families and their caregivers want their cancer journey to take an overall positive trajectory, sometimes the odds are against them. This can set everyone's mind racing with worries about what they need to take care of in their lives and how to remain as comfortable as possible as they reach the end of their lives.

Dr. Kashyap Patel, CEO of Carolina Blood and Cancer Care Associates in Rock Hill, South Carolina, and vice president of the Community Oncology Alliance, recently published the book "Between Life and Death: From Despair to Hope," which focuses on his and some of his patients' experiences as they come to terms with death.

"Patients don't mind accepting the conversation about (dying)," Patel told *CURE*®. "What they don't like is losing control. The happy medium of accepting (death) comes from being very transparent about our ultimate goals."

In the book, Patel wrote about his experience with Harry Falls, a retired military pilot-turned-hang glider who received a diagnosis of stage 4 cancer. Patel and Falls formed a relationship that lasted until Falls died. Patel took notes of their meetings to formulate this collection of discussions.

"I thought if I can make this a conversational piece, jotting down my experiences with Harry and how I was able to prepare him (for death), I felt it probably may help many of my colleagues as well as patients to be ready for this conversation."

Patel also detailed his time with another patient, Annie Carlson, a theater artist who received a diagnosis of advanced breast cancer in her mid-20s.

Both patients' experiences with Patel highlight the importance of these connections with their health care teams during a terminal cancer diagnosis. Patel recommends that every patient or caregiver ask their oncologist very candidly about their life expectancy, which can sometimes be a frightening conversation, but can give a patient the chance to take control of their life.

"The (conversation after that) would be that 'I want to live as long as I can, but I don't want to lose my quality or dignity of my life,'" Patel said. "Life is all about balance … allowing patients to have the liberty of conversation with the physicians that, 'Please be honest with me, please make sure that you respect my cultural, spiritual or personal belief of how I want to be in control and how I want to leave this world with my terminal illness.' I think that will alleviate lots of suffering."

The end goal is not looking for a cure, but rather accepting that the advanced-stage cancer will be a life-limiting event, Patel said. He also emphasized the significance of focusing on quality of life during this time.

"How can we from now until the day (you die) maximize your presence on Earth for you, for your loved ones and for (people's lives) that you can make a difference in?" he said.

Not only are patients a part of this process, but so are their caregivers, who play "a very vital role," Patel said. Caregivers can offer patients the support and love they need to go through this time in their lives, which can include completing a bucket list with trips and activities the patients always wanted to do.

"In time, whatever time is left, we can make that person feel most relevant," Patel said.

Caregivers can also empower the patient to "let go" during a time that can be the most frightening.

"Gently holding the hand and whispering in the ears of the loved one that we give you permission to move on wherever you're heading, it's actually quite soothing," Patel said.

"The caregivers can be there to enable the patient who's been going through these challenges of ensuring that whatever could be fulfilled within the narrow time frame can be achieved and accomplished."

Patel added that we are mortal creatures, but it is up to all of us to decide whether we hide in a constant fear of death or accept it since it is inevitable.

"Accepting, compromising ... and living in equanimity — I call these three a foundation of being happy," Patel said. "Accept what comes your way, compromise with what you have and make it to the fullest where you can have a quality of life combined with longevity if you can and then leave your life in equanimity so that you are not losing (the) pure emotional struggle by the fear of death."

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EMBRACING SUMMER SWIMSUITS WITHOUT Silicone Prostheses as a Breast Cancer Survivor

Summer poses challenges for those who have undergone mastectomy. Learn how one breast cancer survivor found a way to embrace breastlessness while still feeling feminine.

By BONNIE ANNIS

BONNIE ANNIS

IN JUST A FEW WEEKS, my family and I will be taking a much-needed vacation. Since we've basically been under house arrest since the beginning of COVID-19, to say we're excited would be a great understatement. The thought of lying in the warm sunshine and listening to lapping waves sends shivers up my spine, but finding the right swimsuit for my post-mastectomy body is still an issue.

After our last trip to the beach, I threw away the mastectomy swimsuit I'd purchased specifically for that trip. It was a hassle putting the prostheses in each morning and taking them out each day. Though I'd purchased prostheses specifically made for use while swimming, they required special care. After washing them off, I'd lay them on a towel to dry completely before the next day's adventures. I did my best to keep them out of sight but inevitably, my young granddaughter saw them lying on the bathroom counter one day and wanted to play with them. She was too young to understand those were Gigi's boobs and I preferred not to have to explain further. Instead, I said: "Those are Gigi's special things. Let's play with something else right now," while leading her downstairs to find a better plaything.

