FOR PATIENTS, SURVIVORS & THEIR CAREGIVERS

SPRING 2022

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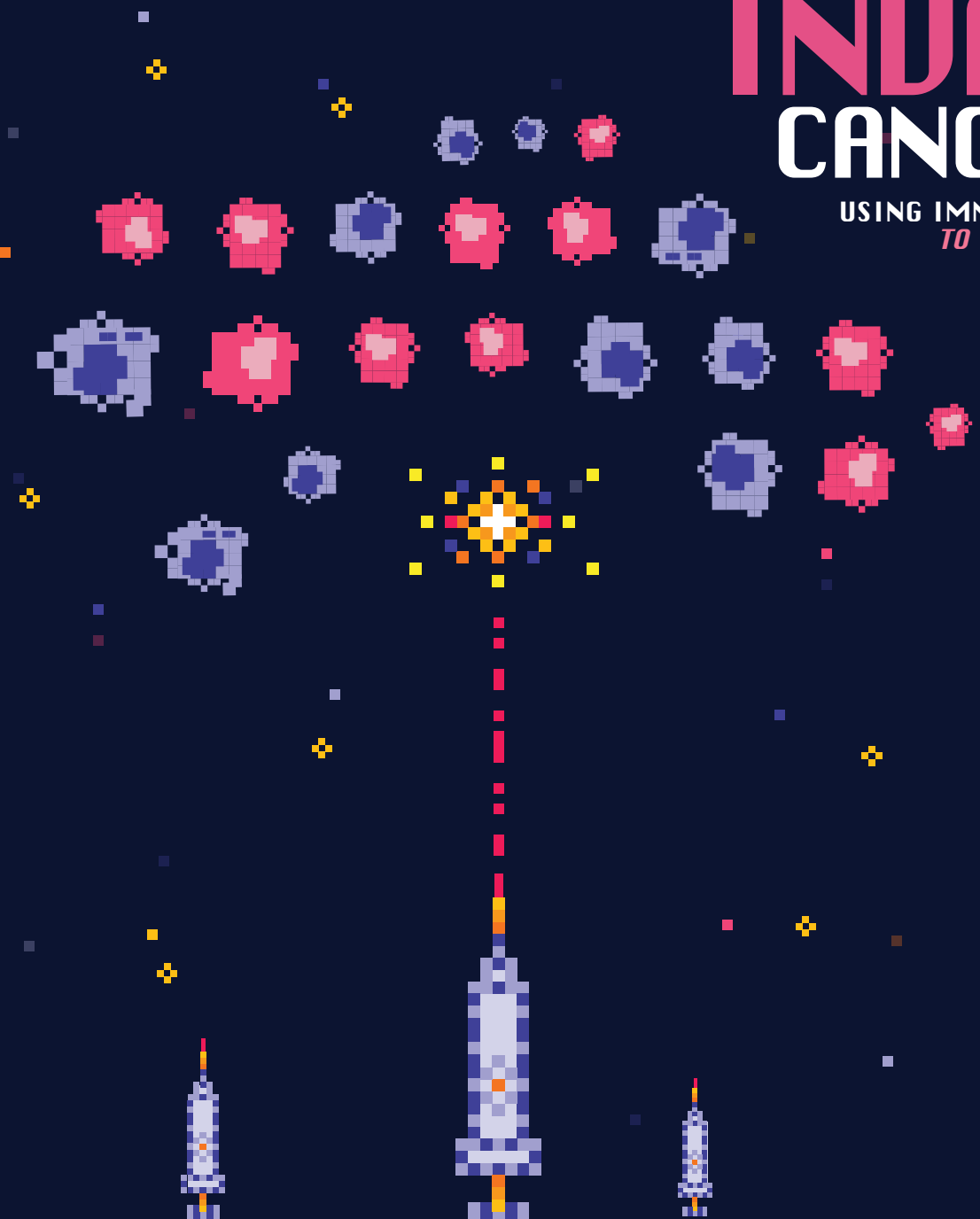
20TH anniversary

Cancer Updates, Research & Education®



INVADING CANCER CELLS

USING IMMUNOTHERAPY COMBINATIONS TO TARGET ADVANCED MELANOMA

ALSO IN THIS ISSUE

curetoday.com

KEYTRUDA IS A BREAKTHROUGH IMMUNOTHERAPY.

FOR TODAY

KEYTRUDA is a potential first treatment for **3 out of 4 patients** with advanced non–small cell lung cancer (NSCLC).

KEYTRUDA is also used to treat **more patients** with advanced lung cancer than any other immunotherapy.

FOR THE FUTURE

Ongoing clinical trials are exploring if KEYTRUDA can help treat more patients.

KEYTRUDA may be your first treatment for advanced NSCLC, either in combination with chemotherapy or used alone as a chemotherapy-free option.
Ask your doctor if KEYTRUDA is right for you.

KEYTRUDA is a prescription medicine used to treat a kind of lung cancer called non–small cell lung cancer (NSCLC).

- **KEYTRUDA + CHEMOTHERAPY, NONSQUAMOUS**
  It may be used with the chemotherapy medicines pemetrexed and a platinum as your first treatment when your lung cancer has spread (advanced NSCLC) **and** is a type called "nonsquamous" **and** your tumor does not have an abnormal "EGFR" or "ALK" gene.
- **KEYTRUDA + CHEMOTHERAPY, SQUAMOUS**
  It may be used with the chemotherapy medicines carboplatin and either paclitaxel or paclitaxel protein-bound as your first treatment when your lung cancer has spread (advanced NSCLC), **and** is a type called "squamous."
- **KEYTRUDA USED ALONE, PD-L1 POSITIVE**
  It may be used alone as your first treatment when your lung cancer has not spread outside your chest (stage III) and you cannot have surgery or chemotherapy with radiation, **or** your NSCLC has spread to other areas of your body (advanced NSCLC), **and** your tumor tests positive for "PD-L1" **and** does not have an abnormal "EGFR" or "ALK" gene.
- **KEYTRUDA AFTER CHEMOTHERAPY, PD-L1 POSITIVE**
  It may also be used alone for advanced NSCLC if you have tried chemotherapy that contains platinum and it did not work or is no longer working **and**, your tumor tests positive for "PD-L1" **and** if your tumor has an abnormal "EGFR" or "ALK" gene, you have also received an "EGFR" or "ALK" inhibitor medicine that did not work or is no longer working.

PD-L1 = programmed death ligand 1;
EGFR = epidermal growth factor receptor;
ALK = anaplastic lymphoma kinase.

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;

Important Safety Information is continued on the next page.

keytruda.com/lung

IMPORTANT SAFETY INFORMATION *(continued)*

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.
- **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 uses 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; rash; diarrhea; fever; cough; decreased appetite; itching; shortness of breath; constipation; bones or joints and stomach-area (abdominal) pain; nausea; and low levels of thyroid hormone.

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; headache; weight loss; stomach-area (abdominal) pain; joint and muscle pain; and trouble sleeping.

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

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

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.

Having trouble paying for your Merck medicine?

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

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

MERCK

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
- 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. 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 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, rash, diarrhea, fever, cough, decreased appetite, itching, shortness of breath, constipation, bones or joints and stomach-area (abdominal) pain, nausea, and low levels of thyroid hormone.

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, headache, weight loss, stomach-area (abdominal) pain, joint and muscle pain, and trouble sleeping.

Common side effects of KEYTRUDA when given with chemotherapy and bevacizumab include: tingling or numbness of the arms or legs, hair loss, low red blood cell count, feeling tired or weak, nausea, low white blood cell count, diarrhea, high blood pressure, decreased platelet count, constipation, joint aches, vomiting, urinary tract infection, rash, low levels of thyroid hormone, and decreased appetite.

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-2112r048 as revised December 2021.

MERCK

CURE® 20TH anniversary Contents

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» Years after her kidney cancer diagnosis, **CYNTHIA CHAUHAN** received a diagnosis of a secondary cancer of the breast.

« **KYLE WOODY** had to learn how to care for his wife, who was undergoing cancer treatment, and himself while juggling other priorities in their lives.

COVER IMAGE: NATALIA / STOCKADOBE.COM. ADAPTED BY GWEN SALAS. CHAUHAN BY JENELLE ROBINSON. WOODY BY LAUREN B. PHOTOGRAPHY; BROWNING BY ALYONA OSBORN.

MARIENA BROWNING was treated with an immunotherapy combination for metastatic melanoma.

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FEATURES

ALSO IN THIS ISSUE

publisher's note

SPRING • 2022

Educating Patients for the Past 2 Decades

THIS YEAR, *CURE*® MAGAZINE is celebrating its 20th anniversary, and it's incredible to think how far cancer care has come in that time. The technology that has been developed and the research that has been performed continue to amaze me as we improve care in patients with cancer.

CURE®'s first issue in spring 2002 covered targeted therapies for non-Hodgkin lymphoma, chemo brain in breast cancer and antiangiogenesis, which involves starving cancer cells from the blood and nutrients they need to survive and grow. As I looked at past issues, it was evident that since day 1, our focus has been to educate patients and their loved ones about cancer care, side effects and other topics in an easy-to-understand way.

"(*CURE*®) gives patients and their caregivers the medical information they need in what we hope is a very understandable way," Dr. Vinay K. Jain, *CURE*®'s publisher at the time, wrote in his note in the first issue. "We have created a new type of publication for the cancer patient — a hybrid of medical information explained from the human perspective of cancer patients and those who care for them." And this is something we continue to strive to do.

***CURE*® 2002** inaugural magazine cover

In this issue of *CURE*®, we spoke to two patients with advanced melanoma who have benefitted from immunotherapy combinations. One patient was diagnosed with stage 3 metastatic melanoma when she was 21. Her doctors tried several treatments including surgery and targeted therapy before moving on to an immunotherapy combination to put her immune system into overdrive and destroy the melanoma cells. Another patient discusses his experience participating in two clinical trials, which he says has allowed him to "live the good life" two years later.

In addition, a feature article examines the unique challenges male caregivers experience when tending to the needs of a patient with cancer. We spoke with three men of varying ages to learn how these obstacles change throughout life, including while juggling a career and fatherhood and at the crossroads of a career and retirement. Each of the men we spoke to highlight the importance of not only caring for the patient with cancer but also caring for themselves.

To recognize our 20 years of publishing, we reviewed the advancements made in reconstruction for patients after cancer treatment. We spoke with four experts who run the gamut from head and neck cancer to prostate and testicular cancer. Innovation has taken place in surgical techniques and prosthetics, but also in how reconstruction is discussed between patients and oncologists.

Also in this issue, we cover topics including the importance of seeking mental health care after a cancer diagnosis, throughout treatment and beyond; using other drugs for potential cancer survival; and the issues often facing younger patients who received a diagnosis of multiple myeloma before age 40.

As always, thank you for reading, and we can't wait to see what the next 20 years bring.

MIKE HENNESSY JR.
President & CEO
MJH LIFE SCIENCES®

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Secondary Cancers: A Diversity of Causes

BAD LUCK CAN HIT twice — sometimes randomly, but in other cases driven by clear factors. Somewhere between 5% to 10% of patients with cancer may experience a secondary cancer, which refers to a malignancy that is not related to the first one; that is, not a recurrence or metastases of the original cancer. Sometimes if the cancer is from the same organ, for example a breast cancer in the same breast 20 years later, it may be impossible to tell if it is a local recurrence or a totally new cancer, although sophisticated gene sequencing might be able to provide an answer. But most secondary cancers arise in a different organ and location.

In this issue, you will read about the range of reasons secondary cancers may develop. One common cause arises from the carcinogenic effects of many of the actual treatments we use for cancer. These therapies can be double-edged swords that damage the tumor's DNA to a greater extent than normal cells, but can spark a new cancer in normal tissue such as bone marrow cells, albeit rarely, causing leukemia. Radiation can cause skin and other soft tissue tumors even though, on average, they are a rare complication. Such cancers may be more difficult to treat, but progress is being made with innovations in surgical techniques and targeted medicines.

Epidemiologists have documented for decades that patients with cancer may have a higher chance of getting a second cancer than the general population has of getting a first one, and their family members may as well, most likely due to inherited genetics. Although a few genes impart a high lifetime risk of several different cancer types when a mutated version is inherited, many other genes may raise the risk by just a small amount. Environmental factors can also cause risk clusters in families or communities — whether it is second-hand smoke, or rarely, radon exposure in certain geographical areas or house designs, as well as other factors.

Growing awareness of this problem and its causes have led to modifications of treatment protocols, such as using lower doses of radiation and schedules that cause less DNA damage and limiting the cumulative amounts of certain chemotherapy drugs. More expanded use of genetic testing is possible with lower costs and more extensive databases to understand the specific risks from different familial mutations, and importantly, the application of enhanced screening to match the heightened risk. When lightning strikes once, we would like to know when and where to get the shields up to avert another bolt.

DEBU TRIPATHY, M.D.
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FIRSTLINE

compiled by CURE® STAFF

Actress Sofía Vergara Speaks Candidly on Surviving Cancer

SOFÍA VERGARA, 49, marked this year's World Cancer Day with an Instagram post in which she opened up about being a cancer survivor. She shared a photo of herself taken just after her surgery for thyroid cancer over 20 years ago.

"At 28, 'cancer' was not a word I expected to hear," Vergara wrote.

After doctors found a lump in her throat at a routine checkup, she began a long treatment process of radiation and surgery.

"Today, I get to call myself a cancer survivor," she continued.

In the photo posted on Instagram, which was taken at her first acting class post treatment, a small scar is visible on her neck.

"Seeing the scar on my throat reminds me of how blessed I felt that day — and (feel) every day since."

Vergara also urged people to attend their routine medical checkups to ensure early prevention.

Snowboarder Wins Olympic Gold 3 Years After Cancer Diagnosis

MAX PARROT, A snowboarder from Canada who won a 2022 Winter Olympics gold medal, has overcome another incredible challenge in his lifetime: cancer.

Parrot, 27, was diagnosed with Hodgkin lymphoma in late 2018. After 12 rounds of chemotherapy, he announced that he had "won against cancer" in July 2019.

"They were really hard times and, at times, I felt like I was a lion in a cage because I wasn't able to do what I love the most, which is snowboarding," Parrot told CNN, reflecting on his win in Beijing. "That was the first time in my life that I had to put my snowboard in the closet. Snowboarding is all I know, so it was really hard for me."

He also explained how his cancer experience allowed him to look at snowboarding with a new perspective.

"Every time I strap my feet onto my snowboard, I appreciate it so much more than before. I appreciate being able to do my passion every day," he said. "You're smiling more, everything's more positive. You put less pressure on yourself, less stress on yourself."

This was Parrot's first-ever Olympic gold medal, which he achieved with a score of 90.96.

"I am extremely proud of myself and to take gold on that run means so much for me," he said.

SNOWBOARDER: SIMPLINE / STOCK.ADOBE.COM; CASTLE: KISELOV / STOCK.ADOBE.COM; SOFÍA VERGARA: STEVE GRANITZ/ WIREIMAGE VIA GETTY IMAGES;

Six-Year-Old Cancer Survivor Meets Princess Tiana in Disney Trip Gift From Ciara

AUBREY ENGLISH, 6, was diagnosed with hepatoblastoma, a rare type of liver cancer, when she was just 3 years old.

English went viral on the internet after her mother recorded a video of her dancing to "Level Up," a song by singer Ciara, in her hospital room. In the post, her mother, Mickeon English, wrote, "Dear childhood cancer, just so you know, I won't give up. I won't give in. You won't take my spirit. You won't take my spunk."

Aubrey has now been in remission for three years, and her family hopes her energy can inspire others.

"She's always been very positive even on her worst days," her mother told "Good Morning America" (GMA). "She was still happy and smiling and dancing. It just brought so much light to us even during our darkest days."

While she was in treatment, English decorated her hospital room like a princess castle, and would dress up as a princess to make the best of her situation.

After Ciara saw the video, she surprised English and her family on GMA, telling them, "Oh my goodness, I'm in tears right now. Aubrey, I just want to say that you are a superhero."

Adding to the surprise, Disney Princess Tiana from "The Princess and the Frog" shared a video for English, telling her to keep on doing her best. The family was then told they were being gifted a trip to Disney World to meet Tiana in person.

Upon meeting English in Disney World, Princess Tiana told her that she is already a princess, because "every princess is kind, hardworking, and believes in herself."

Mail Carrier Surprises Child With Cancer With a Truck and Uniform

A MAIL CARRIER named Van Singletary in Santa Ana, California, befriended a 7-year-old boy who lives in one of the houses on his route. The boy, Jacob Hayward, has stage 4 kidney cancer.

For years, Hayward has watched Singletary deliver his mail, and would dress up as a mail carrier to grab the mail and deliver it to his parents. For Singletary, it became the highlight of his day.

"All the doctors and nurses, child life specialists, even patients (and) other kids on the other floors, would write him a note, knowing that he wasn't able to leave his room," Hayward's mother told ABC7. "So it was (exciting) for him every day to check the mailbox."

Hayward's specific diagnosis is a Wilms tumor, and the cancer has spread to his lungs. He has already undergone over 50 rounds of chemotherapy as well as multiple radiation treatments and surgeries.

For his seventh birthday, Hayward's mother asked Singletary if he could take him on a tour of the local post office, but the carrier had different plans. He surprised him with a child-sized mail truck of his own and a matching uniform.

"What he did will be something we remember for the rest of our lives," Hayward's father said.

Rower With Late-Stage Cervical Cancer Breaks World Record Crossing the Atlantic Ocean

KAT CORDINER IS a 42-year-old rower from St. Neots in the United Kingdom who has late-stage cervical cancer. She recently broke a world record with two teammates, Charlotte Irving and Abby Johnston, for rowing 3,000 miles across the Atlantic Ocean.

Cordiner and her teammates rowed from La Gomera in the Canary Islands to English Harbour on Antigua in 42 days, seven hours and 17 minutes in a 25-foot boat named "Dolly Parton." During the trek, they rowed for two hours on and two hours off continuously.

"Everyone tells you what an amazing experience it is, but no one tells you how difficult it actually is. ... Nothing prepares you for the first 10 days. They were very emotional for all of us and then you settle into a routine and it's fine. We underestimated maybe how tough it would be," Cordiner told the BBC.

The three women made it through scorching heat, dark ocean waves at night, sleep deprivation, sharks trailing their boat and blisters and calluses. Cordiner may be the first patient with cancer to have completed the challenge.

Despite having cancer, she planned for the journey for a long period of time but had to pause her training for treatment. Her cancer kept worsening and she found out she needed heart surgery for a cardiac tumor.

"It was only in May last year that I started training and I'm just glad that I got to start the race and ecstatic that I got to finish it," she said to Sky News.

Although she is considered to be in remission, Cordiner explained that her doctors told her she may only have several years to live, which is why she wants to make the most of them.

"I don't know how long I'll be in remission," she added. "A lot of people think cancer (equals) chemo (equals) death. But today the drugs are so much better — you can live your life with cancer. People live for years on treatment."

Cordiner and her teammates are also hoping to raise funds for Cancer Research UK, Macmillan Cancer Support and The Royal Marsden Cancer Charity.

Comedian Louie Anderson Dies After Being Hospitalized for Lymphoma Treatment

COMEDIAN LOUIE ANDERSON, host of "Family Feud," and "Coming to America" star, died in January after being hospitalized to undergo cancer treatment.

Anderson, who was 68, was previously diagnosed with diffuse large B-cell lymphoma — the most common type of non-Hodgkin lymphoma. He was being treated at a Las Vegas hospital at the time of his death, according to Glenn Schwartz, a representative for Anderson.

Friends and fans have been paying tribute to him on social media. Just before the news of his death, actor Pauly Shore wrote, "I say this with a heavy heart. Just left the hospital in Las Vegas where Louie Anderson, his sisters and close friend were kind enough to let me say my goodbyes. He's still with us but keep him in your prayers."

The comedian had previously talked about his plan to prioritize his health. In interviews, he related how growing up in an underprivileged home with 10 siblings and an alcoholic father had led to his using food as a form of protection.

LOUIE ANDERSON

"I took (my plan) very seriously. I got a trainer. I worked out. I swam. This has been a lifelong struggle for me, food addiction," he told "Daily Blast Live." "I learned a lot and feel good. I'm no longer compulsively eating like I was and that was the big thing for me."

CERVICAL CANCER: DOUBLE BRAIN / STOCK.ADOBE.COM; FILM: IVECTOR / STOCK.ADOBE.COM; LOUIE ANDERSON: EMMA MCINTYRE/ GETTY IMAGES ENTERTAINMENT VIA GETTY IMAGES

What Is IBRANCE® (palbociclib)?

IBRANCE is a prescription medicine used in adults to treat hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer that has spread to other parts of the body (metastatic) in combination with an aromatase inhibitor as the first hormonal based therapy in postmenopausal women or in men.

Important Safety Information for Patients

IBRANCE may cause serious side effects, including:

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking IBRANCE and may cause serious infections that can lead to death. Your doctor should check your white blood cell counts before and during treatment.

If you develop low white blood cell counts during treatment with IBRANCE, your doctor may stop your treatment, decrease your dose, or may tell you to wait to begin your treatment cycle. Tell your doctor right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Lung problems (pneumonitis). IBRANCE may cause severe inflammation of the lungs during treatment that can lead to death. Tell your doctor right away if you have any new or worsening symptoms, including chest pain, cough with or without mucus, and trouble breathing or shortness of breath.

Your doctor may interrupt or stop treatment with IBRANCE completely if your symptoms are severe.