Thinking back to the adventures of our last vacation, I'm grateful I had tucked the prostheses into the suit well before we embarked on an airboat ride through the bay. As we sped along, bouncing over the water, I imagined one of my prostheses escaping and flying into the murky water. Beneath reflections of dangling Spanish moss, I also pictured a Florida gator making haste to retrieve the flesh-colored object. Thankfully, my wandering thoughts didn't come to fruition. As an extra layer of protection, I'd zipped a jacket over my suit when our guide mentioned it might get chilly zooming across the water.

This year, I've decided to be brave. Instead of dealing with the constant hassle of washing and drying the swim prostheses, I'm leaving them at home. Lately, I've found it easier to go flat and my family members have learned to accept me as a flattie because they love me. But I'm wondering how I'll be perceived when we go out to dinner or participate in other touristy adventures. Will people notice my flat chest? Will they care?

I don't like to make others uncomfortable, but it is what it is. Just as someone who has lost an arm or leg because of a terrible accident, health issue or birth defect, being breastless wasn't my choice. I've tried for

ANNIS ILLUSTRATION BY RAY PELESKO; SWIMMER: MONKOGRAPHIC / STOCK.ADOBE.COM

years to conform to society's protocol for breast cancer victims, to hide my deformity by replacing what was lost with a silicone lookalike, but it didn't work for me. Instead, I've accepted my new normal of facing the stigma of flatness.

It's hard to understand why society perceives a person's gender by breasts or lack thereof. Breasts don't make a woman. It's possible to feel sexy without them. It's a state of mind. But because of the constant attention given to breasts by television and movies, women like me may struggle to find their place in the world.

Women who have undergone breast cancer surgery don't want to garner attention because of their breastlessness any more than an amputee might, but breastlessness is often easier to conceal than a lost limb.

Taking breasts out of the equation will make summer a lot easier this year. Instead of looking for a swimsuit made especially for those who've undergone mastectomy, I'm opting for a swim shirt and a cute little skort (skirt/shorts combination). I've chosen a pretty floral pattern that will partially camouflage my chest and I've decided that's good enough.

"There are other things to stress over than mastectomy suits and prostheses."

This year, we're planning to take a catamaran over the glorious gulf waters and I definitely won't be worrying about a wandering boob. It will be such a spectacular experience to feel the wind in my face and the salt water in my hair. Not only will I be breastless, but I'll be maskless, too!

I used to think my breasts were my best asset, but now, I'm OK with them being gone. After making the choice to go flat, I'm happier unhindered by underwires and boning.

One day, breastlessness will be widely accepted. Until that time, those who have experienced the trauma of breast cancer and the loss of body parts that often accompanies it must decide how to adjust. I'd suggest going flat for a day. See how it makes you feel. You may or may not like it, but you'll never know until you try. The beach is a great place for a trial run.

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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

In patients with CSCC that has spread or cannot be cured by surgery or radiation:

LIBTAYO works with your immune system to help treat advanced CSCC

In 1 clinical trial of 137 patients with CSCC that had spread or could not be cured by surgery or radiation treated with LIBTAYO*:

46% 63 out of 137 patients saw an improvement in their advanced CSCC.

Responses to LIBTAYO lasted 6 months or longer in **50 out of 63 patients (79%)** and 12 months or longer in **34 out of 63 patients (54%)**.

In the same clinical trial, in a separate group of 56 patients with CSCC that had spread who took LIBTAYO at the recommended dose†:

41% 23 out of 56 patients saw an improvement in their advanced CSCC.

Responses to LIBTAYO lasted 6 months or longer in **15 out of 23 patients (65%)**.

In this trial, responses lasted between 2 months and more than 2 years (24.2+ months); plus sign (+) denotes ongoing at last assessment.

*Patients were dosed by body weight.
†LIBTAYO 350 mg over a 30-minute infusion every 3 weeks.
CSCC=cutaneous squamous cell carcinoma.

LIBTAYO may not work for everyone.

**LIBTAYO Surround® offers support and resources to patients prescribed LIBTAYO.
If you think LIBTAYO may be right for you, talk to your doctor.**

What is LIBTAYO?

LIBTAYO (Lib-TIE-oh) is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation.

It is not known if LIBTAYO is safe and effective in children.