Before you take IBRANCE, tell your doctor about all of your medical conditions, including if you:

- have fever, chills, or any other signs or symptoms of infection.
- have liver or kidney problems.
- are pregnant or plan to become pregnant; IBRANCE can harm your unborn baby.
  - Females who are able to become pregnant should use effective birth control during treatment and for at least 3 weeks after the last dose of IBRANCE. Your doctor may ask you to take a pregnancy test before you start treatment with IBRANCE.
  - Males with female partners who can become pregnant should use effective birth control during treatment with IBRANCE for at least 3 months after the last dose of IBRANCE.
- are breastfeeding or plan to breastfeed. It is not known if IBRANCE passes into your breast milk. Do not breastfeed during treatment with IBRANCE and for 3 weeks after the last dose.

The most common side effects of IBRANCE include:

- Low red blood cell counts and low platelet counts. Call your doctor right away if you develop any of these symptoms during treatment:
  - dizziness
  - shortness of breath
  - weakness
  - bleeding or bruising more easily
  - nosebleeds

Other most common side effects include: infections, tiredness, nausea, sore mouth, abnormalities in liver blood tests, diarrhea, hair thinning or hair loss, vomiting, rash, and loss of appetite.

IBRANCE may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider about family planning options before starting IBRANCE if this is a concern for you.

These are not all of the possible side effects of IBRANCE. For more information, ask your doctor.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. IBRANCE and other medicines may affect each other, causing side effects.

Do not drink grapefruit juice or eat grapefruit products while taking IBRANCE as they may increase the amount of IBRANCE in your blood.

Tell your doctor if you start a new medicine. Take IBRANCE exactly as your doctor tells you.

If you take too much IBRANCE, call your doctor right away or go to the nearest hospital emergency room.

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 Important Facts About IBRANCE on the following page.

To learn more, talk to your doctor.

Can't afford your medication? Pfizer may be able to help. Visit IBRANCE.com.

*Hormone receptor-positive includes estrogen receptor-positive (ER+) and/or progesterone receptor-positive (PR+)

IBRANCE® palbociclib | 125 mg tablets

 April 2021 PP-IBR-USA-3610-02

IBRANCE®
palbociclib | 125 mg tablets

IMPORTANT FACTS

IBRANCE® (EYE-brans)
(palbociclib)

The risk information provided here is not comprehensive. This information does not take the place of talking to your healthcare provider about your condition or treatment. To learn more about IBRANCE talk to your healthcare provider or pharmacist. To obtain the FDA-approved product labeling call 1-800-438-1985 or visit www.IBRANCE.com.

What is IBRANCE?

IBRANCE is a prescription medicine used in adults to treat hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic) in combination with:

- an aromatase inhibitor as the first hormonal based therapy in postmenopausal women or in men, or
- fulvestrant in people with disease progression following hormonal therapy.

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

What is the most important safety information I should know about IBRANCE?

IBRANCE may cause serious side effects, including:

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking IBRANCE and may cause serious infections that can lead to death. Your healthcare provider should check your white blood cell counts before and during treatment.

If you develop low white blood cell counts during treatment with IBRANCE, your healthcare provider may stop your treatment, decrease your dose, or may tell you to wait to begin your treatment cycle. Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Lung problems (pneumonitis). IBRANCE may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including:

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

Your healthcare provider may interrupt or stop treatment with IBRANCE completely if your symptoms are severe. **See "What are the possible side effects of IBRANCE?" for more information about side effects.**

What should I tell my healthcare provider before taking IBRANCE?

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

- have fever, chills, or any other signs or symptoms of infection.
- have liver or kidney problems.
- are pregnant, or plan to become pregnant. IBRANCE can harm your unborn baby.
  - Females who are able to become pregnant should use effective birth control during treatment and for at least 3 weeks after the last dose of IBRANCE. Your healthcare provider may ask you to take a pregnancy test before you start treatment with IBRANCE.
  - Males with female partners who can become pregnant should use effective birth control during treatment with IBRANCE for at least 3 months after the last dose of IBRANCE.
  - Talk to your healthcare 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 healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if IBRANCE passes into your breast milk. Do not breastfeed during treatment with IBRANCE and for 3 weeks after the last dose.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. IBRANCE and other medicines may affect each other causing side effects.

How should I take IBRANCE tablets?

- Take IBRANCE exactly as your healthcare provider tells you.
- IBRANCE tablets may be taken with or without food.
- IBRANCE should be taken at about the same time each day.
- Swallow IBRANCE tablets whole. Do not chew, crush or split IBRANCE tablets before swallowing them.
- Do not take any IBRANCE tablets that are broken, cracked, or that look damaged.
- Avoid grapefruit and grapefruit products during treatment with IBRANCE. Grapefruit may increase the amount of IBRANCE in your blood.
- Do not change your dose or stop taking IBRANCE unless your healthcare provider tells you.
- If you miss a dose of IBRANCE or vomit after taking a dose of IBRANCE, do not take another dose on that day. Take your next dose at your regular time.
- If you take too much IBRANCE, call your healthcare provider right away or go to the nearest hospital emergency room.

What are the possible side effects of IBRANCE?

IBRANCE may cause serious side effects. See "What is the most important safety information I should know about IBRANCE?"

The most common side effects of IBRANCE when used with either letrozole or fulvestrant include:

- low red blood cell counts and low platelet counts. Call your healthcare provider right away if you develop any of these symptoms during treatment:
  - dizziness
  - shortness of breath
  - weakness
  - bleeding or bruising more easily
  - nosebleeds
- infections (see "What is the most important safety information I should know about IBRANCE?")
- tiredness
- nausea
- sore mouth
- abnormalities in liver blood tests
- diarrhea
- hair thinning or hair loss
- vomiting
- rash
- loss of appetite

IBRANCE may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider about family planning options before starting IBRANCE if this is a concern for you.

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

Keep IBRANCE and all medications out of the reach of children.

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.

To learn more, talk to your doctor.

These IMPORTANT FACTS are based on IBRANCE® (palbociclib) Patient Information LAB-1372-1.0, Rev. 11/2019.

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clinical trial CORNER

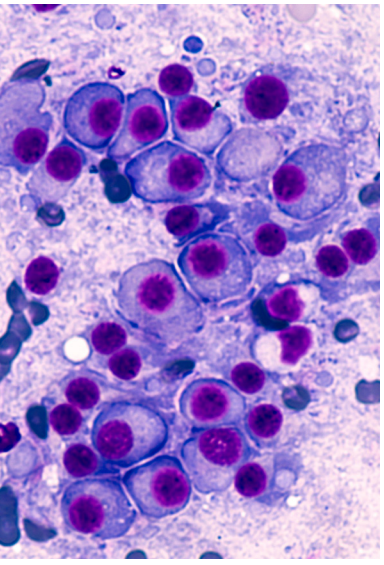
compiled by CURE® STAFF

First Allogeneic RNA Cell Therapy Trial Begins in Multiple Myeloma

A PHASE 1/2A CLINICAL TRIAL of the first allogeneic RNA cell therapy in multiple myeloma has begun, with its first patient receiving treatment at the end of January. The trial aims to examine Descartes-25 in 20 patients with relapsed/refractory multiple myeloma.

"Patients with relapsed and/or refractory multiple myeloma have few treatment options remaining," said Dr. Kenneth C. Anderson, program director at Jerome Lipper Multiple Myeloma Center and LeBow Institute for Myeloma Therapeutics at Dana-Farber Cancer Institute in Boston, in a news release from Cartesian Therapeutics.

Descartes-25 is an RNA cell therapy that affects the antibody and cell activity in a patient's body to deliver antitumor treatment to the tumor microenvironment. The drug is allogeneic, meaning that it is created from blood or tissue unrelated to the patient.



There are few treatment options remaining for patients with relapsed and/or refractory multiple myeloma.

MULTIPLE MYELOMA: DAVID A LITMAN / STOCK.ADOBE.COM; CLINICAL TRIAL: METAMORWORKS / STOCK.ADOBE.COM

In this study, researchers hope to examine the safety, tolerability and efficacy of the treatment. The primary goal is to determine the maximum tolerated dose (during a one-year time frame). Secondary goals include overall response rate (the percentage of patients whose disease responds to treatment) and median duration of response (length of time a tumor responds to treatment without growing or spreading), also measured during a one-year time frame.

Patients are eligible if they are aged 18 or older, have relapsed/refractory multiple myeloma that did not respond to two prior lines of treatment and have measurable disease.

"If approved, it will be a welcome addition to our toolkit for treating this currently incurable disease," Anderson said.

According to Cartesian Therapeutics, the company developing the treatment, Descartes-25 would be the first off-the-shelf RNA cell therapy (meaning the cells involved in the drug do not have to be collected from the patient) to enter clinical trials for cancer.

The trial is currently recruiting patients and is taking place at the Center for Cancer and Blood Disorders in Bethesda, Maryland, as well as the Medical College of Wisconsin in Madison.

The trial has a completion date goal of January 2023.

SCAN THE QR CODE
to read more about ongoing trials in the cancer space.

Trial Assesses Combination Therapy for Head and Neck Cancer

RESULTS FROM A phase 2 clinical trial demonstrated promise for the combination of the novel agent PDS0101 plus Keytruda (pembrolizumab) in treating HPV-associated head and neck cancer. The trial will progress to enroll 54 patients who have not been previously treated with a checkpoint inhibitor.

The trial, VERSATILE002, involves two groups of patients with HPV16-positive head and neck cancer that is either metastatic or has returned after treatment. One group consists of patients who have no prior treatment with checkpoint inhibition immunotherapy, whereas the other group comprises 21 patients whose disease failed checkpoint inhibition.

In the checkpoint inhibitor–naïve group, four or more of the 17 patients achieved an objective response, classified by a 30% or more reduction in tumor size.

"The achievement of this important milestone ... strengthens the evidence of our novel Versamune platform's potential ability to induce high levels of tumor-specific CD8-positive killer T cells that attack the cancer to achieve tumor regression," commented Dr. Lauren V. Wood, chief medical officer of PDS Biotech, the developer of PDS0101, in a statement. "The initial data (solidify) our belief that PDS0101's demonstrated preclinical efficacy when combined with Keytruda has the potential to significantly improve clinical outcomes for patients with advanced HPV16-positive head and neck cancers."

PDS0101 induces large quantities of CD4-positive helper and CD8-positive killer T cells, white blood cells that are pivotal in the functioning of the immune system. This works in tandem with checkpoint inhibitors, such as Keytruda, which help unmask the cancer cells to the immune system, allowing the body to find and fight the cancer.

Upcoming research will determine which regimen is more effective: Keytruda plus PDS0101 or Keytruda alone. Eligible patients must have HPV16-positive head and neck cancer that returned or spread, have recovered from complications from previous surgeries or radiation and have good overall health.

There are 27 sites in the U.S. involved in the trial. Patients interested in enrolling can email info@pdsbiotech.com.

repurposing
drugs

Established Drugs May Provide Cancer Benefit

Drugs that control blood pressure and lower cholesterol, among others, may help patients derive greater benefit from cancer treatment, but study findings have left researchers reassessing their next moves.

By DARLENE DOBKOWSKI, M.A.

SEVERAL EXISTING DRUGS, INCLUDING those that treat high blood pressure and high blood sugar levels, are being investigated alongside other treatments in patients with cancer to see if they provide a survival benefit, although more research is needed to determine whether this is a possibility.

There may be some overlap on what cardiometabolic drugs — those that focus on dysfunctions related to heart disease, diabetes and chronic renal failure — treat and certain aspects of cancer. For example, drugs that control blood pressure, such as angiotensin-converting enzyme (ACE) inhibitors, may alter a patient's vasculature, which may lead to improved therapy responses. In addition, some common risk factors in breast cancer can also increase one's risk for heart disease, such as higher insulin levels and higher inflammation

As it stands, some experts would frown upon using these cardiometabolic drugs for potential cancer survival benefit.

"I would not recommend metformin or aspirin for the purpose of treating breast cancer based on large trials that have tested the impact of these drugs on cancer recurrence and survival in women," said Dr. Jennifer A. Ligibel, director of the Leonard P. Zakim Center for Integrative Therapies and Healthy Living at Dana-Farber Cancer Institute and an associate professor of medicine at Harvard Medical School in Boston, in an interview with *CURE*®.

Despite this recent bump in the road in researching cardiometabolic drugs in patients with cancer, other experts remain hopeful.

"It's safe to say that (cardiometabolic drugs have) the potential to benefit all cancer types and stages, but in the clinical setting, each of those tumor types and stages of disease are going to have to be investigated to determine if this potential can be realized," Dr. Zachary Morris, an associate professor and vice chair of the Department of Human Oncology at the University of Wisconsin School of Medicine and Public Health in Madison, told *CURE*®.

"It will take some time to understand whether and how best to take these agents in conjunction with other cancer therapies. They may work for some diseases or together with certain other treatments better than others, but this remains to be determined through clinical research."

POTENTIAL BENEFITS IN CERTAIN CANCER TYPES

Morris and his colleagues have conducted research in this space and their findings include those of a study published in *Cancer* in 2016. The authors assessed the increased tumor response to neoadjuvant radiation in patients with rectal cancer who took ACE inhibitors or angiotensin receptor blockers, both of which have been traditionally used to lower blood pressure in patients with hypertension. Findings from this particular study demonstrated that incidental use of those two drugs that lower blood pressure was correlated with a three-fold increase in the rate of complete response (the disappearance of all signs of cancer as a response to treatment).

"Some of our drugs that might impact vasculature or blood pressure, for example, could have effects on blood perfusion of the tumor microenvironment," Morris said. "It's not that the drugs themselves directly kill cancer cells, but they may help us to deliver other things like chemotherapy that could then better kill that tumor, or, in the case of radiation, we need oxygen in the tumor to most effectively kill tumor cells with radiation. Just by improving the blood flow to a tumor during the time when radiation is being given, it may impact the efficacy of radiation in that local environment."

Other studies have been conducted including one whose results were published in *Cancer Medicine* in 2021. Findings from this study demonstrated that blood pressure medications may improve survival in patients with colorectal cancer.

A number of older studies suggested that metformin in particular might help to prevent breast cancer, and that

women who took metformin after a cancer diagnosis might have a lower risk of dying from breast cancer. These studies led to the development of a large trial called MA-32 that tested whether adding metformin as a part of breast cancer treatment would reduce the risk that the cancer returned after initial treatment.

Early results from the MA-32 trial, which included more than 3,000 women, showed that patients who received metformin during treatment had improvements in weight and metabolic factors compared with those who received placebo. However, the final results of the study published early this year showed that metformin did not prevent or stop the spread of breast cancer.

"That was very disappointing," Ligibel said. "We were certainly hoping that metformin would be a helpful treatment for breast cancer, but this study unfortunately showed that metformin was not helpful as a breast cancer treatment. This is why it is so important to conduct clinical trials. Sometimes, treatments are not helpful even when there's great preliminary information that says maybe this (medication) makes a difference."

TIME TO REGROUP

Based on the negative results of recent studies in this area, Ligibel said, "We're in a regrouping phase for this concept."

She added that the benefit observed in earlier studies of metformin may be due to the types of studies that had previously been conducted. For example, some have been observational in nature, meaning that researchers asked a large group of patients with cancer about the medications they are taking. Although researchers are able to observe any patterns, the study doesn't take into consideration whether other factors play an effect, such as why patients are taking a particular drug or what other health conditions they might have. In addition, preliminary studies are often done in animal models, and although these models can be helpful in the trajectory of research, dosages can be different in animals compared with humans.

More research is needed to determine whether cardiometabolic drugs may have benefits in other kinds of cancer, despite the disappointing findings in breast cancer. Some areas of interest include which cancer types may benefit from this regimen compared with others; whether patients obtain the benefit immediately or whether the drug must be taken for a certain amount of time before initiating cancer treatment; and whether statins (which lower cholesterol) and aspirin (often used to prevent blood clots) pose a similar benefit in patients with cancer.

Morris mentioned that patients can play a huge role in the studies needed in this area.

"We really appreciate and respect the patients when they contribute to clinical trials," Morris said. "It's such an altruistic gesture because we don't know if (a trial is) going to benefit a given patient, but we know that it will benefit our understanding of cancer and the disease overall. … If patients are interested … (and) if it seems like the right thing for them, … participating in clinical trials is a really thoughtful gesture on (their) behalf."

Ligibel also advised patients to take good care of themselves with physical activity, a healthy diet and maintaining a healthy weight.

"So far, the medications haven't really shown as much benefit, but there's a huge benefit in living a healthy lifestyle," she said, "(and,) if you do have diabetes or high blood pressure, in making sure that you take care of those conditions. … It is incredibly important if you have cancer or you don't have cancer to make sure that your blood pressure is under good control, that your diabetes is under good control. We know that managing those conditions absolutely prolongs life and is very important to people's overall health."

ADVANTAGES OF REPURPOSING DRUGS

According to a World Health Organization policy brief published in 2021, there are several advantages of repurposing existing drugs compared with developing new drugs. For example, the time dedicated to development can be shortened because many of the drug's preclinical assessments have already been performed.

"It's a great opportunity to potentially make use of safe and known entities like these drugs in a different context," said Dr. Zachary Morris, an associate professor and vice chair of the Department of Human Oncology at the University of Wisconsin School of Medicine and Public Health in Madison. "There's well-established data demonstrating a high degree of safety for these. Many times, we're willing to take much greater risks in the setting of cancer than we are, for example, (in) the treatment of blood pressure, diabetes or cholesterol management. The fact that these (drugs) can be given in those settings makes them very appealing from a safety standpoint in a cancer setting."

In addition, less investment is needed both for drug development and for the patients who may eventually fill these prescriptions. In the U.S., bringing a repurposed drug to market costs an estimated $300 million compared with $2 to $3 billion for a new drug. Also, patent protection for many of these repurposed drugs has lapsed, making them far more affordable for patients than new therapies.

Easing Nerves and Uncertainty Through Advocacy

A patient's experience with polycythemia vera led to her becoming an advocate for others. *By* DARLENE DOBKOWSKI, M.A.

BECOMING AN ADVOCATE FOR lesser-known cancers including myeloproliferative neoplasms (MPNs) is important to raise awareness and create a sense of community among patients, families and caregivers, but how does one get started?

Lea Fosbenner, a 31-year-old project manager lead in technology and product development in Pittsburgh, took it upon herself to be the person she was searching for when she was first diagnosed with polycythemia vera, a type of MPN, at 28. She shares her experiences with the disease on social media to be a support person for patients who need it.

"One of the reasons that I opened up a little bit more on social media about (polycythemia vera) was because that was one of the first things I did … try to look up things myself and find people," Fosbenner said. "I know there's research, and that's obviously very important, but I wanted to talk to a person that's going through this too. I wanted to talk to doctors, but I really wanted to (know) what your actual day is like, what are the things you actually deal with."

Fosbenner thanks her participation in a local support group for opening her eyes to becoming an advocate to not only increase awareness, but to bring a human aspect to polycythemia vera.

NAVIGATING THE UNKNOWN

Fosbenner received a diagnosis of polycythemia vera in 2018, although doctors originally diagnosed her with essential thrombocythemia. The polycythemia vera diagnosis came when she and her mother sought a second opinion after her original diagnosis. During her second opinion appointment, the doctor said, "You definitely have polycythemia vera."

This spearheaded her efforts to find a doctor in the Pittsburgh and Philadelphia area, near where her parents live, to determine which treatment plan would be best for her. That ended up being a weekly injection of Pegasys (peginterferon alfa-2a) along with weekly bloodwork monitoring until she became very sick in the fall of 2019. This led to numerous trips to the hospital to figure out what might be wrong, a failed transjugular intrahepatic portosystemic shunt procedure, complications and a stay at the intensive care unit for three weeks, among other issues.

Currently, Fosbenner regularly visits three MPN doctors, in addition to a liver doctor, a primary care provider and an endocrinologist. Although she has some outstanding symptoms, she's happy to report that she is now in the maintenance phase of treatment.

"It took me definitely a couple years to get there, but I get regular blood work every week (and) injections every week; I give myself Lovenox (enoxaparin sodium), which was another change. I have to be on blood thinners for the rest of my life. I have to give myself two shots a day of blood thinners."

When Fosbenner first received her diagnosis of polycythemia vera, she knew a little bit about the disorder, as she had come across it while researching her original diagnosis of essential thrombocythemia. Since then, she has delved more into the polycythemia vera space, joined a support group led by Jean Diesch and has even become an advocate herself.

"(Jean) made sure I got what I needed in terms of helping me navigate a lot of this because she had probably lived a lot of her life without a diagnosis. (Then) it became more standard practice to look for some of these things and figure out her symptoms," Fosbenner said. "She really struggled earlier on in her life to get a proper diagnosis and to feel heard (by) doctors. She is definitely my biggest inspiration. I call her my Pittsburgh mom."

Fosbenner and Diesch bonded over their polycythemia vera experiences and often meet for dinners, conferences and fundraising events.

continued on page 18 »

CONFERENCES

Educational conferences on cancer-related topics including:

- Understanding your health insurance options
- Managing medical bills
- How to get help working through treatment or taking time off
- Applying for disability insurance
- Accessing financial help
- Estate planning
- ...and more!

Open to everyone! Free registration, gift bags, & prizes!

WEBINARS

Free educational webinars on practical topics, such as work, school, insurance, advocacy, caregiving, finances, exercise, and nutrition.

Open to everyone!

**Free contact hours/CEs/PDCs for nurses, social workers, board certified patient advocates, & HR professionals.*

REGISTER HERE
TriageCancer.org/Conferences

REGISTER HERE
TriageCancer.org/Webinars

TRIAGE CANCER

Triage Cancer is a national, nonprofit organization that provides free education on the legal and practical issues that may impact individuals diagnosed with cancer and their caregivers, through events, materials, and resources.

« *continued from page 16*

LEA FOSBENNER encourages her family and friends to join her for events like Light the Night, which aims to increase awareness surrounding MPNs.

"She's really helped me find my voice in being an advocate," Fosbenner said. "It's great to have a role model like her. That's setting the standard. … I wouldn't be here without her."

ADVOCATING FOR AWARENESS

Fosbenner is closely connected with the Eastern Great Lakes chapter of the Leukemia & Lymphoma Society, including their Light the Night event at which she and her support group fundraise for the cause. In addition, she works with the MPN Research Foundation, attends blood cancer conferences and participates in Facebook support groups, where patients discuss recent data, articles they have read and other pertinent information. She also posts about her journey with polycythemia vera on social media, including Instagram.

When Fosbenner started looking for people to connect with online about the disease, she said it was difficult to find anyone as it is such a limited space. Through sharing her story, she wants people to know about polycythemia vera because it may be able to help someone else along the way. For example, her friend's father was diagnosed with the disease and the friend referred him to Fosbenner so he can learn more about the patient experience, what doctors she goes to and symptoms she experiences.

"To be able to talk to someone immediately would definitely help ease all of those nerves and uncertainty that you have when you hear the word cancer," Fosbenner said.

Since she has started sharing her experience on social media, she has received messages from people who were recently diagnosed with polycythemia vera and want to ask questions about the disorder.

"I'm always open and willing to talk to anyone about (polycythemia vera)," Fosbenner said. "I'm not going to pretend to give actual medical advice, but I can at least share my story. I can share things that I've been through, the things that maybe I would have done a little bit differently or wish I had done. It's definitely nice to connect to people to bring that human aspect to it because it can get very technical."

She offered advice for patients with polycythemia vera (or another cancer type) who are interested in entering the advocacy space, including finding a support group like she did through Diesch. Several support groups have opened up for patients outside of their geographical areas, with some meetings being held virtually because of the COVID-19 pandemic. Patients can also ask their doctors about support groups.

"You have friends and your family that are caregivers and your support system, but there's definitely something different about being able to talk to someone that is going through the exact same thing you are going through or … a different variation of it," Fosbenner said.

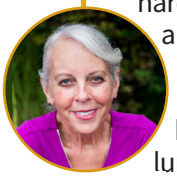
PHOTO PROVIDED BY FOSBENNER

LC LUNG CANCER HEROES®

HEROES AMONG US

CURE®'s Lung Cancer Heroes® Award Program celebrated and thanked the heroes who make a difference in the lives of patients with lung cancer. Essays were submitted by colleagues, patients and family members that identified over 30 Lung Cancer Heroes® nominees, all detailing noble acts of patients, physicians, caregivers and others involved in the lung cancer community.

HERE ARE SOME QUOTES FROM THE MANY INSPIRING ESSAYS WE RECEIVED:



DUSTY DONALDSON

"For the past 10 years, Dusty has worked so hard to support patients like me. She serves a large number of patients locally and in other states and is always eager to create partnerships with other organizations to better serve all of us. She is an amazing lung cancer advocate and an inspiration to us all. *– BY CARMEN M. WAGNER, PH.D., NBC-HWC, NOMINATING DUSTY DONALDSON*"

UPAL BASU ROY, PH.D, M.P.H., and, JILL FELDMAN

"Upal's generosity with his time, his skills and his heart extend to the whole lung cancer community. Despite watching the disease destroy, debilitate and take the lives of his own loved ones and people he has grown to love and care about, he still — off the clock — fights with us and for us. To be able to maintain this dedication through so much devastation is true compassion that cannot be learned. *– BY JILL FELDMAN, NOMINATING UPAL BASU ROY, PH.D., M.P.H.*"

KELSEY AHMED, and, CORI DUBIE-O'CONNOR

"After Kelsey's mother, Martha, was diagnosed with stage 4 non-small cell lung cancer, Kelsey and her family got to work raising funds and spreading awareness for the American Lung Association. Since I was introduced to Kelsey just a few years ago, she has since spoken at our Annual LUNG FORCE Walk: Providence about the importance of raising funds and celebrating life. *– BY CORI DUBIE-O'CONNOR, NOMINATING KELSEY AHMED*"

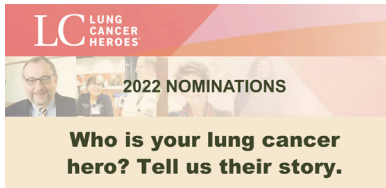
ELIZABETH PRECHTEL DUNPHY, DNP, CRNP, AOCN, and, SUZANNE WALKER, PH.D, CRNP

"Suzy is a consummate professional, a caring provider, a mentor, a teacher, a trusted and valued partner and a cancer expert. She does not wear a cape, but she is a hero to me, to our clinical and teaching staff, and to patients and their caregivers. She is very deserving of this honor. *– BY ELIZABETH PRECHTEL DUNPHY, DNP, CRNP, AOCN, NOMINATING SUZANNE WALKER, PH.D., CRNP*"

DR. BRUNO FANG

"We went on family trips and cruises and my wife lived a full, quality life — because of the caring and knowledgeable Dr. Fang, who kept himself up-to-date on new drugs and therapies being approved by the Food and Drug Administration. We loved Dr. Fang, and I can thank him thousands of times for giving my beautiful wife the additional three-and-a-half years of life and for his support and reassurance to our family to keep our chins up. *– BY MARK KLEIN, NOMINATING DR. BRUNO FANG*"

LEARN MORE ONLINE



CURE® is now accepting nominations for the 2022 Lung Cancer Heroes® award.

Visit **CURETODAY.COM** or **SCAN** the QR code.

What is LIBTAYO?

LIBTAYO (Lib-TIE-oh) is a prescription medicine used to treat people with a type of lung cancer called non–small cell lung cancer (NSCLC). LIBTAYO may be used as your first treatment when your lung cancer has not spread outside your chest (locally advanced lung cancer) and you cannot have surgery or chemotherapy with radiation, OR your lung cancer has spread to other areas of your body (metastatic lung cancer), and your tumor tests positive for high "PD-L1," and your tumor does not have an abnormal "EGFR," "ALK," or "ROS1" gene.

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
- **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

In a study,

LIBTAYO was proven to help patients with advanced NSCLC live longer versus chemotherapy

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Median overall survival (OS)*

- At 22.1 months, **half of the patients taking LIBTAYO (178 out of 356 patients) were alive** versus 14.3 months for patients taking chemotherapy (177 out of 354 patients)

*Median overall survival (OS) is the time in a trial—expressed in months or years—when half of the patients are still living.

More patients were alive with LIBTAYO compared with chemotherapy

- As of March 2020, results from the trial showed that **248 out of 356 patients (70%) taking LIBTAYO were alive**, compared with 213 out of 354 patients (60%) taking chemotherapy†

Individual results may vary.

†Patients were enrolled between June 27, 2017, and February 27, 2020. Patients were treated with LIBTAYO for an average of 27 weeks. The study is still ongoing, and patients will be followed up for up to 4 years.

Important Safety Information (continued)

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.

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

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

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Explore what could be possible with LIBTAYO

Scan this QR code with your phone to learn more, or visit LIBTAYO.com/NSCLC

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

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

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

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- 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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- dizziness
- feel like passing out
- fever
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Continued on following page

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- 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.

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

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Caring for the Mind

SEEKING MENTAL HEALTH care during one's cancer journey can help improve symptoms related to anxiety, depression, fear and stress, but how does a patient or caregiver get started to find the best modality for them?

"Sometimes we think it's more commonplace for somebody to experience anxiety, depression or stress in the middle of treatment or at the beginning, but once somebody completes treatment, that's when those stressors become even more prevalent," Diane Schaab told *CURE*®. "Your work, your life has changed, you feel different physically, psychologically, you want to go back to normal. … It's really important to make sure we focus on mental health from the day of diagnosis all the way through survivorship."

CURE® spoke with Schaab and Elaine Smith, behavioral health therapists at Cancer Treatment Centers of America in Atlanta, to learn more about why mental health is important from diagnosis through survivorship, the different types of therapy and helpful resources.

WHY IS MENTAL HEALTH IMPORTANT?

- When you receive a diagnosis of cancer, it's a six-letter word full of trauma. There's a multitude of emotional responses, and it can be very difficult to determine the most immediate need.
- You're going to have levels of distress, or "adjustment issues," at any point along the spectrum. For many, at immediate diagnosis, throughout treatment and during survivorship, there will be levels of anxiety and fear.

WHAT DOES THERAPY ENTAIL?

- Various issues can affect the mental health care patients need and can be related to practical matters (i.e., family, finances, work, communication), spiritual matters, physical matters or relationship matters. Different approaches can be utilized to fit one's needs.
- Modalities of therapy include individual, marital, group and family; spiritual care; psychiatric evaluation for medications; cognitive behavioral therapy for pain, sleep, anxiety and depression; psychoeducation and webinars.
- Physicians can refer patients to behavioral health therapists. This referral can also happen with the first nurse visit or the first general assessment. Behavioral health services may be offered through the hospital providing cancer care or externally depending on resources.

HOW DO I KNOW WHAT'S RIGHT FOR ME?

- Consider what the primary stressor is (communication, anxiety, etc.). It's normal for stressors to change from day to day, and it can be difficult to determine the best path forward. Be open and share your ever-changing needs so you and your therapist can formulate the best treatment plan.
- Remember, quality of life is important. What is this problem and what's causing it? What resources can help produce a better quality of life? Whether the problem is related to sleep, fatigue, anxiety or depression, tackle it and enhance it with talk therapy, a psychiatrist and webinars.

Cancer Treatment Centers of America
part of City of Hope
Comprehensive Cancer Care Network

WHAT MAY PREVENT ME FROM SEEKING THE CARE I NEED?

- It's common for patients to focus on the physical challenges of cancer when talking to their doctors, but often they may minimize or forget to talk about psychological challenges.
- Fears: Will I like my therapist? How can I reveal this? Am I going to be judged? Patients have the ability and the power to meet with a therapist and create a treatment plan.
- Saying, "I'm afraid I'm going to die," and loved ones not wanting to hear that. Loved ones want to encourage and not discourage. When the patient voices a deep fear, caregivers think it is a negative statement. Family members and caregivers should encourage loved ones to get emotional support.
- Adding another layer of appointments and possible medications. Mental health counseling during cancer treatment marries the mind to the body and helps the patient feel empowered during their healing journey.

WHAT SHOULD I BE AWARE OF WHEN LOOKING FOR SUPPORT?

- A support group may present some challenges depending on how it is facilitated. Find out what a group entails and make sure it's a good fit. The same goes for finding a therapist.
- Not everybody has an accessible pathway, depending upon their insurance. This includes Medicaid and Medicare. State laws can affect how a Medicaid patient gets access to mental health care, among other hurdles. Centers for Medicare and Medicaid Services (CMS) can direct patients to appropriate community providers.

HELPFUL RESOURCES

- American Cancer Society Helpline – **(800)227-2345**
- Children's Treehouse Foundation – **www.childrenstreehousefdn.org**
  If worrying about children is a primary stressor, this organization out of Colorado offers several programs.
- DivorceCare – **www.divorcecare.org**
  For patients who may be struggling with divorce, which can affect their mental health.
- GriefShare – **www.griefshare.org**
  A nationwide program for those who may be struggling with the death of a loved one.
- Psychology Today – **www.psychologytoday.com/us/therapists**
  The system can help patients secure a therapist with insurance in mind.

The donna Foundation
CARING FOR THOSE WITH BREAST CANCER

LORETTA HAYCOOK-HAUGHT (center) was surprised by her daughter, **CHRISTINE** (left), who finished the last few miles of the marathon together.

DONNA Marathon
Recognizes Merits of 'Streakers'

As the foundation's 15th annual event brings the breast cancer community together, two "streakers" discuss their experience in running every marathon. *By* DARLENE DOBKOWSKI, M.A.

PHOTOS PROVIDED BY THE DONNA FOUNDATION

MORE THAN 4,000 RUNNERS participated in person during the 15th annual DONNA Marathon Weekend on Feb. 4-6, 2022, in Jacksonville, Florida, with thousands more participating virtually. In-person and virtual participants included runners from all 50 states and eight countries who ran various distances including 5K, half and full marathons and even ultra-marathons.

DONNA Marathon Weekend is a survivorship event of The DONNA Foundation, whose mission is to provide financial assistance and support to individuals living with breast cancer and fund groundbreaking research. This event welcomes patients, survivors and supporters to celebrate survivorship and fundraise for the foundation's programs. This year marked the return of an in-person race, which had been fully virtual in 2021 due to COVID-19.

Throughout the event's 15 years, several runners, whom the Foundation refers to as "streakers," have participated in every single race. *CURE*® spoke with Loretta Haycook-Haught, who ran the marathon in person this year and has run since the event began.

"That call can come any day that says, 'We have breast cancer' or 'Someone in our family has it,'" Haycook-Haught said. "If there's something, anything we can do to treat it better, to prevent it, to cure it, to have better medications, to have support for the family while undergoing treatment, it's a no-brainer. Why wouldn't we do it?"

Haycook-Haught, a lactation consultant from Florida, has had several connections with breast cancer, including her older sister who was diagnosed with breast cancer 20 years ago, underwent a double mastectomy and treatment and has since been in remission. More recently, her best friend's daughter, a mother of three children, died from metastatic breast cancer three years ago at the age of 35. Haycook-Haught also continues to run this race for all women including her daughter, Christine, because breast cancer can affect so many women.

Tracy Dawson, a language arts teacher from Florida, is also a DONNA Marathon Weekend "streaker," who ran this year's race virtually. In fact, the first DONNA Marathon in 2008 was the first marathon she had ever run.

"I didn't run a marathon to run a marathon; I ran a marathon for the foundation," Dawson said about her very first marathon. "It was really near and dear to my heart. … I remember really, really struggling the last few miles and went, 'Lord, just give me some strength.' I opened my eyes and this woman, who was clearly physically going through (cancer) treatment, passed me. I went, 'OK, got the sign. Perfect. Let's go.'"

Dawson said that since then, she has drawn strength from patients with breast cancer, whose names she writes on her shirts every year.

Like Haycook-Haught, Dawson has not personally experienced breast cancer, but has seen what it can do through the experiences of her mother-in-law, extended family, friends and cousins.

"I've watched what it takes to go through diagnosis, through surgery, through any type of treatment plan, whether that's chemo, radiation or both. And it's very inspiring to me," Dawson said.

ALL ABOUT COMMUNITY

Excitement for marathon weekend starts weeks before the event itself.

"All the excitement is because it's in our own community. Everybody knows the DONNA Marathon," Haycook-Haught said. "It's for all levels of runners. I do the marathon, but there are runs for little ones doing a one-mile dash, and there are 5Ks, 10Ks and people who want to do the 110-mile run. (It's) for all abilities, all levels, no speed involved. … The weekend, the event is all about community, seeing friends and people that you haven't seen in a while, but knowing you're all connected. It's a great cause and a great weekend. We're fortunate to have it."

Dawson said not only is the marathon emotional, but so is the exposition that takes place during the weekend.

"The expo is amazing," she said. "You have all sorts of inspiring messages. I love that you can sign the placards that go along the race. … You walk in, everything's pink, everyone's kind and there's all sorts of interesting, inspiring notes."

Dawson added that the people at the DONNA Marathon Weekend — runners or otherwise — add to the sense of community felt throughout the event.

"I've done a lot of other races, not just marathons, … you say thank you to someone who's cheering you on or … to an officer who's closing the road and letting you go by, (but) this is the only race where you say thank you and the fans thank you back," she said. "I remember the first time I ran (the) »

DR. EDITH PEREZ (left) and **DONNA DEEGAN**, founder of the Foundation, joined in the weekend-long festivities.

Runners of all different skill sets come together to raise funds for research and financial support for people affected by breast cancer.

DONNA just going, wow. It's different. There (are) people lining the streets that have either battled (or are) still battling (cancer), had family or friends that are no longer on Earth, and they're just like, 'Thank you for doing this for us.' … And it's every year. It never changes."

Haycook-Haught, and other runners, also mention the camaraderie felt with everyone at the marathon.

"Running promotes friendship and bonds that you keep forever," she said. "(There are) so many of those people out there on race day that you are standing up (for) — freezing — saying hello to before the race, (whom) you've known for years or maybe you don't know them, you just nod at them as you run by them on weekends. DONNA always (causes) huge excitement out there. It's amazing and it's exhilarating."

Haycook-Haught's daughter has run the marathon with her several times, but as she now lives farther south in Florida, she was unable to join her mother this year, or so Haycook-Haught thought. A surprise appeared toward the end of the race, when she needed the motivation; Haycook-Haught's training for this marathon wasn't on point due to a fall and broken jaw she endured in October 2021.

"My daughter surprised me at mile 20 and said, 'You started the race for your friend, but you're ending it with your daughter,'" she said. "It brings tears to my eyes. It was wonderful. … She knew that last part of the marathon would be almost walking me in, and she did (with) the rain and the wind, but it meant everything to me."

Dawson noted that even though she ran the marathon virtually this year, there was that feeling of motivation.

"You don't have the fans (or) anything like that, but you do have the emails from the DONNA Foundation," Dawson said. "I follow Instagram and there's always a big thank you to the virtual runners. That's special. You always feel like it's family. … I have experienced this with so many. I miss being on the course."

CONTINUING EFFORTS TO A CURE

Haycook-Haught and Dawson, among others, know that the DONNA Marathon Weekend needs to continue to make a difference for those living with breast cancer and support more breast cancer research.

"Until we run this race with a huge party saying we've cured breast cancer, we have to keep doing it," Haycook-Haught said. "We need the support from the community and the country to do all of that. Even if we don't have a cure for breast cancer yet, every day they get better with medication, treatment and financial support for families going through this."

Dawson added, "We need to continue to raise as much money as we can. It's a terrible disease and we need to help as much as we can. Those of us that can still do it need to do our part."

The donna Foundation
CARING FOR THOSE WITH BREAST CANCER

Additional details on the DONNA Marathon Weekend are available at **breastcancermarathon.com**. The 16th annual marathon weekend will be held ***Feb. 3-5, 2023.***

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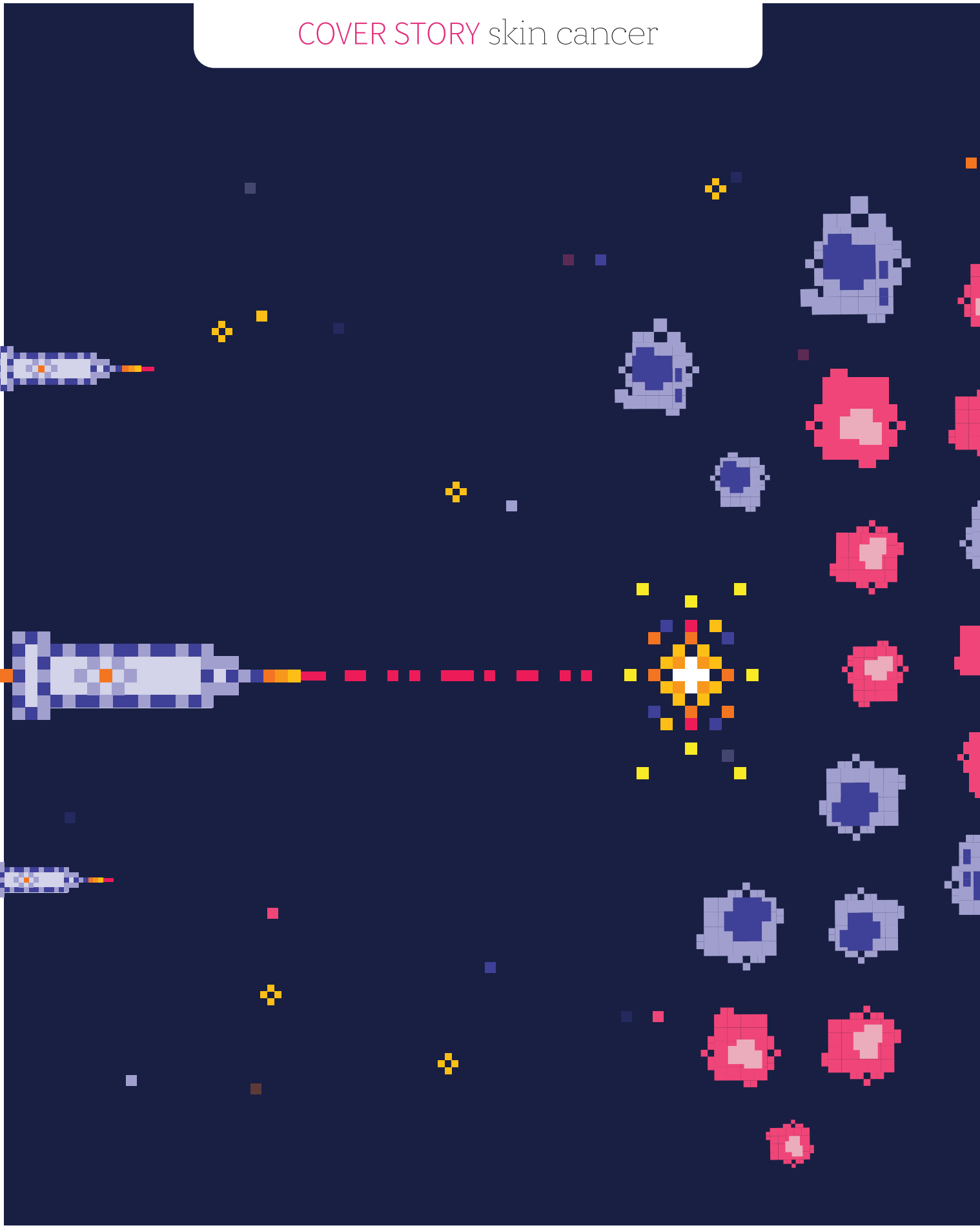


INVADING CANCER CELLS

RECENT RESEARCH HAS DEMONSTRATED THE ABILITY OF IMMUNOTHERAPY COMBINATIONS TO TARGET ADVANCED MELANOMA

By DARA CHADWICK

Mariena Browning of Pocatello, Idaho, was just 22 when she noticed a strange lump in her groin during the summer of 2018. Over the next few weeks, the lump grew and more lumps — swollen lymph nodes — appeared. She saw her primary care doctor, who referred her for an ultrasound and biopsy. The results indicated melanoma.