Important Safety Information

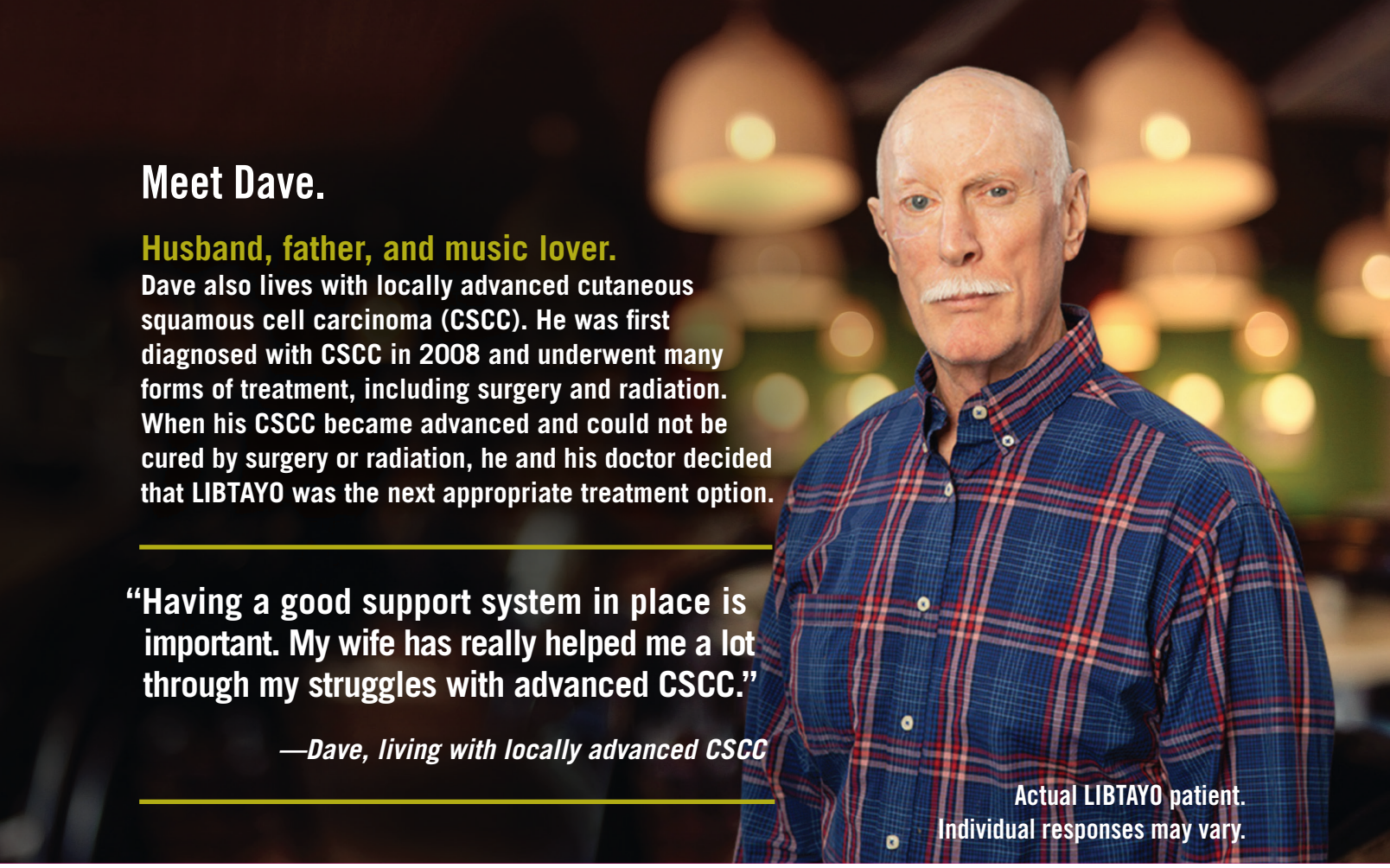
What is the most important information I should know about LIBTAYO?