Browning then traveled to the University of Utah Huntsman Cancer Institute in Salt Lake City, where she was diagnosed with stage 3 metastatic melanoma with no primary source. "They did a full body exam, checked all my moles and removed any mole they saw," Browning says. "None of them were positive for melanoma or any sort of cancer. It just happened, unfortunately."

Her care team recommended that she join a clinical trial, but the trial was stopped just as Browning was set to join. In the meantime, new lumps developed on her stomach and neck. Biopsies of the new lumps showed melanoma, changing Browning's diagnosis to stage 4. Tumor biomarker testing showed she had a mutation in the BRAF gene, causing the gene to make an abnormal version of the BRAF protein involved in a growth pathway that fueled melanoma's growth. »

MARIENA BROWNING's doctors recommended an immunotherapy combination after the cancer spread to her brain.

Browning had surgery to remove all the lymph nodes in her left groin followed by an eight-month course of Braftovi (encorafenib) and Mektovi (binimetinib), targeted therapies to inhibit the BRAF protein. But she developed infections — specifically Clostridioides difficile (C. diff) and cellulitis — while taking the medications, so her care team decided to stop them.

Then the melanoma spread to her brain. That's when Browning began immunotherapy treatment — specifically, a combination of Yervoy (ipilimumab) and Opdivo (nivolumab). Her doctors explained that the immunotherapy combination would put her immune system into "overdrive," helping her system destroy the melanoma cells, she says.

WHAT IS IMMUNOTHERAPY?

Immunotherapy is different from other cancer therapies that work in a patient's bloodstream (systemically). Instead of destroying both cancer cells and healthy cells, as chemotherapy does, immunotherapy drugs help the immune system recognize cancer cells as invaders and work to eliminate them.

"What we've learned is that the immune system has the ability to actually recognize and treat melanoma on its own, but it often needs a little bit of a boost to do that," says Dr. Allison Betof Warner, a melanoma medical oncologist at Memorial Sloan Kettering Cancer Center in New York. Immunotherapy drugs help immune cells in the body — white blood cells known as T lymphocytes or T cells — recognize that cancer cells don't belong there. "The second function of immune therapy is to help boost the strength of the T cells to actually kill the cancer," she says.

The immune system uses immune checkpoints to make sure healthy cells aren't destroyed during an immune response. The T cells recognize and bind to certain proteins,

ALYONA OBORN

creating a stop sign (immune checkpoint) that tells the T cells to stop their disease-fighting work and protect healthy cells. But immune checkpoints keep the immune system from recognizing cancer cells, allowing tumors to grow.

BROWNING with her husband, **TREVOR**, and their dog, **COOP**. Her family has been by her side during her cancer journey.

Immunotherapy drugs called immune checkpoint inhibitors keep these proteins from binding and prevent the body from sending a stop signal to T cells. When they don't receive this stop signal, T cells attack cancer cells, shrinking tumors or preventing them from growing.

"Immunotherapy basically retrains the immune system and turns it back on so that it then recognizes cancer as something that shouldn't be there," says Dr. Elizabeth I. Buchbinder, a medical oncologist at the Melanoma Disease Center at Dana-Farber Cancer Institute in Boston. "Unlike therapies that work on the cancer itself, it's helping the immune system do something that it does already but isn't doing well in this particular circumstance."

Oncologists use different immunotherapy drugs to inhibit different checkpoint proteins from binding. The checkpoint proteins currently targeted by immune checkpoint inhibitors include interleukin-2 (IL-2), cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4), lymphocyte activating gene 3 (LAG-3) and programmed death 1 (PD-1).

The first immunotherapy approved by the Food and Drug Administration (FDA) for melanoma was Proleukin (aldesleukin). The agency went on to approve Yervoy, Keytruda (pembrolizumab) and Opdivo for treating melanoma.

The FDA also approved a combination treatment of Opdivo and Yervoy for people with advanced melanoma. Today, new immunotherapy combinations are changing the potential course of treatment for people with this disease.

HOW IMMUNOTHERAPY COMBINATIONS HELP

One of the challenges with immunotherapies for people with advanced melanoma is that some people's cancers don't respond to them — or they stop responding to the drug after showing initial progress.

"I think the biggest issue is treating that percentage of patients that don't respond," Buchbinder says. "It's figuring out what … we need to do differently or what can we add."

In some scenarios, it's quite clear that combination immunotherapy is the best choice, according to Betof Warner, who added that data support improved outcomes with combination immunotherapy for people with liver metastases. "Similarly, patients who have brain metastases and, in general, patients who have bone metastases, I typically treat with combination immunotherapy as well," she says.

New immunotherapy combinations to treat advanced melanoma with fewer side effects are an area of great interest among cancer researchers. Dr. Hussein A. Tawbi, professor of melanoma medical oncology at The University of Texas MD Anderson Cancer Center in Houston, released data earlier this year from the phase 2/3 RELATIVITY-047 clinical trial of combined treatment with the checkpoint inhibitors relatlimab and Opdivo. Treatment with the combination doubled progression-free survival (the time when a patient lives with cancer without disease progression) in study participants compared with Opdivo alone. And, Tawbi adds, toxicities in the combination treatment were manageable.

Tawbi expects a combination of relatlimab (which blocks the LAG-3 protein) and Opdivo (which blocks the PD-1 protein) to replace Opdivo as a single-agent first-line »

CYNTHIA AUGUST

treatment for people with advanced melanoma. "If the FDA approves it, I don't see any reason to ever use a single agent at this point because this is more effective and almost the same toxicity as (Opdivo) alone," he says.

According to Tawbi, after one year the progression-free survival rate for the combination treatment was 47.7% (compared with 36% in patients treated with Opdivo alone). Moreover, he adds, side effects occurred in only 18% of participants treated with the combination therapy.

"I think one of the most impressive aspects of this is not just how much better it is than single-agent (Opdivo), but the fact that it comes at a very low cost of toxicity," Tawbi says. "(Yervoy) and (Opdivo) gives you a one-year progression-free survival rate of 49%, but 55% have grade 3 (serious) or grade 4 (severe) toxicity."

If approved, the relatlimab and Opdivo combination will be another tool doctors can use when melanoma continues to progress in patients, according to Tawbi. "It adds to our armamentarium of drugs against cancer and will help us think about better solutions for those patients," he says.

For Betof Warner, the approval of relatlimab is something to look forward to. "For patients currently getting (Yervoy) plus (Opdivo), many or most of them will still get that combination," she says. "But if a patient was going to be treated with single-agent PD-1, you expect that many of those patients will go on to get (Opdivo) plus relatlimab if and when that's approved."

ARE IMMUNOTHERAPY COMBINATIONS RIGHT FOR EVERYONE?

Potential toxicities are a critical consideration when weighing treatment with an immunotherapy combination versus a single immunotherapy agent, Buchbinder says. "The rate of toxicity is very, very high," she notes. "Because they are activating the immune system — turning it on and making it recognize the tumor — they also can make it recognize normal things in the body as being abnormal or as something the immune system reacts against."

When this happens, side effects can be challenging. People taking immunotherapy combinations can develop

> I believe the immunotherapy combination treatment I received has allowed me to live the good life I am currently living. —LARRY WEBSTER

inflammation in the colon that causes diarrhea or inflammation in the lungs that creates respiratory problems. People may also have inflammation in the heart or liver.

"The good news is we're getting better and better at treating these side effects," Buchbinder says. "We'll give steroids, such as prednisone or other drugs, that dampen down the immune system. Frequently, patients end up hospitalized because we want to make sure that inflammation decreases quickly and that they don't get sick from something else while we try to fix the side effect from immunotherapy."

The side effects of combination immunotherapy treatment were so severe for Browning that she had to discontinue after two infusions. Her eyes became yellow and enzymes in her liver became so elevated that she needed an immunosuppressant drug to control immune-related hepatitis. "I stopped treatment for about six months," Browning says. "I was on prednisone during that time to get my liver healthy enough to be able to do treatment again."

In June 2020, Browning began immunotherapy treatment again, but this time she was treated with Opdivo only. She finished her course in October 2021 and her scans continue to show no evidence of disease.

Of course, not all people treated with immunotherapy combinations experience severe side effects. Larry Webster, 68, of Haverhill, Massachusetts, was initially diagnosed with melanoma in 2017 after a shave biopsy (when a thin piece of skin is removed from the surface with a blade). He had two radical lymphadenectomies, surgery to remove a growing malignant mole on his left calf and cryoablation to destroy a small mass near his liver. He also participated in two immunotherapy combination clinical trials — one of a combined novel single agent PD-1 inhibitor, neoantigen vaccine and Opdivo and the other combining injectable CMP-001 with Keytruda.

"I generally felt fine while undergoing treatment," Webster says. "The only side effects I experienced were some fatigue and flu-like symptoms toward the evening. I had chills, body aches and soreness at injection sites."

Overall, side effects lasted about an hour or two and he managed them by going to bed. "I was always able to return to work the following morning," he says.

In people who do experience side effects, one of the biggest fears is whether treating the side effects will dampen the effectiveness of immunotherapy, Betof Warner says. She compares the balance to a threshold — the drug needs to activate the immune system above a certain threshold to fight cancer. "Ideally, we'd be right at that threshold where it's enough to treat your cancer and not enough to cause the side effect," she says. "But unfortunately, we don't have the ability yet to tune that as well as we would like. My goal with treating their side effect is to bring their immune system back down to the point where we are still above the threshold but they're no longer (experiencing) a side effect."

LOOKING TO THE FUTURE

It has been two years since Webster's last treatment and he now sees his care team for regular scans and dermatology appointments. Although he acknowledges having initial concerns about participating in clinical trials, he says, "I realized immunotherapy was my best bet for treating the advanced melanoma. I believe the immunotherapy combination treatment I received has allowed me to live the good life I am currently living."

Browning encourages others considering treatment with an immunotherapy combination to do their own research and trust their doctors. "Find a care team that listens to your opinions, worries and thoughts because that's something that helped us for sure," she says. "Find the care team you completely trust."

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

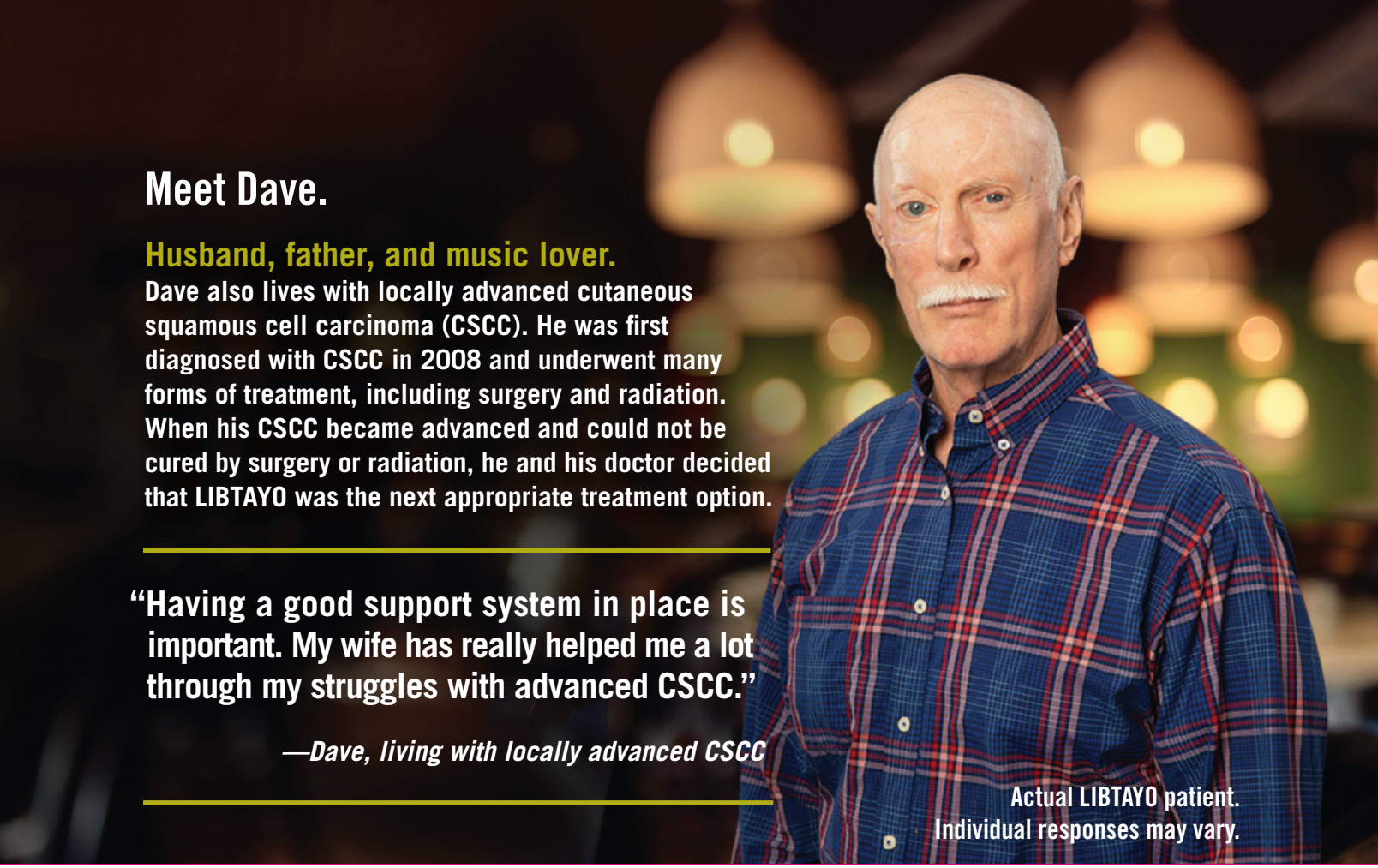
What is the most important information I should know about LIBTAYO?

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.

What is the most important information I should know about LIBTAYO? LIBTAYO is a medicine that may treat certain types of 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.

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Lung problems.
- cough
- shortness of breath
- chest pain

Intestinal problems.
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- severe stomach-area (abdomen) pain or tenderness
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Liver problems.
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- 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.
- 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

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, bruising

Infusion reactions that can sometimes be severe. Signs and symptoms of infusion reactions may include:
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- itching or rash
- flushing
- shortness of breath or wheezing
- dizziness
- feel like passing out
- fever
- back or neck pain
- facial swelling

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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.

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- 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

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- 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.

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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

SECOND TIME AROUND

What happens when patients develop a secondary cancer years after undergoing treatment?

By KAREN BLUM

Michael Kimbarow was 13 years old in 1966 when he received a diagnosis of Hodgkin lymphoma. Doctors surgically removed a tumor within the parotid (salivary) gland on the left side of his face and applied radiation treatments to the area. He was then considered cancer-free and went on to live his life.

Nearly 40 years later, Kimbarow was working as a professor of communicative disorders and sciences at San Jose State University in California when one day, the left side of his face started to droop and became paralyzed. A series of tests revealed a secondary cancer — a parotid tumor, which doctors thought was a late effect of the radiation he had received decades before. In contrast to the lymphoma that originated from lymphocytes in the parotid gland area, the second cancer arose from the parotid gland cells, likely induced by radiation. »

"I was really just devastated to hear that I had another cancer," says Kimbarow, now 69, "and I didn't know at that point what all of the implications were." But he continued to work while undergoing treatment, and a year later underwent reconstructive surgery to restore some facial symmetry.

NEW AND DIFFERENT TUMORS FROM TREATMENTS

Kimbarow's experience is not isolated. Nearly 1 in 5 cancers diagnosed today occurs in an individual with a previous diagnosis of cancer, according to the National Cancer Institute.

The term "secondary cancers" can be confusing, explained Dr. Stephanie Schaub, an assistant professor of radiation oncology at the University of Washington in Seattle. She usually describes them to patients as "new and different tumors caused by treatments," such as radiation, chemotherapy or targeted therapy. "That helps just emphasize to patients that it's not their (original) tumor coming back."

Treatments such as radiation or radioactive iodine (for thyroid cancer) are one known cause of secondary cancers. Chemotherapy can later lead to leukemias or other blood cancers. The hormonal therapy tamoxifen, used to treat breast cancers, increases the risk of developing uterine cancer later on. Despite associations such as these, the benefits of cancer treatment far outweigh the risk of developing secondary cancers, according to experts.

However, not all secondary cancers are caused by earlier treatment. Other risk factors include family history, or genetic predisposition. Certain racial and ethnic groups, such as Ashkenazi Jews, have a higher prevalence of mutations to the BRCA1 and BRCA2 genes associated with breast, ovarian and pancreatic cancers. People with a family history of ovarian cancer may be at higher risk of developing the condition, too, as genetic mutations can be inherited. Some secondary cancers are unrelated to the initial cancer.

Age also plays a role. People like Kimbarow who are first diagnosed with cancer as a child or adolescent, or under age 45, are at a higher likelihood of experiencing a secondary cancer later, as the risk of cancer increases with age. Exposure to environmental pollutants such as cigarette smoke is also a contributing factor. And some cancers themselves promote a higher risk of secondary cancer. People with chronic lymphocytic leukemia and non-Hodgkin lymphoma, for instance, have a higher than normal risk of developing other cancers such as skin cancers, says Dr. David A. Bond, a hematologist at The Ohio State University Comprehensive Cancer Center in Columbus.

Overall, a decrease in the immune system associated with the initial cancer can increase the risk of developing a secondary cancer, explains Dr. Jennifer A. Woyach, a hematologist-oncologist at Ohio State. This is especially true in cases where the epithelium, the lining of the body's tissues, is damaged, such as skin cancers associated with damage caused by ultraviolet light.

In general, secondary cancers take at least three to five years to develop, but the majority are seen years to decades after the initial diagnosis of a patient's original tumor, Schaub says. The risk can depend on many factors such as younger age, genetic predisposition and treatments given for the original tumor. If it's genetic, each gene has its own peak in incidence for secondary cancer, mentions Dr. Siddartha Yadav, a breast and gynecologic cancer specialist at Mayo Clinic and an assistant professor of oncology at Mayo Clinic College of Medicine in Rochester, Minnesota.

> When I got a second breast cancer, I was really angry. In my head, I had done that. I was moving on.
>
> —MARY LOU SMITH

DIAGNOSING SECONDARY CANCERS

Adding complexity, it may not always be easy to tell if a new cancer that develops is related to treatment for the first cancer, says Schaub. The biggest indicators are the type of new tumor that develops, coupled with the prior therapies received. If a teenager with Hodgkin lymphoma is treated with radiation to the chest and later develops a breast cancer within the area that received radiation, the new cancer is likely linked to treatment. However, no pathologic or genetic studies are available to date to prove the association between new and prior cancers, she explains.

That's the case for Mary Lou Smith. Smith, who is over 70 and lives in the Chicago area, has survived three types of cancer. She received a diagnosis in her early 40s with early-stage ductal carcinoma in situ (DCIS) breast cancer and had a second DCIS 21 years later. Smith had ovarian cancer about eight years after the second breast cancer, followed by colon cancer three years later. The breast and colon cancers were detected through routine screenings, and the ovarian cancer was found based on Smith reporting symptoms. After myriad treatments and follow-ups, Smith is considered as having no evidence of disease (NED). Two types of genetic testing found nothing to suggest she is at risk of developing cancers, but Smith finds it hard to believe she doesn't have some genetic predisposition.

"When I got a second breast cancer, I was really angry," she says. "In my head, I had done that … I was moving on. With the ovarian cancer, I was very frightened. I knew that was lethal, and by the time it's found there's not much to do except a lot of treatment. … With the colon cancer, I was just irritated to be honest. Like, *really*?"

Cynthia Chauhan, too, has had several bouts with cancer. Her first cancer was detected in 1998, when she was hospitalized for a surgical procedure and started having significant

CYNTHIA CHAUHAN'S cancer journey began in 1998 when she had tumors removed from her kidney.

JENELLE ROBINSON

pain. Imaging tests revealed a tumor in the center of one of her kidneys. Cancer specialists at Mayo Clinic, where she was seen, surgically removed the kidney and continued to monitor her.

Three years later, while waiting to undergo a routine mammogram, Chauhan thought about an aunt who had died from inflammatory breast cancer. The next thing she knew, Chauhan herself was sitting down with a radiologist to discuss the findings, which had identified a DCIS breast cancer.

"It was scary," says Chauhan, now 79, of Wichita, Kansas. "I (already) had been through a pretty rough sequence with the kidney cancer." But she mentions she was not overwhelmed by the diagnosis because she felt she was in a good medical center for treatment and care.

Chauhan took her secondary cancer as a sign to do new things. She left her job as a clinical social worker and took up rock climbing, drawing and painting. "Those are ways that allowed (me) to see myself differently," she explains, and they enabled her to support herself emotionally while going through radiation treatment. She also used visualization techniques, calling on her love of gardening. She began thinking of her breasts as a beautiful garden of flowers that had been invaded by a weed that needed removal. Today her status also is considered NED.

CHANGE IN THE TIDE

Kimbarow, Chauhan and Smith all say their doctors didn't talk to them about their risk of developing secondary cancers. Cancer still had a lot of stigma attached to it in the 1960s, »

Kimbarow says: “It was still kind of whispered about. So we really didn’t talk too much about it.” Smith recalls seeing information about secondary cancers in reading material given to her about the carboplatin and paclitaxel drugs she was prescribed for ovarian cancer.

“By that time it was like, ‘Oh well, what do you want me to do about that? I want to live today, so I’ll take a chance on five years down the road,’” she relates.

Fortunately, times are changing. Woyach and Schaub note that they discuss the risks of secondary cancer with their patients during the initial visit.

“I think sometimes people have this impression like, ‘I already have one cancer, so I don’t need to worry about something else. I have enough on my plate,’” Woyach says. “But it’s really important to continue other recommended, age-appropriate screenings.”

Depending on the type of treatments given, there may be adjusted screening recommendations to allow for earlier detection and/or prevention of secondary cancers, explains Schaub.

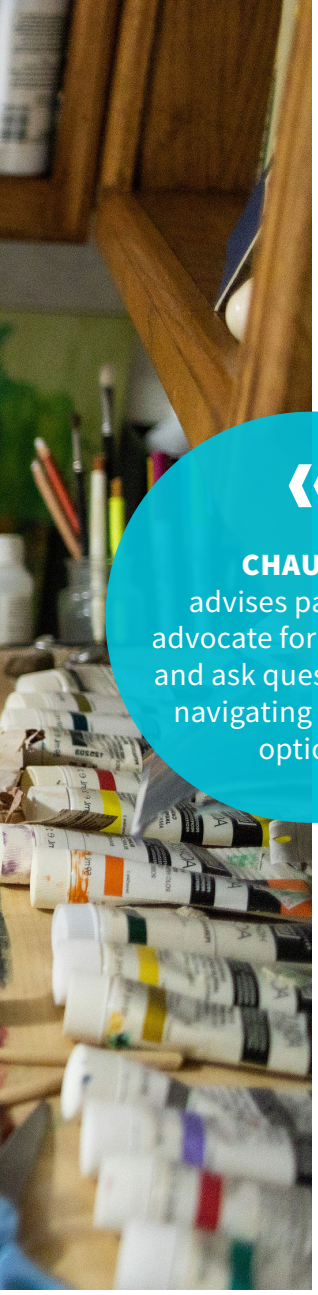
Throughout the cancer journey, whether secondary or primary, support and self-advocacy are crucial, Chauhan and Smith noted.

“It’s important to have a caregiver who is very supportive and to understand that you are the most important person in your cancer care team,” Chauhan says. “You have a right and almost a responsibility to advocate for yourself, … to ask questions and to expect to get meaningful, understandable answers to those questions, and then to really focus on how you can best take care of yourself as you go through this.”

For example, back when Chauhan’s physician told her he was 98% sure she had kidney cancer and wanted her to schedule surgery the next day, Chauhan asked to hold off so she could do her own research, make a list of questions and have all her concerns answered before the procedure. “The surgeon reluctantly agreed,” she says.

Smith added her own advice: Make sure you attend all appointments for treatments and follow-up care and keep track of your health. “It is important to know your own

JENELLE ROBINSON



CHAUHAN advises patients to advocate for themselves and ask questions when navigating treatment options.

body. If you feel there's something that isn't going the way it should, then tell someone."

Secondary cancers generally are diagnosed based on a patient's symptoms or routine screenings and follow-up care. Oncologists monitor some cases more closely, Yadav points out, such as for patients who receive chemotherapies known to be associated with second cancers or who receive PARP inhibitor drugs associated with blood-based cancers.

Some secondary cancers identified early, such as skin cancers, are more likely to be curable and can be screened for easily, Woyach explains. But blood cancers such as myelodysplastic syndrome or acute leukemia tend to be more subtle and come on slowly, and don't have as many screening tests.

INDIVIDUALIZED TREATMENT OPTIONS

Treatment for secondary cancers generally is the same as for primary cancers, but there are times when oncologists have to consider additional options. Prior cancer therapies may have limited a patient's reserves to tolerate a full dose of radiation therapy, Schaub says, or make it more difficult to perform surgery in a particular area. Chemotherapies also may be limited. One routinely used in breast cancer called doxorubicin should only be prescribed as a limited dose over a lifetime, according to Yadav. If a patient develops a secondary cancer for which the standard of care would be giving them the same drug, it becomes challenging.

"Really, it does become an individualized, thoughtful approach to patient care," Schaub says. "There's definitely no exact textbook (recommendation) for how to treat them."

Kimbarow has been taking anti-cancer medications off and on since 2018 for lung tumors thought to be a metastasis from his 2006 parotid tumor. But he doesn't worry about it or let it slow him down, saying he has two mantras: "The first is that I refuse to stop living before I die. And the second is that I've yet to read any scientifically peer-reviewed study that shows or demonstrates that sitting in a dark room feeling sorry for myself will improve my outcome. Until I do, there's no point in it, so I just move forward day by day and enjoy it."

Although no surefire way exists to prevent the development of subsequent cancers, cancer survivors can take steps to boost their health. Most important, mentions Woyach, is to undergo any recommended cancer screenings. Any young woman who had radiation to the chest under the age of 30 should be screened twice a year for breast cancer beginning eight years after completing radiation, using MRI and mammograms, notes Bond. Survivors of chronic lymphocytic leukemia and low-grade lymphomas should undergo skin cancer screenings at least annually, he says.

Also understand that if a patient has a genetic profile that increases their chance of developing a secondary cancer, they should be screened, Yadav says. If they haven't had genetic testing, Yadav recommends they ask their oncologist if that might be right for them.

If there are no related genetics or family history, patients are advised to control other lifestyle and environmental factors. Experts advise patients the following: don't smoke; limit sun exposure and use sunscreen; eat a healthy diet; increase consumption of fruits, vegetables and other vegetarian foods; and decrease consumption of meat.

Exercising also may reduce the recurrence of cancers, Yadav explains. "This can be just walking around … it does not have to be full cardio exercise, but it should be a minimum of one hour, three to four times a week," he advises.

Cancer researchers are continuously working to develop newer treatments with fewer side effects while also trying to understand their association with risks for developing secondary cancers. Proton therapy, a newer form of external beam radiation therapy that minimizes radiation to healthy tissues surrounding a tumor, or immunotherapies that reinvigorate the body's natural immune system to fight cancer eventually may be affiliated with fewer secondary cancers.

Research in breast and other cancers focuses on the genetic risk of developing secondary cancers, Yadav says. He also notes that over the past 20 years or so, scientists have found that genes such as ATM, CHEK2 and PALB2 cause breast cancer and are associated with secondary cancers. Current studies are looking to pinpoint what an individual's risk is and what factors can modify that risk. Other studies are focused on the nature of secondary cancers and potential prevention.

"Right now, our recommendations are saying, 'OK, if you're genetically predisposed to developing ovarian cancer, we need to take the ovaries out,'" Yadav explains. "But are there other ways beyond doing surgeries? It's not quite (at the point) where we can take certain medications and prevent secondary cancers … but that's the goal."

Kimbarow's attitude has been so positive that his oncologist featured him as one of three patients in a talk on people who didn't give up and showed remarkable response to treatment.

"Don't stop living before your body gives out on you," Kimbarow says. "You never know what the next therapy is that's right around the corner. … The advances in science are amazing." C

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NAVIGATING A GAUNTLET OF CHALLENGES

Regardless of a man's age, caregiving for a partner or family member can take a toll on a person.

By DON VAUGHAN

Cassie Cramer, 52, of St. Paul, Minnesota, received a diagnosis of early-stage breast cancer in 2002. She underwent a mastectomy and lived disease-free until summer 2018, when she began to experience fatigue and chest and back pain. A positron emission tomography scan revealed that Cassie's breast cancer had spread to her lungs; she was told it was manageable but incurable.

In that moment, Cassie's husband, Dan, saw his world turn upside down. He went from being a consultant and business owner to a full-time caregiver overnight, providing for Cassie's medical needs as well as her emotional support and encouragement.

"There's a word I use to describe living with metastatic cancer: unrelenting," says Dan, 54. "There's never a day, never a moment when Cassie doesn't know she has cancer. And because of that, there's never a day when I'm not her caregiver. When you love someone who has cancer, you're with them all the time. The emotional toll has been significant for me." »

Dan Cramer is one of a growing number of men who are taking up the gauntlet of caregiving for a spouse or other family member with cancer. Many are wholly unprepared for the job's grueling emotional, physical and psychological challenges, yet they readily accept the responsibility, often because there is no other choice.

According to a March 2017 report from the AARP Public Policy Institute titled "Breaking Stereotypes: Spotlight on Male Family Caregivers," 40% of family caregivers are now men compared with 34% eight years earlier. This equates to approximately 16 million male caregivers in the United States. More than half (63%) reported that they were the primary caregiver in their family after their partner became ill.

As men increasingly find themselves in the caregiving role, societal attitudes have also changed, experts note. "Traditionally, women have been socialized into the caregiving role," observes Susan R. Mazanec, an assistant professor at Case Western Reserve University Frances Payne Bolton School of Nursing in Cleveland, Ohio, and a nurse scientist at University Hospitals Seidman Cancer Center in Cleveland. "However, in contemporary society, as women assume other roles in terms of work and family, male caregivers have stepped up and helped out with providing care and other needs. It's very important for oncology nurses to recognize that the primary caregiver in a situation could potentially be a man and that they, like women who are caregivers, will need to be educated, trained and supported in their role."

Men bring unique skills and experiences to the caregiving role, reports Allison J. Applebaum, a psychologist specializing in cancer and caregiving at Memorial Sloan Kettering Cancer Center in New York. "A recent systematic review of studies enrolling male caregivers found that men appear to focus on the more traditionally masculine behaviors that accompany their caregiver role, including their ability to take control, use of their technical skills and (completion of) practical tasks such as managing finances or providing transportation," she notes. "Male caregivers were also found to value independence and autonomy as a caregiver and often reframe their role from 'carer' to 'protector' or 'provider' of the patient."

A 2008 meta-analysis on gender in caregiving, published in *Psychological Bulletin*, found that male caregivers tend to report experiencing a higher quality of life and life satisfaction than female caregivers, as well as lower rates of depression and anxiety, Applebaum adds. "While these relationships are certainly not definitive, the gender differences here may reflect male caregivers' 'problem-focused' approach to caregiving that views each issue that arises during caregiving as a problem to be solved," she explains. "It may also be a reflection of the fact that overall, male caregivers tend to be less comfortable admitting that they are experiencing difficulties."

A variety of factors can influence the degree of stress and responsibilities a man may face in his new role as caregiver, including his relationship to the patient, employment status and age. Compared with all older caregivers, younger ones

JAKE JACOBSEN took care of his wife, **CHERYL**, from when she was diagnosed in 2019 until she died in late 2021.

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struggle with different challenges because caring for a person with cancer at a young age is atypical, notes Applebaum. They may lack the experience and coping skills to manage the emotional and communication challenges that accompany caregiving, and as a result often have a difficult time adjusting to the caregiving role. Young adult caregivers may have to forego pursuing higher education, career advancement or romantic relationships due to the time demands of caregiving, which can have a long-term impact on their developmental trajectory.

Daniel McLeod, 36, of Perry, Florida, was in his mid-20s when he was asked by his mother and aunt to assist in the care of his grandfather, Pete Lavoie, who was recovering from bladder and prostate cancer. McLeod was between jobs, divorced and had shared custody of his young son, Peyton, which added to his responsibilities. Worse, Papa Pete, as McLeod called his grandfather, was also in the throes of Lewy body dementia, a particularly pernicious form of dementia that often results in paranoia, agitation and aggression.

Initially, McLeod's caregiving consisted of assisting his grandfather with the usual activities of daily living, as well as maintaining his stoma and ostomy bag. But when Lavoie's dementia worsened, McLeod moved into the home to attend to his care full-time and keep him safe. "Papa Pete would sometimes wander into his woodworking shop when I was preoccupied with Peyton," he explains. "He couldn't safely work the machinery anymore, and I would have to gently redirect him back into the house."

As his grandfather's cognition declined, McLeod's responsibilities increased. His social life dwindled and the constant stress had a negative impact on his interpersonal relationships, including with his fiancée. Other family members helped when they could, but McLeod remained responsible for most of his grandfather's care.

"I went through crisis training when I was in law enforcement," McLeod notes, "but when it comes to a family member, someone you care deeply about, that all goes out the window. The care was nonstop, and there were times when I would put Papa Pete and Peyton to bed, and just sit on the couch thinking, when am I going to have a life?"

Jake Jacobsen, 76, of Eagan, Minnesota, had an altogether different experience. In 2019, as he was enjoying life as a retired executive, his wife, Cheryl, was diagnosed with stage 1 pancreatic cancer. She received chemotherapy, radiation and a pancreaticoduodenectomy (a surgery to remove the head of the pancreas, the gallbladder, the first part of the small intestine and the bile duct) and was deemed cancer-free until August 2021, when she learned that the cancer had spread to her liver. She died in December 2021, too ill to continue treatment.

"I cared for Cheryl 24/7," Jacobsen says.

Jacobsen was luckier than many male caregivers in that he shared the responsibility with his daughter, Ann. "She remotely participated in all doctor calls and made a record of all discussions," Jacobsen reports. "This was extremely helpful in making necessary care changes. Ann also prepared »

KYLE WOODY founded a nonprofit organization dedicated to male caregivers after caring for his wife with metastatic colon cancer.

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> Before, I never asked for help because to me it was a sign of weakness.
>
> —KYLE WOODY

charts that directed us in what to do for pain, anxiety, constipation, diarrhea, etc., and created daily logs specifying the timing of meds and recording of hydration, nutrition and bowel movements. The careful organization improved our ability to care for Cheryl."

A notable difference found among male caregivers is a reluctance to ask for social support from loved ones and the community (38% versus 47% of women, per the "Caregiving in the U.S. 2020" survey). "As such, they tend to be more isolated and lack emotional support … compared (with) female caregivers," Applebaum observes. "This may be due to societal expectations that stigmatize male vulnerability and make asking for help seem like a weakness."

Kyle Woody, 42, was caregiving for his wife during her treatment for metastatic colon cancer when some family friends asked what they could do to help him. Woody was perplexed; it was his wife who needed help, not him. They then told him the story of a friend named Jack who had been through the same difficult experience.

"Jack told them, serve the caregiver — they're always forgotten," Woody recalls. "So that's what they were going to do, bring his wisdom into my life. That moment inspired me after a lot of reflection, and in 2014, we founded Jack's Caregiver Coalition, a nonprofit organization dedicated to improving the way guys think, feel and act through every phase of their caregiving journey. Before, I never asked for help because to me it was a sign of weakness."

Another big challenge is a lack of preparedness for the caregiving role, especially if someone is thrown into it unexpectedly. Mazanec worked with oncology nurses to conduct a 2018 study of 50 male caregivers of women with gynecological cancer post-surgery, which found that the caregivers had a number of informational needs, as well as a necessity for training specific to equipment and procedures.

Additional struggles arise if the caregiver is the sole financial support for the family. In 2015, according to "Breaking Stereotypes," two-thirds of male caregivers reported having to make changes in the workplace as a result of their caregiving experience, including shortening working hours or taking a leave of absence. "Caregivers of all genders report conflicts between their work and caregiving responsibilities; however, men's societal expectation to be financial providers for their families could make these conflicts more difficult to reconcile," notes Applebaum.

Left unaddressed, the challenges that commonly face male caregivers can become overwhelming and negatively affect their health and quality of life. Jake Jacobsen, for example, gained 30 pounds during the two years he was his wife's caregiver because he no longer had time to exercise and rarely left the house because of the COVID-19 pandemic. This is why outside support can be so helpful.

"There are phenomenal support services available to all caregivers, though male caregivers may have unique needs," says Applebaum. "For example, male caregivers I see in our Caregivers Clinic often report feeling ill-equipped to carry out medical as well as personal or intimate caregiving tasks such as dressing, bathing and toileting. As a result, they may especially benefit from support services that provide »

LAUREN B. PHOTOGRAPHY

To hear more about how **KYLE WOODY** started Jack's Caregiver Coalition, **SCAN THE QR CODE AND LISTEN IN!**

education on how to complete these tasks, as well as disease-specific information and education."

Peer support, in particular, can be a critical component in helping male caregivers cope with and manage the stress of the job, Applebaum adds. "Support groups can help men feel validated and less isolated and alone in their caregiving journeys," she explains. "Peer-to-peer mentoring, (in which) men who were once caregivers can provide support to current caregivers, is one model of care many male caregivers have found helpful. Support services such as these can help to normalize the emotional challenges associated with caregiving and encourage male caregivers to continue to take care of themselves while taking care of a loved one with cancer."

Jake Jacobsen and Dan Cramer both found support through Jack's Caregiver Coalition, where they worked with trained facilitators. "It gave me the sense that it can be done, you just have to learn how to do it," Jacobsen says. "It was helpful to me, and I regret that I didn't get in touch with them earlier."

Male caregivers may find it helpful to ask themselves a series of questions as they go through their caregiving journey, says Mazanec. Because they are often thrown into the role with little preparation, the first question should be, "What do I need to learn, and who can I turn to for that information?" Once they become immersed in the role, they should ask how they can find time for themselves, whether it's a visit with friends or a daily walk, and who they can turn to on those days when they simply aren't able to give 100%.

Applebaum agrees, noting, "As a caregiver, you cannot meet all of your loved one's needs on your own. It's important to give yourself permission to ask others for support — for yourself emotionally and for support around helping with caregiving responsibilities."

The caregiving role can be fraught with anxiety and have as dramatic an impact on the caregiver's life as on that of the patient. But it also is an opportunity for caregivers to learn new things about themselves, Applebaum observes, including their deep capacity for strength and resilience, and the ability to create a deeper, more intimate relationship with the patient for whom they are providing care. "For all caregivers, the challenges endemic to caregiving have the potential to eventually serve as learning and growing experiences that can help them to live more full, authentic lives both during caregiving and after," she says.

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.

Welireg May Promote Strong Clinical Activity With Mild Side Effects

As surgical procedures are often the standard treatment for renal cell carcinoma related to VHL disease, the use of Welireg may reduce surgical burden in patients.

By DARLENE DOBKOWSKI, M.A.

TREATMENT WITH WELIREG (BELZUTIFAN) demonstrated responses in patients with renal cell carcinomas, the most common type of kidney cancer, and non-renal cell carcinoma neoplasms associated with von Hippel-Lindau (VHL) disease, according to findings from a recent trial.

The trial results also demonstrated that responses to Welireg were linked with mild to moderate side effects.

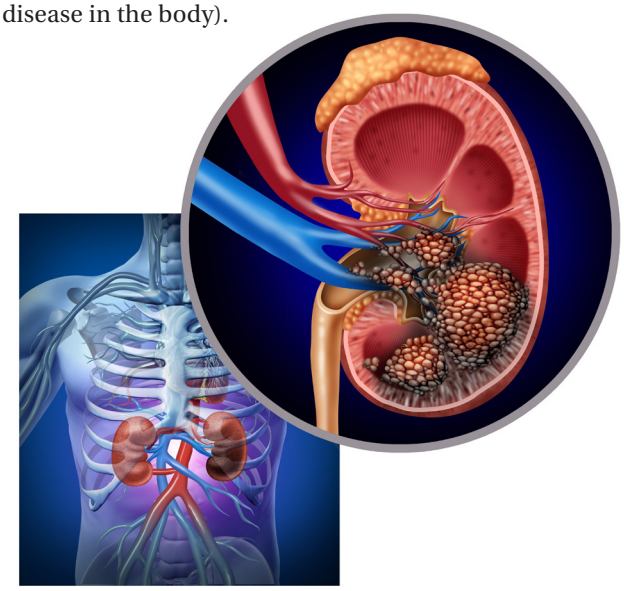
"Until this year, patients with von Hippel-Lindau disease, which is a rare hereditary disorder affecting right around 10,000 people in the U.S., didn't have any therapeutic treatment options," said Dr. Eric Jonasch, a professor of medicine in the Department of Genitourinary Medical Oncology at The University of Texas MD Anderson Cancer Center in Houston, in an interview with *CURE*®.

"Individuals with VHL spend a lifetime undergoing surveillance studies, and when lesions arise — which can occur in their eyes, cerebellum, spinal cord, middle ear, pancreas, adrenal glands, the kidneys, epididymis and round ligaments — … these individuals may need to undergo surgical procedures to prevent either organ damage or the development of metastasis. Having a systemic therapy that can decrease the need for surgical interventions was really very big in the minds of the patients as well as physicians."

Welireg is a hypoxia-inducible factor 2α (HIF-2α) inhibitor that blocks a particular pathway from inhibiting tumor growth in clear cell renal cell carcinoma.

Researchers assessed the efficacy and safety of this drug in 61 patients (median age, 41 years; 52% men) with renal cell carcinoma or non-renal cell carcinoma neoplasms associated with VHL disease. All patients were treated with 120 milligrams of Welireg daily. Compared with patients in a randomized controlled trial, in which researchers assign a treatment or standard of care, patients in this trial received the same regimen "because (a randomized trial) was not considered to be reasonable or ethical in this patient population," Jonasch said.

Researchers focused on the objective response to Welireg, defined as a measurable response to the treatment. This included a complete response (the disappearance of all signs of disease) or a partial response (a decrease in tumor size or the extent of disease in the body).



Kidney cancer associated with VHL may benefit from systemic therapy to decrease the need for surgery.

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During a median follow-up of 21.8 months, an objective response was observed in 49% of patients with renal cell carcinoma.

"We were hoping to get (objective response) numbers in that range," Jonasch said. "If you look at the percentage of individuals who had any degree of shrinkage, you see that almost all the patients — more than 90% — had some degree of reduction in size, but 49% had a confirmed 30% shrinkage. So it looks like this agent is capable of decreasing the size of these tumors in a fairly consistent manner. … All in all, this 49% objective response rate is impressive."