LIBTAYO is a medicine that may treat certain cancers by working with your immune system. LIBTAYO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- **Lung problems:** cough, shortness of breath, or chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual, stools that are black, tarry, sticky or have blood or mucus, or severe stomach-area (abdomen) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), or bleeding or bruising more easily than normal
- **Hormone gland problems:** headache that will not go away or unusual headaches, eye sensitivity to light, eye problems, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, feeling more hungry or thirsty than usual, urinating more often than usual, hair loss, feeling cold, constipation, your voice gets deeper, dizziness or fainting, or changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in your amount of urine, blood in your urine, swelling of your ankles, or loss of appetite
- **Skin problems:** rash, itching, skin blistering or peeling, painful sores or ulcers in mouth or nose, throat, or genital area, fever or flu-like symptoms, or swollen lymph nodes
- **Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with LIBTAYO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:** chest pain, irregular heartbeat, shortness of breath or swelling of ankles, confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs, double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight, persistent or severe muscle pain or weakness, muscle cramps, low red blood cells, or bruising
- **Infusion reactions that can sometimes be severe.** Signs and symptoms of infusion reactions may include: nausea, chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, back or neck pain, or facial swelling

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.



Meet Dave.

Husband, father, and music lover.

Dave also lives with locally advanced cutaneous squamous cell carcinoma (CSCC). He was first diagnosed with CSCC in 2008 and underwent many forms of treatment, including surgery and radiation. When his CSCC became advanced and could not be cured by surgery or radiation, he and his doctor decided that LIBTAYO was the next appropriate treatment option.

"Having a good support system in place is important. My wife has really helped me a lot through my struggles with advanced CSCC."

—Dave, living with locally advanced CSCC

Actual LIBTAYO patient.
Individual responses may vary.

To learn more about Dave and other patient stories, visit MeaningfulStories.com

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **Rejection of a transplanted organ.** Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had
- **Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with LIBTAYO. Your healthcare provider will monitor you for these complications

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with LIBTAYO. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with LIBTAYO if you have severe side effects.

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. LIBTAYO can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment
- You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of LIBTAYO. Talk with your healthcare provider about birth control methods that you can use during this time
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO

- are breastfeeding or plan to breastfeed. It is not known if LIBTAYO passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of LIBTAYO include muscle or bone pain, tiredness, rash, and diarrhea. These are not all the possible side effects of LIBTAYO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Regeneron Pharmaceuticals and Sanofi at 1-877-542-8296.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Brief Summary of full Prescribing Information on the following pages.

REGENERON | SANOFI GENZYME

IMPORTANT PATIENT INFORMATION ABOUT LIBTAYO® (cemiplimab-rwlc) INJECTION

Please speak with your healthcare provider regarding LIBTAYO. Only your healthcare provider knows the specifics of your condition and how LIBTAYO may work with your overall treatment plan. If you have any questions about LIBTAYO (pronounced Lib-TIE-oh), speak with your healthcare professional. Prescription Only.

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- pain on the right side of your stomach-area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

Hormone gland problems.
- headache that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Kidney problems.
- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite

Skin problems.
- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in mouth or nose, throat, or genital area
- fever or flu-like symptoms
- swollen lymph nodes

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- chest pain, irregular heartbeat, shortness of breath or swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising

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- itching or rash
- flushing
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What is LIBTAYO? LIBTAYO is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation. It is not known if LIBTAYO is safe and effective in children.

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you:
- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. LIBTAYO can harm your unborn baby

Continued on following page

IMPORTANT PATIENT INFORMATION ABOUT LIBTAYO® (cemiplimab-rwlc) INJECTION

Females who are able to become pregnant:
- Your healthcare provider will give you a pregnancy test before you start treatment with LIBTAYO.
- You should use an effective method of birth control during your treatment and for at least 4 months after the last dose of LIBTAYO. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO.

• are breastfeeding or plan to breastfeed. It is not known if LIBTAYO passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive LIBTAYO?
- Your healthcare provider will give you LIBTAYO into your vein through an intravenous (IV) line over 30 minutes.
- LIBTAYO is usually given every 3 weeks.
- Your healthcare provider will decide how many treatments you will need.
- Your healthcare provider will do blood tests to check you for side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of LIBTAYO?
LIBTAYO can cause serious side effects, including:
- **See "What is the most important information I should know about LIBTAYO?"**

The most common side effects of LIBTAYO include muscle or bone pain, tiredness, rash, and diarrhea.

These are not all the possible side effects of LIBTAYO.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LIBTAYO. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about LIBTAYO, talk with your healthcare provider. You can ask your healthcare provider for information about LIBTAYO that is written for health professionals.