Responses to Welireg also occurred in patients with central nervous system hemangioblastomas (30%) and in those with pancreatic lesions (77%). Researchers also assessed 16 eyes in 12 patients with retinal hemangioblastomas at the start of the study. All patients in this subgroup experienced improved outcomes while receiving Welireg.

"I think it's important to mention that we did see a 91% objective response rate in pancreatic neuroendocrine tumors, which is unprecedented," Jonasch said. "We saw that there was a 30% objective response rate in hemangioblastomas. Once again, this is unprecedented. And amongst those pancreatic neuroendocrine tumors and hemangioblastomas, there were some complete responses as well."

The most common side effects associated with Welireg were fatigue (66%) and anemia (90%).

"This drug is relatively well tolerated, which is critical in this patient population, which I would call a well-but-at-risk population," Jonasch explained. "For a large part, these individuals have excellent performance status and are trying to avoid having the adverse events of undergoing surgery, so you need to have a well-tolerated regimen."

> This drug is relatively well tolerated, which is critical in this patient population, which I would call a well-but-at-risk population. —DR. ERIC JONASCH

During the trial, seven patients discontinued treatment. In particular, four patients voluntarily discontinued treatment, one discontinued after an investigator observed disease progression, one discontinued for mild dizziness and one patient died from acute toxic effects of fentanyl.

"We now know that by using a targeted HIF-2α inhibitor in individuals with von Hippel-Lindau disease, we are capable of shrinking lesions in the kidney, … pancreatic neuroendocrine tumors (and) central nervous system hemangioblastomas," Jonasch explained. "(With) at least a 21.8-month follow-up that we have so far, these responses are durable. We've had very few people who have come off study because of progression, and most people have remained on with continued response."

Regarding further research, Jonasch added that the data from this phase 2 trial were so strong that there may not be a need for a randomized trial to assess the efficacy and safety of Welireg.

"When it became apparent how strong the data were, the FDA, … the physicians and the patient community (didn't) feel that this particular study (needed) to be turned into a randomized study," he mentioned. "We have gone beyond the point of saying we need to do a randomized study to confirm this particular question, which is (whether Welireg is) capable of shrinking VHL-related lesions."

This doesn't mean that questions don't remain about Welireg, Jonasch said. These include how long Welireg will continue to benefit patients and how early it should be administered.

"This was a trial that was designed to treat established disease," he explained. "Can this therapy be used as a prevention strategy, (in which) you treat individuals who have a high probability of developing lesions in the future? In that scenario, you could perform a randomized study, where you randomize between treatment and placebo, testing the hypothesis that this therapy would prevent the development of lesions. I think (that) would be an ethical trial design." C

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

What is CABOMETYX?

CABOMETYX is a prescription medicine used to treat:

- People with kidney cancer (renal cell carcinoma). CABOMETYX may be used:
  - Alone to treat people with renal cell carcinoma (RCC) that has spread (advanced RCC)
  - In combination with nivolumab when your cancer has spread (advanced RCC), and you have not already had treatment for your advanced RCC

It is not known if CABOMETYX is safe and effective in children younger than 12 years of age.

What are the possible side effects of CABOMETYX?

CABOMETYX may cause serious side effects, including:

Bleeding (hemorrhage). CABOMETYX can cause severe bleeding that may lead to death. Tell your healthcare provider right away if you get any signs of bleeding during treatment with CABOMETYX, including:

- Coughing up blood or blood clots
- Vomiting blood or if your vomit looks like coffee grounds
- Red or black (looks like tar) stools
- Menstrual bleeding that is heavier than normal
- Any unusual or heavy bleeding

A tear in your stomach or intestinal wall (perforation) or an abnormal connection between 2 parts of your body (fistula). Tell your healthcare provider right away if you get tenderness or pain in your stomach area (abdomen) that is severe or that does not go away.

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Talk to your doctor about how CABOMETYX® + OPDIVO® may help you

The following support services are available for people who take CABOMETYX:

- Ongoing educational support through **BE CONNECTED**
- Cost and financial support with Exelixis Access Services (**EASE**)

Terms and Conditions Apply

Blood clots, stroke, heart attack, and chest pain. Get emergency help right away if you get:

- Swelling or pain in your arms or legs
- Shortness of breath
- Feel lightheaded or faint
- Sweating more than usual
- Numbness or weakness of your face, arm, or leg, especially on one side of your body
- Sudden confusion, trouble speaking or understanding
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking
- Dizziness, loss of balance or coordination
- A sudden severe headache

High blood pressure (hypertension). Hypertension is common with CABOMETYX and sometimes can be severe. Your healthcare provider will check your blood pressure before starting CABOMETYX and regularly during treatment with CABOMETYX. If needed, your healthcare provider may prescribe medicine to treat your high blood pressure. Tell your healthcare provider if you develop severe headaches, nose bleeds, tiredness or confusion, vision changes, chest pain, trouble breathing, irregular heartbeat, or blood in your urine.

Diarrhea. Diarrhea is common with CABOMETYX and can be severe. If needed, your healthcare provider may prescribe medicine to treat your diarrhea. Tell your healthcare provider right away if you have frequent loose, watery bowel movements.

A skin problem called hand-foot skin reaction. Hand-foot skin reactions are common and can be severe. Tell your healthcare provider right away if you have rashes, redness, pain, swelling, or blisters on the palms of your hands or soles of your feet.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

CABOMETYX® (cabozantinib) tablets + OPDIVO® (nivolumab)

Liver problems. Liver problems may happen during treatment with CABOMETYX. When CABOMETYX is taken in combination with nivolumab, severe changes in liver function tests may happen more often than if you take CABOMETYX alone. Your healthcare provider will do blood tests to check your liver function before and during treatment with CABOMETYX. Tell your healthcare provider right away if you develop symptoms of liver problems including: 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, bleeding or bruising more easily than normal.

Adrenal gland problems. Your healthcare provider will monitor you for this problem. Your healthcare provider may prescribe hormone replacement therapy or corticosteroid medicines if needed. Tell your healthcare provider right away if you develop any of the following signs or symptoms: extreme tiredness, dizziness or fainting, weakness, nausea, or vomiting.

Protein in your urine and possible kidney problems. Symptoms may include swelling in your hands, arms, legs, or feet. Your healthcare provider will check you for this problem during treatment with CABOMETYX.

Severe jaw bone problems (osteonecrosis). Your healthcare provider should examine your mouth before you start and during treatment with CABOMETYX. Tell your dentist that you are taking CABOMETYX. It is important for you to practice good mouth care during treatment with CABOMETYX. Tell your healthcare provider right away if you develop any symptoms of jaw problems, including: jaw pain, toothache, or sores on your gums.

Wound healing problems. Wound healing problems have happened in people who take CABOMETYX. Tell your healthcare provider if you plan to have any surgery before or during treatment with CABOMETYX.

- You should stop taking CABOMETYX at least 3 weeks before planned surgery.
- Your healthcare provider should tell you when you may start taking CABOMETYX again after surgery.

Reversible posterior leukoencephalopathy syndrome (RPLS). A condition called reversible posterior leukoencephalopathy syndrome can happen during treatment with CABOMETYX. Tell your healthcare provider right away if you have headaches, seizures, confusion, changes in vision, or problems thinking.

Change in thyroid function. CABOMETYX can cause changes in your thyroid function, including changes to thyroid hormone levels in your blood. Your healthcare provider will do blood tests to check your thyroid function before and during treatment with CABOMETYX.

Decreased calcium level in your blood (hypocalcemia). CABOMETYX can cause you to have a decreased amount of calcium in your blood. Your healthcare provider will do blood tests to check you for this problem and give you calcium if needed. **Tell your healthcare provider right away if you get any of the following signs or symptoms:**

- Muscle stiffness or muscle spasms
- Numbness or tingling in your fingers, toes, or around your mouth
- Seizures
- Sudden weight gain
- Swelling of your arms, hands, legs, and ankles

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with CABOMETYX if you have certain side effects.

The most common side effects of CABOMETYX include:

- Tiredness
- Decreased appetite
- Nausea and vomiting
- Weight loss
- Constipation

The most common side effects of CABOMETYX when used with nivolumab include:

- Tiredness
- Mouth sores
- Rash
- Low thyroid hormone levels (hypothyroidism)
- Pain in muscles, bones, and joints
- Decreased appetite
- Nausea
- Changes in the way things taste
- Stomach-area (abdominal) pain
- Cough
- Upper respiratory tract infection

CABOMETYX may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of CABOMETYX. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

If your healthcare provider prescribes CABOMETYX in combination with nivolumab, also read the Medication Guide that comes with nivolumab.

Before you take CABOMETYX, tell your healthcare provider about all of your medical conditions, including if you:

- Have had a liver problem other than liver cancer.
- Have a recent history of bleeding, including coughing up or vomiting blood, or black tarry stools.
- Have an open or healing wound.
- Have high blood pressure.
- Have a low calcium level in your blood (hypocalcemia).
- Plan to have any surgery, dental procedure, or have had a recent surgery. You should stop treatment with CABOMETYX at least 3 weeks before planned surgery.
- Are pregnant, or plan to become pregnant. CABOMETYX can harm your unborn baby.
  - — If you are able to become pregnant, your healthcare provider will check your pregnancy status before you start treatment with CABOMETYX.
  - — Females who are able to become pregnant should use effective birth control (contraception) during treatment and for 4 months after your final dose of CABOMETYX.
  - — Talk to your healthcare provider about birth control methods that may be right for you.
  - — If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- Are breastfeeding or plan to breastfeed. It is not known if CABOMETYX passes into your breast milk. Do not breastfeed during treatment and for 4 months after your final dose of CABOMETYX.

Tell your healthcare provider about all the medicines you take, including prescription or over-the-counter medicines, vitamins, and herbal supplements. CABOMETYX and certain other medicines may affect each other, causing side effects.

What should I avoid while taking CABOMETYX?

Avoid drinking grapefruit juice, eating grapefruit, or taking supplements that contain grapefruit or St. John's wort during treatment with CABOMETYX.

Please see additional Important Safety Information on the previous pages and brief summary of full Prescribing Information on the following pages.

EXELIXIS®

CABOMETYX® (cabozantinib) tablets

Consumer Brief Summary for CABOMETYX® (Ka-boe-met-iks) cabozantinib tablets

Please read the Patient Information before you start taking CABOMETYX and each time you get a refill. There may be new information.

If your healthcare provider prescribes CABOMETYX in combination with nivolumab, also read the Medication Guide that comes with nivolumab.

What is CABOMETYX?

CABOMETYX is a prescription medicine used to treat:

- People with kidney cancer (renal cell carcinoma). CABOMETYX may be used:
  - Alone to treat people with renal cell carcinoma (RCC) that has spread (advanced RCC).
  - In combination with nivolumab when your cancer has spread (advanced RCC), and you have not already had treatment for your advanced RCC.
- People with liver cancer (hepatocellular carcinoma) who have been previously treated with the medicine sorafenib.
- Adults and children 12 years of age and older who have a type of thyroid cancer called differentiated thyroid cancer (DTC) that has spread (locally advanced or metastatic), **and**,
  - has progressed after treatment with a VEGFR-targeted treatment, **and**
  - your DTC can no longer be treated with radioactive iodine, or you are not able to receive radioactive iodine treatment.

It is not known if CABOMETYX is safe and effective in children younger than 12 years of age.

Before you take CABOMETYX, tell your healthcare provider about all of your medical conditions, including if you:

- Have had a liver problem other than liver cancer.
- Have a recent history of bleeding, including coughing up or vomiting blood, or black tarry stools.
- Have an open or healing wound.
- Have high blood pressure.
- Have a low calcium level in your blood (hypocalcemia)
- Plan to have any surgery, dental procedure, or have had a recent surgery. You should stop taking CABOMETYX at least 3 weeks before planned surgery.
- Are pregnant, or plan to become pregnant. CABOMETYX can harm your unborn baby.
  - If you are able to become pregnant, your healthcare provider will check your pregnancy status before you start treatment with CABOMETYX.
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment and for 4 months after your final dose of CABOMETYX.
  - Talk to your healthcare provider about birth control methods that may be right for you.
  - If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- Are breastfeeding or plan to breastfeed. It is not known if CABOMETYX passes into your breast milk. Do not breastfeed during treatment and for 4 months after your final dose of CABOMETYX.

Tell your healthcare provider about all the medicines you take, including prescription or over-the-counter medicines, vitamins, and herbal supplements. CABOMETYX and certain other medicines may affect each other causing side effects.

How should I take CABOMETYX?

- Take CABOMETYX exactly as your healthcare provider tells you to take it.
- **Do not** take CABOMETYX with food. Take CABOMETYX at least 1 hour before or at least 2 hours after eating.
- Swallow CABOMETYX tablets whole.
- **Do not** crush CABOMETYX tablets.
- If you miss a dose and your next scheduled dose is in less than 12 hours, take your next dose at the normal time. Do not make up the missed dose.

What should I avoid while taking CABOMETYX?

Avoid drinking grapefruit juice, eating grapefruit or taking supplements that contain grapefruit or St. John's wort during treatment with CABOMETYX.

What are the possible side effects of CABOMETYX?

CABOMETYX may cause serious side effects, including:

- **Bleeding (hemorrhage).** CABOMETYX can cause severe bleeding that may lead to death. Tell your healthcare provider right away if you get any signs of bleeding during treatment with CABOMETYX, including:
  - coughing up blood or blood clots
  - vomiting blood or if your vomit looks like coffee-grounds
  - red or black (looks like tar) stools
  - menstrual bleeding that is heavier than normal
  - any unusual or heavy bleeding
- **A tear in your stomach or intestinal wall (perforation) or an abnormal connection between 2 parts of your body (fistula).** Tell your healthcare provider right away if you get tenderness or pain in your stomach-area (abdomen) that is severe or that does not go away.
- **Blood clots, stroke, heart attack, and chest pain.** Get emergency help right away if you get:
  - swelling or pain in your arms or legs
  - shortness of breath
  - feel lightheaded or faint
  - sweating more than usual
  - numbness or weakness of your face, arm or leg, especially on one side of your body
  - sudden confusion, trouble speaking or understanding
  - sudden trouble seeing in one or both eyes
  - sudden trouble walking
  - dizziness, loss of balance or coordination
  - a sudden severe headache
- **High blood pressure (hypertension).** Hypertension is common with CABOMETYX and sometimes can be severe. Your healthcare provider will check your blood pressure before starting CABOMETYX and regularly during treatment with CABOMETYX. If needed, your healthcare provider may prescribe medicine to treat your high blood pressure. Tell your healthcare provider if you develop severe headaches, nose bleeds, tiredness or confusion, vision changes, chest pain, trouble breathing, irregular heartbeat, or blood in your urine.

- **Diarrhea.** Diarrhea is common with CABOMETYX and can be severe. If needed, your healthcare provider may prescribe medicine to treat your diarrhea. Tell your healthcare provider right away, if you have frequent loose, watery bowel movements.
- **A skin problem called hand-foot skin reaction.** Hand-foot skin reactions are common with CABOMETYX and can be severe. Tell your healthcare provider right away if you have rashes, redness, pain, swelling, or blisters on the palms of your hands or soles of your feet.
- **Liver problems.** Liver problems may happen during treatment with CABOMETYX. When CABOMETYX is taken in combination with nivolumab, severe changes in liver function tests may happen more often than if you take CABOMETYX alone. Your healthcare provider will do blood tests to check your liver function before and during treatment with CABOMETYX. Tell your healthcare provider right away if you develop symptoms of liver problems including: 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, bleeding or bruising more easily than normal.
- **Adrenal gland problems.** Your healthcare provider will monitor you for this problem. Your healthcare provider may prescribe hormone replacement therapy or corticosteroid medicines if needed. Tell your healthcare provider right away if you develop any of the following signs or symptoms: extreme tiredness, dizziness or fainting, weakness, nausea, or vomiting.
- **Protein in your urine and possible kidney problems.** Symptoms may include swelling in your hands, arms, legs, or feet. Your healthcare provider will check you for this problem during treatment with CABOMETYX.
- **Severe jaw bone problems (osteonecrosis).** Your healthcare provider should examine your mouth before you start and during treatment with CABOMETYX. Tell your dentist that you are taking CABOMETYX. It is important for you to practice good mouth care during treatment with CABOMETYX. Tell your healthcare provider right away if you develop any symptoms of jaw problems, including: jaw pain, toothache, or sores on your gums.
- **Wound healing problems.** Wound healing problems have happened in people who take CABOMETYX. Tell your healthcare provider if you plan to have any surgery before or during treatment with CABOMETYX.
  - You should stop taking CABOMETYX at least 3 weeks before planned surgery.
  - Your healthcare provider should tell you when you may start taking CABOMETYX again after surgery.
- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** A condition called reversible posterior leukoencephalopathy syndrome can happen during treatment with CABOMETYX. Tell your healthcare provider right away if you have headaches, seizures, confusion, changes in vision, or problems thinking.
- **Change in thyroid function.** CABOMETYX can cause changes in your thyroid function, including changes to thyroid hormone levels in your blood. Your healthcare provider will do blood tests to check your thyroid function before and during treatment with CABOMETYX.
- **Decreased calcium level in your blood (hypocalcemia).** CABOMETYX can cause you to have a decreased amount of calcium in your blood. Your healthcare provider will do blood tests to check you for this problem and give you calcium if needed. **Tell your healthcare provider right away if you get any of the following signs or symptoms:**
  - muscle stiffness or muscle spasms
  - numbness or tingling in your fingers, toes, or around your mouth
  - seizures
  - sudden weight gain
  - swelling of your arms, hands, legs, and ankles

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with CABOMETYX if you have certain side effects.
The most common side effects of CABOMETYX include:

- tiredness
- decreased appetite
- nausea and vomiting
- weight loss
- constipation

The most common side effects of CABOMETYX when used in combination with nivolumab include:

- tiredness
- mouth sores
- rash
- low thyroid hormone levels (hypothyroidism)
- pain in muscles, bones, and joints
- decreased appetite
- nausea
- changes in the way things taste
- stomach-area (abdominal) pain
- cough
- upper respiratory tract infection

CABOMETYX may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.
These are not all of the possible side effects of CABOMETYX. 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 CABOMETYX?

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

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

General information about the safe and effective use of CABOMETYX.

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

Manufactured for Exelixis, Inc. Alameda, CA 94502
For more information, go to www.cabometyx.com or call 1-855-292-3935.
This brief summary is based on CABOMETYX® (cabozantinib) Patient Information. Issued: 09/2021

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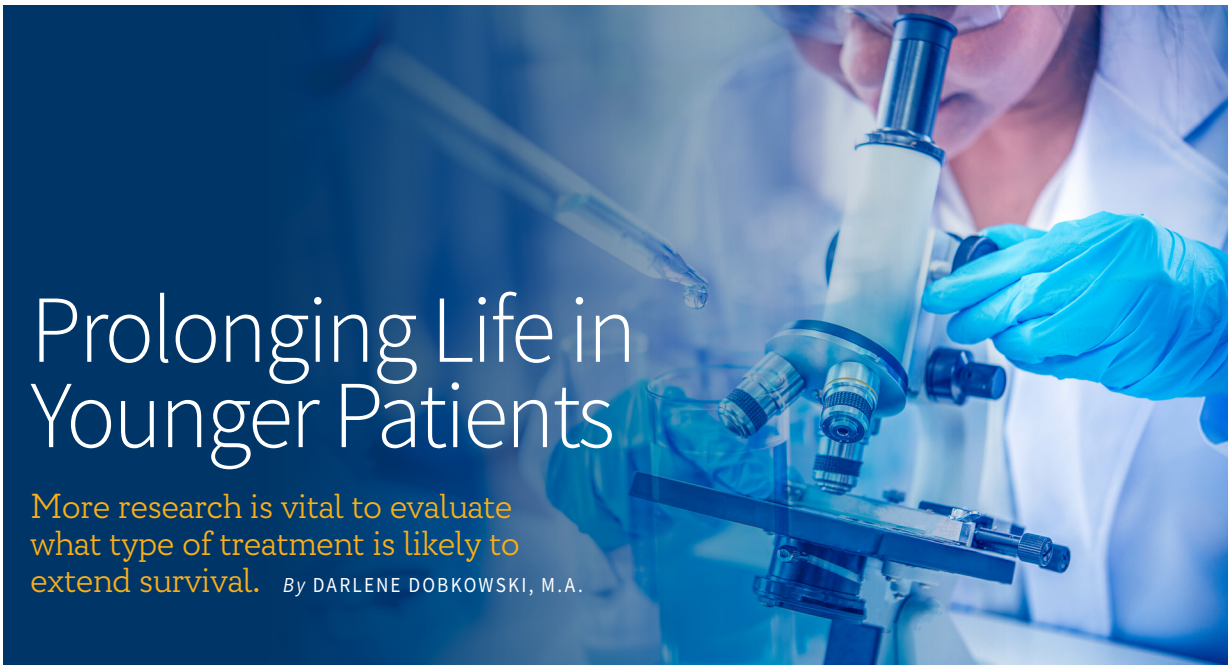
09/2021 CA-1895-1



Prolonging Life in Younger Patients

More research is vital to evaluate what type of treatment is likely to extend survival. *By* DARLENE DOBKOWSKI, M.A.

AS THE MULTIPLE MYELOMA patient population is becoming younger, more aggressive treatment may be warranted to improve survival in patients in their 20s and 30s. But researchers and oncologists alike question why this trend of younger patients is continuing.

The risk for developing multiple myeloma increases as patients age. According to the American Society of Clinical Oncology, the average age a patient is diagnosed with multiple myeloma is 70. In addition, the National Cancer Institute estimated that there would be approximately 35,000 new cases of multiple myeloma in 2021, of which approximately 1,500 to 2,000 cases would be in patients in their 30s and 40s.

Dr. Cristina Gasparetto, a professor of medicine at Duke University School of Medicine and director of the Multiple Myeloma Program at Duke Health in Durham, North Carolina, recalled treating a "fair amount of younger patients" over the past 20 years, with the youngest being 19 years old. She has also treated patients in their mid-20s and -30s, as well as pregnant women.

"It's always very interesting because if you read the (data) about multiple myeloma, the median age of diagnosis used to be in the 70s when I was in the beginning of my (career)," Gasparetto said. "It was clearly a disease of the elderly."

As the median age at first diagnosis of multiple myeloma decreases over time, oncologists like Gasparetto are left wondering why this is occurring.

"It's always been unclear to me if it was a culmination of a genetic predisposition and environmental toxin exposure," she said. "I don't think we have a lot of research in this population of patients, so we don't know much (about the reasons why)."

Researchers recently published study findings in the journal *Blood*, in which they assessed outcomes over a 15-year period in 214 patients diagnosed with multiple myeloma at age 40 and younger. Younger patients with multiple myeloma had similar disease characteristics to older patients. Regarding treatment, 90% of younger patients received intensive chemotherapy then autologous stem cell transplant, and 25% of patients underwent an allogenic stem cell transplant when they relapsed.

"I was very surprised by the number (of patients who) had the allogenic transplant," said Gasparetto, who is not associated with this study. "It's a huge number because we don't offer this type of approach very often."

Younger patients in the study had a median overall survival (the time a patient with multiple myeloma is still alive) of 14.5 years.

"If you look at the projected survival of this population, a patient definitely (has) higher (survival) than (those in) the older population," said Gasparetto. "The median overall survival was 14 years, which is much higher than we projected for the older patients. (For those who are) 60-plus, (it's) shorter than 10 years."

Gasparetto added that this difference in overall survival between younger and older patients may be due to more aggressive treatment, especially as younger patients may be able to tolerate it better than older patients.

Younger patients in the study also had a median progression-free survival (the time after treatment when a patient lives with multiple myeloma without disease progression) of 41 months.

"Now we can keep their disease at bay for a longer period of time," Gasparetto said. "We probably treat them longer and more aggressively. … If you look at the percentage of patients that we're treating (at) the time of diagnosis versus later lines of therapy, (progression-free survival) goes down tremendously

(in older patients) because we lose patients to myeloma, they can't tolerate the toxicity (or they have) other comorbidities. In this younger population of patients, we probably can keep treating them for years, and they sustain therapy much longer."

Gasparetto has some personal experience with the aggressive treatment of younger patients with multiple myeloma in her clinic. One patient, who was in their 20s at the time of diagnosis, was treated aggressively with transplant, consolidation (treatment given for a short time) and maintenance regimens (given for one to two years to keep multiple myeloma in remission and potentially prevent relapse), among other tactics that Gasparetto referred to as "outside the box because … back then, we were not doing that." The patient is now in their 40s, married with two children and with a career.

She also recalled another patient whom she treated with three transplants when they were diagnosed at age 34. That patient is currently 50 years old and serving as a multiple myeloma advocate to spread awareness.

> In this younger population of patients, we probably can keep treating them for many years, and they sustain therapy much longer. —DR. CRISTINA GASPARETTO

"You keep them alive," Gasparetto said. "I know that I keep manipulating his myeloma, his graft and doing things. It's something that you were capable of doing because they're young and they're sustaining therapy. This is fascinating. He always fascinated me because I have a weak spot for younger patients because myeloma can take life away. It can take (away) their dreams, their future. And I always felt like no, no, no, we need to be more aggressive. We need to treat them differently."

Gasparetto offered some advice for younger patients diagnosed with multiple myeloma.

"You have to be careful to understand your disease, understand that it's a very difficult disease to live with (and that) relying on the guidance of a physician will span (your) entire life. (You need to) understand that unfortunately, (multiple myeloma) is going to affect your quality of life, but we might be able to prolong your life."

LEARN MORE ONLINE
SCAN the QR code for a collection of content on myeloma.

CURE® turns 20 in 2022. To celebrate this milestone, we will be providing our readers with some in-depth coverage of some of the major advances in the cancer space.

Turning the Tide

Advancements in the reconstruction space over the past 20 years have transformed the lives of patients after undergoing debilitating cancer treatments. *By* DARLENE DOBKOWSKI, M.A.

AFTER CANCER TREATMENT, some patients may have to undergo some form of reconstruction. This can include the removal of a limb after sarcoma resection, grafts after skin cancer removal, fat and skin grafts for breast reconstruction and even prosthetics to address urinary incontinence in prostate cancer. Regardless of what type of reconstruction a patient may require, advances in this area over the past two decades have furthered what surgeons can do for patients to restore as normal an appearance as possible.

As surgical techniques, prosthetics and even conversations about reconstruction have improved over time, patients and their cancer teams can feel more comfortable and confident about what they want to achieve with these procedures to address expectations.

An evolution has occurred in the cancer treatment reconstruction space regarding where tissue can be taken from and placed during surgery. The improvements allow tissue to be moved from one part of the body to the other with less trauma to patients, such as decreased scarring and decreased manipulation of the anatomy. In patients undergoing breast reconstruction, for example, tissue connected to skin and fat can be taken from anywhere on the body — including the buttocks, belly and thigh — as long as it is connected to an artery and vein. Although similar procedures were performed 20 years ago, they were not nearly as widespread as they are now.

"Not everyone was that good at it, and people were not as efficient at it," said Dr. Justin M. Sacks, Shoenberg Professor and chief of the Division of Plastic and Reconstructive Surgery at Washington University School of Medicine in St. Louis, in an interview with *CURE®*. "Nowadays, we can do flaps called perforator flaps, where we stick skin, fat and blood vessels without cutting in or taking the muscle and transplanting it to

> A major difference is in our focus on the patient's voice, (on their) goals and desires in the reconstruction.
>
> —DR. MICHELE MANAHAN

the chest wall. It happens routinely on a daily basis at private and academic medical centers all over the country."

A similar technique can also be used for patients requiring head and neck reconstruction after treatment. Surgeons can use soft tissue and bone from another part of the body and transfer it to the jaw and tongue, enabling people to eat, speak and smile. This procedure has also become less traumatic for patients.

Many of these techniques were made possible by advancements in microvascular surgery — the ability to connect blood vessels that are 1 to 3 millimeters in diameter together. These advancements have also allowed surgeons to perform better facial nerve resections, which can restore a patient's ability to express emotions on their face. Twenty years ago, if a patient with cancer had part or all of their facial nerve removed, half their face or their entire face would be paralyzed, leaving them unable to blink their eyes or breathe through their nose and causing them to drool while eating. Nowadays, surgeons can move a few nerves in the face, depending on what functional issues a patient has. For example, the temporalis muscle can be moved to help a patient smile again, and the master nerve can be repositioned to restore chewing.

In the prostate and testicular cancer space, the quality of prosthetics and an understanding of what they can achieve have also improved. For example, the surgery to place a prosthetic in patients with testicular cancer is cleaner, which leads to fewer infections. Additionally, prosthetics are now more widely available in hospitals than they were previously, when surgeons would sometimes have to wait until they were in stock, sometimes after a patient had undergone an orchiectomy (the surgical removal of one or both testicles).

Infection prevention also has come a long way in reconstruction for patients with prostate cancer, especially with the introduction of prosthetics coated in antibiotics. These can reduce the frequency of infections.

Technologies such as 3D printing and artificial intelligence have also played a critical role in virtual surgical planning. For example, if a patient required head/neck cancer reconstruction that focused on their jaw, surgeons could map out the surgical resection, create the bony segment that needed to be reconstructed and customize the plate formation that would eventually be the metal plate holding the bone in place.

"It's been done for extremity reconstruction for cancer, sarcoma — the upper extremity (and) lower extremity," Sacks said. "Utilizing overlaying technology onto typical surgical procedures allows us to be more efficient and (produces) better outcomes."

Advancements have been made not only in surgical techniques and prosthetics, but also in the conversations patients have with their cancer team before, during and after these surgeries.

"A major difference is in our focus on the patient's voice, (on their) goals and desires in the reconstruction," explained Dr. Michele Manahan, a professor in the Department of Plastic and Reconstructive Surgery at Johns Hopkins University School of Medicine in Baltimore, in an interview with *CURE*®. "While the surgical techniques have evolved somewhat, as you would expect over the course of time, we've had more of a tidal wave shift toward making sure that we have a deep, rich conversation with each new patient who comes to us. (This is) so we can … really understand, out of this wide menu of options that we have, what might work better or worse for any patient based on where they want to go with things."

IMPROVING THE LIVES OF PATIENTS WITH CANCER

Advancements in reconstruction and prosthetics have improved the lives of patients with cancer in several ways, such as by minimizing the impact on other parts of the body where skin and other structures may be taken from.

"If we can minimize the disruption (to) another area of the body … then the patient may be able to get back to more normal exercise more quickly or eventually maintain the level of exercise they had before surgery rather than worrying about sliding backwards," Manahan said.

Further, more medical centers across the United States are offering these reconstruction procedures, many of which can now be performed more quickly and efficiently. This can speed up recovery and lead patients to "have better function both in the head and neck and in the extremities," Sacks said.

Not only can advancements improve recovery and function, they can also bring back certain actions that people often take for granted, such as speaking naturally or even smiling.

"People who had bone resections and people that had radiation therapy … were significantly worse off in terms of the psychosocial and aesthetic outcome measures," Dr. P. Daniel Knott, a professor and director »

Improved Color Matching for Facial Skin Reconstruction

DR. P. DANIEL KNOTT, a professor and director of the Division of Facial Plastic and Reconstructive Surgery at the University of California, San Francisco (UCSF), and colleagues have recently published a paper in *The Laryngoscope* journal on a new technique that may help patients look like they did before cancer treatment. Flaps for facial skin reconstruction are often taken from the thigh, which "is a wonderful donor site for tissue because it gives you the opportunity to harvest skin, skin plus fat, fat alone, fat with muscle, fat with nerve, nerve alone or any combination of all those elements," Knott said.

Taking a skin graft from a patient's thigh is a small price to pay, but the price is sometimes paid once the graft is placed on a patient's face; if not done well, it can be obvious that someone has had skin from a different part of the body grafted onto their face. The graft can look significantly lighter than the rest of the face, especially with faces that have had extensive, life-long sun exposure. Knott and his colleagues aimed to improve the color-matching process on a patient's face.

In the study, researchers took full thickness skin flaps from the thigh of patients who were being treated for facial cancer or sarcoma. They lifted off the very top of the skin using special skin razors, thereby permitting removal of the permanent color-containing layer of the skin — the dermis — and then placed the thin skin grafts back down on the flaps.

"I found out that once I had removed the pale color of the dermis, the skin grafts (functioned) like privacy glass, so … the red, pink, yellow color of the fat and the blood vessels … shine through

the skin, (allowing the) diffusion of light through it without being too crystal clear to show underlying structures," Knott said. The resulting color matched much better with the patients' faces than using an unmanipulated thigh skin flap.

Knott uses a handheld color meter to measure a patient's facial color so he can decide which technique to use for reconstructive surgery. This ensures he obtains the most closely matched color.

"The goal is not to need a face transplant; the goal is to make people look normal," Knott said. "The goal is to get our patients to be able to resume their lives and avoid the psychosocial shame of looking disfigured."

CURE® spoke with Orville Schell, one of Knott's patients who underwent this surgery at the end of 2021. Schell, the director of a U.S.-China relations think tank in New York City, lives in Berkeley, California, where he learned that an original diagnosis of "undissolved stitches" from a Mohs surgery was a recurrence of squamous cell carcinoma skin cancer. Upon his arrival at UCSF, where this diagnosis was confirmed via biopsy, Schell was connected with Knott, who performed this new technique on nearly half of his forehead during a seven-and-a-half-hour surgery.

"(Dr. Knott) said this to me a number of times, that he is very determined when he does facial reconstruction not to have it look like you're a patchwork quilt — in other words, to match skin color tone," Schell said. "It never occurred to me that it was an issue, but now I … can see why that's important."

As of February 2022, Schell said that the grafted area on his forehead had healed, though there is still a bulge, which he hopes Knott can reduce by liposuction.

of the Division of Facial Plastic and Reconstructive Surgery in the Department of Otolaryngology-Head and Neck Surgery at the University of California, San Francisco, told *CURE*®. "Being able to replace bone accurately and appropriately allows the patients to then feel and look normal. It allows them to bite correctly. Because the teeth have to meet — for example, both the upper and lower jaws — it allows them to have the correct contour of the cheeks. It allows them to have the ability to speak naturally, because the mouth opens and closes naturally. It has just tremendous improvements in quality outcomes and patient satisfaction."

WHAT'S NEXT?

Although a lot of progress has been made over the past 20 years, patients should look for more innovation during the next 20 years (or even sooner). For example, Sacks said, surgical simulation with virtual reality may aid surgeons by enabling them to visualize the tumor in real time, removing it and performing the reconstruction even before the patient is in the operating room. Sacks also hopes that soft and hard tissues can be engineered in a laboratory setting rather than being taken from a patient's body.

"The future is for us to be able to help reconstruct the human form using synthetic and biological constructs that reduce morbidity (in) patients so that we don't have to cut them in another part of the body to help reconstruct them," Sacks said.

3D cameras may also be used during surgery to help guide surgical resections, allowing surgeons to perform precise surgeries with real-time imaging. Previously, patients would undergo a CT scan or an MRI and those images would be shown to surgeons, which they

would use to base their surgeries on. Real-time imaging can help surgeons know exactly what they're doing as they're doing it.

The use of robotic technology may also be on the horizon, which may allow surgeons to enter the body through natural orifices such as the mouth, nose and ears to perform surgeries deep within the body.

Smart devices may have a place in the penile and incontinence prosthetic space, which would help those patients who have dexterity and hand strength issues due to their age. In particular, incontinence prosthetics and penile prostheses are pump controlled, with pumps implanted in the scrotum. If updates occur in the future, such devices may be controlled via app or remotely to simplify their use.

"Especially in elderly patients and the frail elderly, if you can reduce incontinence in them, it does help prevent things like falls at night, which could lead to … fractures, hospitalizations and (so on)," Dr. Christopher E. Wolter, an assistant professor of urology at Mayo Clinic in Phoenix, Arizona, told *CURE®*. "They're not having to rush to go to the bathroom in the middle of the night or trying to keep their bladder empty so they don't leak so much."

Some developments may focus on techniques rather than the devices themselves. For example, Manahan explained how she and her colleagues are striving to refine techniques, minimize scars and potentially minimize the disruption of tissue.

"Those are all things that we think of as natural evolution," she added. "It's something that everybody doing these surgeries is working toward every day. But when we step back, how do we make (these surgeries) OK and ease the process when (patients are) facing it?

"We know what we know now, but we learn more over time and we progress over time," she said. "I think we will always strive to know more and do better in the future, as our techniques, tools, technology, etc., develop. We're working to the best of our abilities where we are now, but we always want to keep an eye on the future and look to make it better."

FEELING EMPOWERED WHILE MAINTAINING GOALS

For patients, it can be overwhelming to navigate the area of reconstruction and prosthetics, especially in light of so many advancements. Experts advise patients to have in-depth conversations and consultations with their cancer surgeon and plastic/reconstructive surgeon to learn as much as they can about what they might undergo, but also to understand that curing their cancer comes first and foremost. Once that has been achieved, a conversation about reconstruction can begin.

"My advice to you, as a cancer patient, is that we are going to restore form, function and dignity at the same time, and that you should seek consultation with a plastic and reconstructive surgeon so that you can have that form, function and dignity restored to you," Sacks said. "It's not a death sentence if you have cancer, and it shouldn't change necessarily the way you look, function or feel over time. You will be changed, but you will be cancer free and you will be reconstructed."

Throughout this conversation, it is important for the cancer team to address the patient's needs, no matter how unique those may be.

"(I urge patients) to maintain their individual goals (and) to share with their care team those goals," Manahan said. "Patients feeling empowered to really share what they truly believe and think and their reactions to the facts that are delivered is important; and then asking questions — that's part of the whole thing about having an open conversation. It's a partnership, so you want to feel comfortable in your partnership."

Wolter mentioned that men with testicular cancer are often younger — in their late teens to mid-30s — and may be somewhat more self-conscious about how they look. This highlights the importance of patients knowing their options immediately, especially as it is much easier to place an implant at the time of the orchiectomy because the space has already been created.

In contrast, patients with prostate cancer have a little bit more lead time into the discussion about if and when reconstruction and prosthetics may be needed. These patients should know that although there is a chance they may lose urinary control and the ability to have erections, treatments exist that can serve as solutions down the road.

"(Patients) knowing that, yes, (they are) incontinent is obviously life altering," Wolter said. "It can lead to increased rates of depression, isolation, those kinds of things. But knowing that there would be an end to that in sight, … something that you can almost place on the calendar when you would be experiencing that relief from that problem, is very, very encouraging to patients."

Although functional outcomes are a critical component of this process, patients are also allowed to focus on appearance-related outcomes.

"After surgery, those aesthetic things are important," Knott said. "It's hard to go back and change what's already been done. You'd want to make sure that for patients that do (place) an element of aesthetic importance on their tumor resections, (you) choose the reconstruction wisely; that will enable them to look as normal as possible." C

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Learning to Live After Learning How to Die

A pancreatic cancer survivor explains how he learned to live after cancer and reflects on lessons learned from the book, "Tuesdays with Morrie."

By WILLIAM RAMSHAW

WILLIAM RAMSHAW

NINE YEARS AGO, I faced the news no one wants to hear: I not only had cancer, but it was pancreatic cancer. With few people with this diagnosis living to see two years and most not seeing five, I am cosmically blessed to still be around.

Back then, I didn't think I would be there for any of my three daughters' big days to walk them down the aisle. Thankfully two are now married and I'm holding out for the third.

Over the past few days, I have been reading "Tuesdays with Morrie" by Mitch Albom, a New York Times bestseller for over four years. I am surprised I didn't read it sooner. It chronicles the story of Morrie Schwartz, one of Albom's sociology professors at Brandeis University, who was facing Lou Gehrig's disease — also known as amyotrophic lateral sclerosis (ALS).

For those who might not know, ALS is a progressive neurodegenerative disease that systematically shuts down a person's muscles. Unlike many cancers, ALS has no cure and always leads to death.

In the Navy, I had a neurologist friend who worked at Balboa Naval Hospital in San Diego where he specialized in treating ALS. He once told me, "I get to know my ALS patients so when they can no longer speak, I will understand what they need." All these years later this dire statement remains with me as though he said it yesterday.

While at Brandeis, Mitch and Morrie became quite close, meeting on Tuesdays to chat about life and its meaning. On graduation day, Mitch promised to stay in touch with Morrie, but as with many of us, life happened, and thoughts of his friend faded away.

Years later, Mitch was a high-flying sports journalist for the Detroit Free Press with his life moving in fast-forward mode. One evening while flicking through some TV channels, he happened upon ABC's "Nightline" in which Ted Koppel was interviewing Morrie about his ALS.

Feeling bad that he had not stayed in touch with Morrie as he had promised, Mitch soon flew from Detroit to visit his dying friend in West Newton, Massachusetts, about 10 miles outside Boston. This set in motion a series of Tuesday visits with Morrie, hence the book title, "Tuesdays with Morrie."

When they met, rather than talking about Morrie's certain death, they chatted about life and its meaning much as they had done at Brandeis. Among the many things they talked about were not feeling sorry for yourself, living with regrets, learning to forgive and the importance of family — all topics of interest to anyone facing cancer.

For those of us who have faced cancer, it is all too easy to feel sorry for ourselves. We shouldn't, but we do. One way to avoid this is to realize that no matter how bad our cancer news may be, it could be far worse.

For instance, I've discovered that although pancreatic cancer is horrific and for the most part a death sentence, there are other cancers

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« continued from page 68

for which the survival rate is better but the treatment regimen far worse. Don't feel sorry for yourself.

Learning to live with regrets is easier to talk about than to do. We all have cemeteries of regrets buried in our past. Tombstones of things we said or did, sometimes awful things, opportunities missed. Although we would like to go back and get a do-over, we can't. What was said or done is forever. The opportunity is lost. We can't go back and change anything. Everyone has regrets. Learn to live with them.

This leads to learning to forgive. This speaks not only to forgiving others but forgiving yourself and moving on with your life. Thus, a key part of learning to live with regrets is learning to forgive, not just others but ourselves too.

Lastly, the importance of family cannot be understated. Most people, except our families, won't or can't sit with us during our chemotherapy sessions or visit us each day in the hospital, especially when we've been there for weeks.

Facing death is so overwhelming, and our friends don't know what to say let alone do. Although they are sad for us, they are at the same time thankful it is not them. As close as some friends can be, they're not family and never will be. Missing a DNA connection to us lets them off the hook to be there for us. (I do have some awesome friends, but it is not the same as family.) Family is beyond important.

Perhaps the biggest takeaway from the book for me was this simple point: "Once you learn how to die, you learn how to live." Let that sink in.

I suppose this is one of the blessings of cancer if we'll take it on board. Most of us live our lives for ourselves. We involve others when it's convenient but otherwise we focus on surviving rather than living. Then cancer happens to us. Everything changes.

If you haven't read "Tuesdays with Morrie," read it. It is so helpful, especially if you are facing cancer or have survived it. It offers a thoughtful discourse on not feeling sorry for yourself, living with regrets, learning to forgive and the importance of family. Remember, "Once you learn how to die, you learn how to live."

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In our "Speaking Out" video series, *CURE*® spoke with two experts about how updated guidelines can help patients make informed decisions about their treatment.