REGENERON | SANOFI GENZYME

This is a brief summary of the most important information about LIBTAYO. For more information, talk with your healthcare provider, call 1-877-542-8296, or go to www.LIBTAYO.com

AIMING FOR NEW TARGETS

In its Speaking Out video series, on behalf of Aim at Melanoma, *CURE*® spoke with Dr. Sunandana Chandra about emerging therapies in melanoma. By KRISTIE L. KAHL

IN 2021, MORE THAN 200,000 new cases of melanoma are expected to be diagnosed, according to Aim at Melanoma. For all stages, the survival rates are estimated at 93% — and hope continues to rise among those with the disease as new therapies are under clinical evaluation.

DR. SUNANDANA CHANDRA

In particular, treatment options that involve patients' immune systems in attacking malignant cells continue to be expanded upon.

As part of its Speaking Out video series, *CURE*® spoke with Dr. Sunandana Chandra, from the Robert H. Lurie Comprehensive Cancer Center of Northwestern University in Chicago, on behalf of Aim at Melanoma, about emerging therapies in the treatment of melanoma.

Q: Can you talk about what adoptive T-cell therapy is?

A: Adoptive T-cell therapy is a way of treating a person's cancer with their own immune cells. It requires collecting and growing or expanding a patient's own T cells. So the way that that's accomplished is that a piece of the tumor — or melanoma in this case — is surgically removed and then processed at a separate facility or sometimes at the institution's own facility. It's processed at a separate location so that these immune cells in the tumor, known as tumor infiltrating lymphocytes, can be extracted and then expanded or grown. And what's unique about those immune cells is that they have the ability to recognize that person's own melanoma. So then the patient undergoes chemotherapy, and those expanded T cells are then infused back into the patient, along with a few doses of this drug called interleukin 2, or IL-2. So that's essentially what adoptive T-cell therapy is.

continued on page 80 »

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cure® EDUCATED PATIENT® WEBINARS

Stomach Cancer 101 Series: Part II – Treatment

Monday, August 23, 2021 • 6 PM ET | 3 PM ET

Earlier this year, *CURE*®'s Educated Patient® Webinars partnered with Debbie's Dream Foundation to kick off its 3-part webinar series discussing news and updates related to stomach cancers. Join us on Monday, August 23 for "Part II – Treatment" where an expert panel will discuss topics highly relevant to patients, caregivers and advocates right now. Participants will have the opportunity to submit questions to be answered live by our expert panel.

Topics for discussion include:

- Treatment options, such as gastrectomy, chemotherapy, immunotherapy and targeted therapies
- Recent clinical data that shows the benefits of immunotherapies for patients
- Clinical trial options available to patients with stomach cancers

Later this year, Part III of the series will highlight a variety of tools to benefit mental health and overall quality of life for patients living with stomach cancer and their caregivers. Stay tuned for details.

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« *continued from page 78*

Q: Where are we in evaluating these therapies like TIL?

A: The therapy is logistically a little bit more challenging to administer. But this therapy is quite promising. It is important to note that it's not yet (Food and Drug Administration [FDA]) approved.

Q: What kind of data are we seeing with these therapies?

A: We are seeing that this is a very promising therapy for patients who have progressed on immunotherapy and/or a BRAF/MEK therapy if they have a BRAF mutation. And if a patient is well enough to receive TIL therapy, then it is definitely another option for us, the medical oncologist, to consider for a particular patient. Now, not all patients may be eligible for TIL therapy based on certain clinical characteristics and tumor characteristics, but it's certainly something that we could at least consider.

Q: What do patients with melanoma have to look forward to in the treatment landscape?

A: In cutaneous melanoma, there's a lot of new therapies that are being looked at to try to improve the patient's survival outcomes. Newer agents that are being studied in addition to TIL therapy are ones that target LAG-3, TIGIT — this class of oral drugs called tyrosine kinase inhibitors. And all of these that I just mentioned can be used in combination, we think, with our existing immunotherapy drugs. And so that's being actively studied in clinical trials. And in addition, other options such as immunomodulators, or drugs that tweak or affect the immune system, such as STING agonists, toll-like receptor 9 agonists may also affect the immune system in a positive way that ultimately lead to cancer cell death.

Q: That sounds like a lot to look forward to.

A: Absolutely, I mean, in general, we are trying to use combination approaches either with our existing FDA-approved drugs or new drugs all together that target different proteins to ultimately try to cause melanoma cell death. C

LEARN MORE ONLINE SCAN the QR code to watch videos from our Speaking Out series.

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Jamie Foxx for Stand Up To Cancer. Photo By G L Askew II

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