By KRISTIE L. KAHL

AS TREATMENTS CONTINUE TO evolve for patients with metastatic triple-negative breast cancer, updates to the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines are crucial for both health care providers and patients. The guidelines give health care professionals information on the latest treatments, drug and management decisions, and interventions.

"The National Comprehensive Cancer Network is a consortium of about 30 academic and cancer institutes that are constantly looking at new science (and) constantly looking at updating guidelines for doctors to share with their patients for the best type of treatment," Dr. Rebecca L. Moroose explained.

It is vital that patients not only understand their treatment options but also discuss them with their providers to ensure they are receiving treatment based on shared decision-making, Moroose said.

As part of the "Speaking Out" video series, *CURE*® spoke with Moroose, an oncologist at Orlando Health, and Dr. Virginia G. Kaklamani, a professor of hematology/oncology at UT Health San Antonio, about the NCCN guidelines and what they mean for patients.

Q: Dr. Moroose, can you discuss the NCCN guidelines for metastatic triple-negative breast cancer — in particular, the recently updated physician guidelines?

A: Moroose: In addition to systemic chemotherapy, which was always the foundation of treating metastatic triple-negative breast cancer, now we know we can look for certain subtypes. For example, if a person has inherited … a germline BRCA1 and BRCA2 mutation, (there are now) specific poly (ADP ribose) polymerase inhibitors, known as PARP inhibitors, for that situation. If patients have expression of a receptor that makes a cancer hide from the immune system, now we have checkpoint inhibitors and immunotherapy we can add. Then for the first time, an antibody-drug combination, also called an antibody drug conjugate, actually targets a specific protein that's overexpressed on triple-negative breast cancer. And (these are some) of the exciting breakthroughs in metastatic breast cancer.

Q: Dr. Kaklamani, in particular, what does this mean for these patients?

A: Kaklamani: We've been able to show that we can improve patient survival by giving them these more targeted approaches to their therapy. With chemotherapy — which we've been using for more than 30 years to treat triple-negative breast cancer — there are some good therapeutic drugs, but not all breast cancers are the same. And to be able to find subtypes of breast cancers where we can get the help from the immune system by using immunotherapy is extremely important. Thankfully, those are shown so far to improve survival for patients who have these specific markers.

Q: How do these guidelines play a role in the conversations that you're having with your patients? And what should patients discuss with their health care providers about treatment options?

A: Kaklamani: I always tell patients that they have to be their own best advocate. They need to be informed,

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obviously, they need to seek our help and guidance, but they need to know what's going on with their cancer, with their body. At the end of the day, they're going to be the ones who decide what treatment they will be receiving, regardless of what we recommend.

Our job is to know the latest and the greatest and to be able to apply that to the specific patient we have in front of us. But their job is to also have some understanding. And that's why these guidelines are so important. They don't just talk to physicians, they also talk to patients, so the patients can understand what we are doing and why we're doing it and make the right decision for themselves.

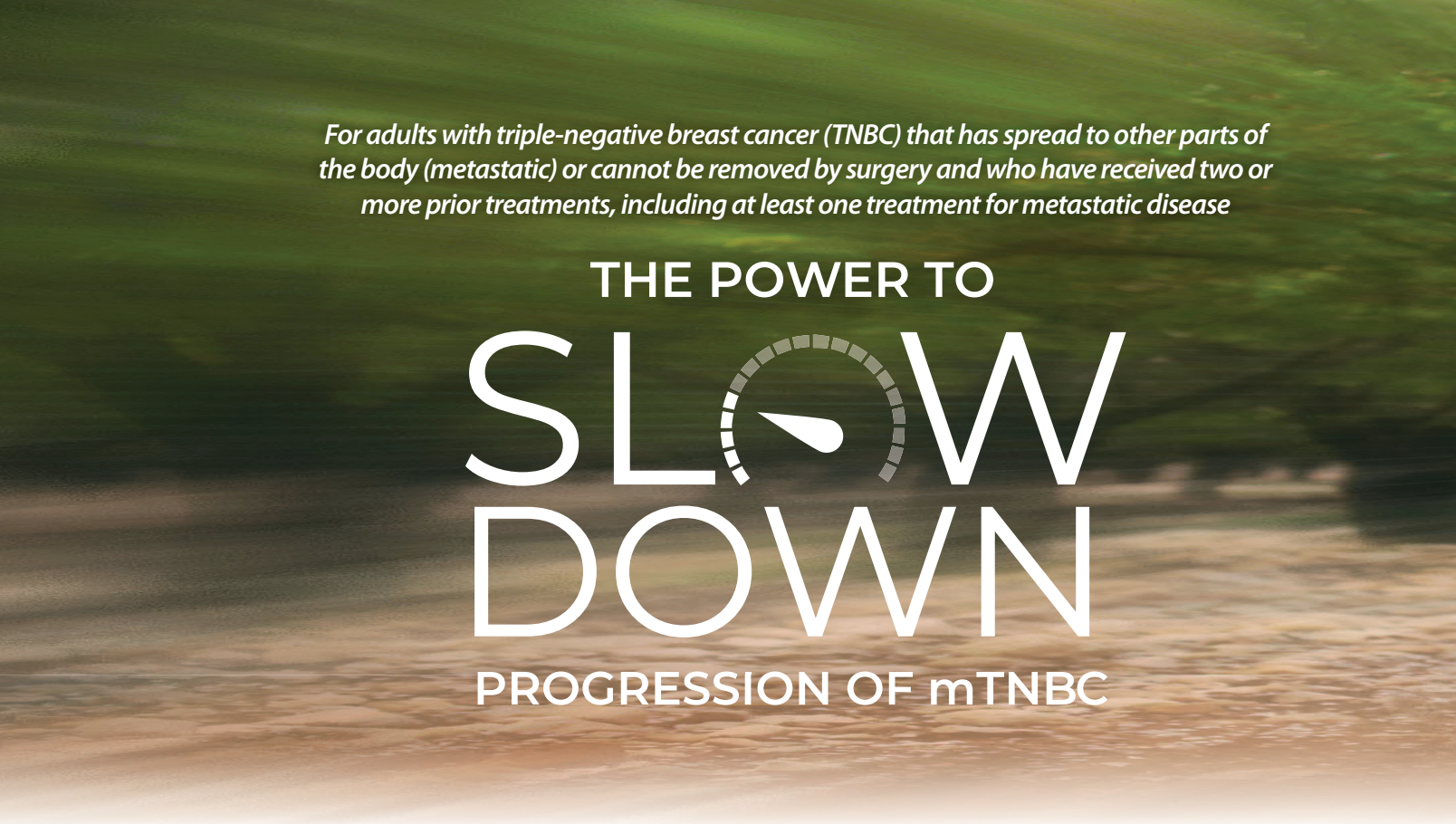
A: **Moroose:** I absolutely agree with that. Patients need to understand their therapy options and the side effects from those options, and they should always ask if there is a clinical research trial in which they could enroll and participate.

Q: Do you have any final thoughts for our patients with metastatic triple-negative breast cancer?

A: **Moroose:** Just continue to ask questions. If your oncologist doesn't want you to ask questions, think about whether that's the right oncologist for you. Stay as informed as you can — not just about your therapy, but also about your options.

A: **Kaklamani:** I think the only thing I would add … is how important clinical trials are. We are where we are today because brave men and women before us were able to participate in clinical trials to define what the standard of care is. And if we want to improve on that standard of care, we have to do clinical trial research to get to our next better medication, eventually get to the cure, even with metastatic disease. Even as difficult as triple-negative breast cancer is, we will get to the cure, but we will only get to the cure if we (have) clinical trials.

LEARN MORE ONLINE SCAN THE QR CODE to see more videos from our "Speaking Out" series.



TRODELVY may not work for everyone. Individual results may vary.

WHAT IS TRODELVY?

TRODELVY® (sacituzumab govitecan-hziy) is a prescription medicine used to treat adults with triple-negative breast cancer (negative for estrogen and progesterone hormone receptors and HER2) that has spread to other parts of the body (metastatic) or cannot be removed by surgery, and who have received two or more prior treatments, including at least one treatment for metastatic disease.

It is not known if TRODELVY is safe and effective in people with moderate or severe liver problems or in children.

IMPORTANT SAFETY INFORMATION

TRODELVY can cause serious side effects, including low white blood cell count and diarrhea:

- **Low white blood cell count (neutropenia)** which is common and can sometimes be severe and lead to infections that can be life-threatening or cause death. Your healthcare provider should check your blood cell counts during treatment. If your white blood cell count is too low, your healthcare provider may need to lower your dose, give you a medicine to help prevent low blood cell count with future doses of TRODELVY, or in some cases may stop TRODELVY. Your healthcare provider may need to give you antibiotic medicines if you develop fever while your white blood cell count is low. **Call your healthcare provider right away if you develop any of the following signs of infection:** fever, chills, cough, shortness of breath, or burning or pain when you urinate.
- **Severe diarrhea.** Diarrhea is common and can be severe. Your healthcare provider should monitor you for diarrhea and give you medicine as needed to help control it. If you lose too much body fluid (dehydration), your healthcare provider may need to give you fluids and electrolytes to replace body salts. If diarrhea happens later in your treatment, your healthcare provider may check you to see if it may be caused by an infection. Your healthcare provider may decrease your dose or stop TRODELVY if your diarrhea is severe and cannot be controlled with anti-diarrheal medicines.

-Call your healthcare provider right away the first time that you get diarrhea during treatment with TRODELVY; if you have black or bloody stools; if you have symptoms of dehydration, such as lightheadedness, dizziness, or faintness; if you are unable to take fluids by mouth due to nausea or vomiting; or if you are not able to get your diarrhea under control within 24 hours.

Do not receive TRODELVY if you have had a severe allergic reaction to TRODELVY. Ask your healthcare provider if you are not sure.

Allergic and infusion-related reactions which can be serious and life-threatening. Tell your healthcare provider or nurse right away if you get any of the following symptoms during your infusion of TRODELVY or within 24 hours after: swelling of your face, lips, tongue, or throat; hives; skin rash, itching, or flushing of your skin; fever; difficulty breathing or wheezing; lightheadedness, dizziness, feeling faint, or pass out; or chills or shaking chills (rigors).

TRODELVY WAS PROVEN TO BE MORE EFFECTIVE AT SLOWING DISEASE PROGRESSION THAN TRADITIONAL CHEMOTHERAPIES IN A PHASE 3 STUDY

TRODELVY (sacituzumab govitecan-hziy) was studied in 529 patients randomized for treatment with TRODELVY (n=267) or the physician's choice of single-agent chemotherapy (traditional chemotherapies; n=262). These included eribulin, vinorelbine, gemcitabine, or capecitabine. The trial tested median Progression-Free Survival (PFS), which is how long a treatment stops the growth or spread of metastatic triple-negative breast cancer (mTNBC) in half the people who take it. Some patients taking TRODELVY showed no signs of their mTNBC getting worse for at least 4.8 months vs 1.7 months for patients taking traditional chemotherapies.

Nausea and vomiting are common with TRODELVY and can sometimes be severe. Before each dose of TRODELVY, you will receive medicines to help prevent nausea and vomiting along with medicines to take home with instructions about how to take them. Call your healthcare provider right away if you have nausea or vomiting that is not controlled with the medicines prescribed for you. Your healthcare provider may decide to decrease your dose or stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

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

- have been told that you carry a gene for UGT1A1*28, which can increase your risk of getting side effects with TRODELVY, especially low white blood cell counts, with or without a fever, and low red blood cell counts.
- have liver problems.
- are pregnant or plan to become pregnant. TRODELVY can harm your unborn baby. Your healthcare provider should check to see if you are pregnant before you start receiving TRODELVY. TRODELVY may cause fertility problems in females, which could affect your ability to have a baby. Talk to your healthcare provider if fertility is a concern for you.
  - -Females who can become pregnant should use effective birth control during treatment and for 6 months after your last dose of TRODELVY. Talk to your healthcare provider about birth control choices that may be right for you during this time.
  - -Males with a female partner who can become pregnant should use effective birth control during treatment and for 3 months after your last dose of TRODELVY.
  - -Tell your healthcare provider right away if you or your partner become pregnant during treatment with TRODELVY.
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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the way TRODELVY works.

The most common side effects of TRODELVY include feeling tired or weak, hair loss, decreased red blood cell count, constipation, decreased appetite, rash, and stomach-area (abdominal) pain or discomfort.

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

Please see Important Facts about TRODELVY, including Important Warning, on the next page.

Ask your doctor where **TRODELVY** *may fit into your plan*

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MOST IMPORTANT INFORMATION ABOUT TRODELVY

TRODELVY can cause serious side effects, including:

- **Low white blood cell count (neutropenia)** which is common and can sometimes be severe and lead to infections that can be life-threatening or cause death. Your healthcare provider should check your blood cell counts during treatment. If your white blood cell count is too low, your healthcare provider may need to lower your dose, give you a medicine to help prevent low blood cell count with future doses of TRODELVY, or in some cases may stop TRODELVY. Your healthcare provider may need to give you antibiotic medicines if you develop fever while your white blood cell count is low. **Call your healthcare provider right away if you develop any of the following signs of infection:**
  - fever
  - cough
  - burning or pain when you urinate
  - chills
  - shortness of breath
- **Severe diarrhea.** Diarrhea is common and can be severe. Your healthcare provider should monitor you for diarrhea and give you medicine as needed to help control it. If you lose too much body fluid (dehydration) your healthcare provider may need to give you fluids and electrolytes to replace body salts. If diarrhea happens later in your treatment, your healthcare provider may check you to see if it may be caused by an infection. Your healthcare provider may decrease your dose or stop TRODELVY if your diarrhea is severe and cannot be controlled with anti-diarrheal medicines.

Call your healthcare provider right away:

- the first time that you get diarrhea during treatment with TRODELVY
- if you have black or bloody stools
- if you have symptoms of dehydration, such as lightheadedness, dizziness or faintness
- if you are unable to take fluids by mouth due to nausea or vomiting
- if you are not able to get your diarrhea under control within 24 hours

ABOUT TRODELVY

TRODELVY is a prescription medicine used to treat adults with:

- breast cancer that is estrogen and progesterone hormone receptor (HR) negative, and human epidermal growth factor receptor 2 (HER2)-negative (also called triple-negative breast cancer) that has spread to other parts of the body (metastatic) or cannot be removed by surgery, **and** who have previously received two or more prior treatments, including at least one treatment for metastatic disease.
- bladder cancer and cancers of the urinary tract that have spread or cannot be removed by surgery. TRODELVY may be used if you have received a platinum-containing chemotherapy medicine **and** also received an immunotherapy medicine.

It is not known if TRODELVY is safe and effective in people with moderate or severe liver problems or in children.

Do NOT receive TRODELVY if you have had a severe allergic reaction to TRODELVY. Ask your healthcare provider if you are not sure.

POSSIBLE SIDE EFFECTS OF TRODELVY

TRODELVY can also cause serious side effects, including:

- **Allergic and infusion-related reactions** which can be serious and life-threatening. Tell your healthcare provider or nurse right away if you get any of the following symptoms during an infusion or within 24 hours after:
  - swelling of your face, lips, tongue, or throat
  - hives
  - skin rash, itching, or flushing of your skin
  - fever
  - difficulty breathing or wheezing
  - lightheadedness, dizziness, feeling faint or pass out
  - chills or shaking chills (rigors)

IMPORTANT FACTS

This is only a brief summary of important information about TRODELVY and does not replace talking to your healthcare provider about your condition and your treatment.

POSSIBLE SIDE EFFECTS OF TRODELVY *(cont'd)*

- **Nausea and vomiting** are common with TRODELVY and can sometimes be severe. Before each dose of TRODELVY, you will receive medicines to help prevent nausea and vomiting along with medicines to take home with instructions about how to take them. Call your healthcare provider right away if you have nausea or vomiting that is not controlled with the medicines prescribed for you. Your healthcare provider may decide to decrease your dose or stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

The most common side effects of TRODELVY include feeling tired or weak, hair loss, decreased red blood cell count, constipation, decreased appetite, rash, and stomach-area (abdominal) pain or discomfort.

TRODELVY may cause fertility problems in females, which could affect your ability to have a baby. Talk to your healthcare provider if fertility is a concern for you.

Before and during treatment with TRODELVY, your healthcare provider will need to do tests to monitor your health. Tell your healthcare provider right away if you have any new symptoms while taking TRODELVY.

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

BEFORE RECEIVING TRODELVY

Tell your healthcare provider about all of your medical conditions, including if you:

- have been told that you carry a gene for UGT1A1*28, which can increase your risk of getting side effects with TRODELVY, especially low white blood cell counts, with or without a fever, and low red blood cell counts.
- have liver problems.
- are pregnant or plan to become pregnant. TRODELVY can harm your unborn baby. Your healthcare provider should check to see if you are pregnant before you start receiving TRODELVY.
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  - Males with a female partner who can become pregnant should use effective birth control during treatment and for 3 months after your last dose of TRODELVY.
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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the way TRODELVY works**.**

HOW TO RECEIVE TRODELVY

- Your healthcare provider will give you TRODELVY into your vein through an intravenous (IV) line.
- TRODELVY is given 1 time each week, on Day 1 and on Day 8 of a 21-day treatment cycle.
- You will receive the first dose over 3 hours; if well-tolerated, future doses may be given over 1 to 2 hours.
- Before each dose, you will receive medicines to help prevent infusion reactions, and nausea and vomiting.
- You will be monitored for side effects during and for at least 30 minutes after you receive each infusion of TRODELVY.
- Your healthcare provider may slow down or temporarily stop your infusion if you have an infusion-related reaction, or permanently stop TRODELVY if you have a life-threatening infusion-related reaction.
- Your healthcare provider will decide how long you stay on treatment.

GET MORE INFORMATION

This is only a brief summary of important information about TRODELVY. Talk to your healthcare provider or pharmacist to learn more.

To learn more, go to TRODELVY.com or call 1-844-TRODELVY (1-844-876-3358)

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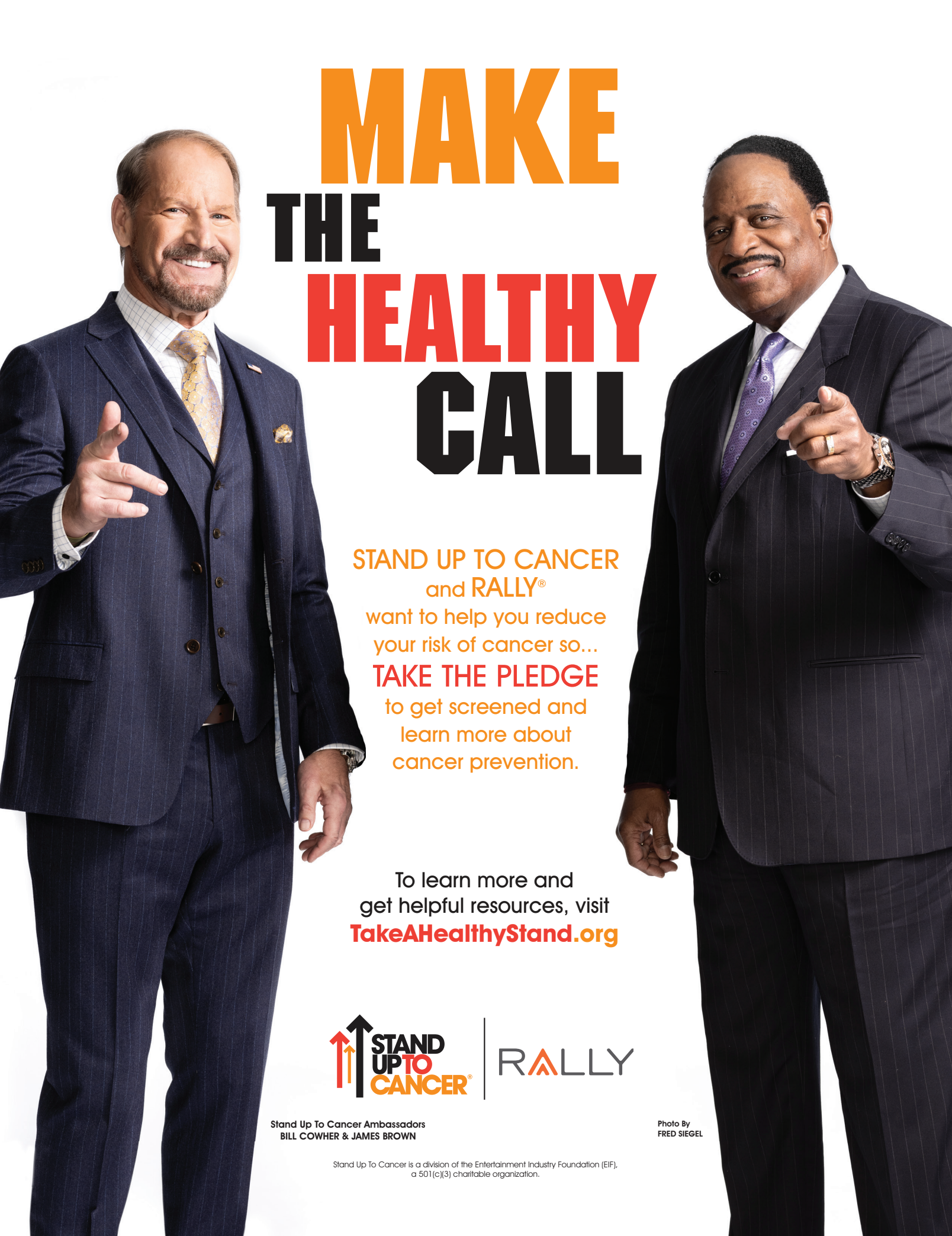
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