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Cancer Updates, Research & Education®

THE LANGUAGE of SURVIVAL

ZULMA ZORAIDA LIMAS RODRIGUEZ, who is among the 145,000 people with limited English proficiency who receive a cancer diagnosis in the U.S. every year, volunteers for fellow patients.

GIST
TREATMENT OPTIONS ARE AT AN ALL-TIME HIGH, WITH MORE ON THE WAY

ENDOMETRIAL CANCER
ADVANCES IN TREATMENT THANKS TO IMMUNOTHERAPY

MAINTAINING MINDFULNESS
EXPLORING THE BENEFITS OF MEDITATION

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SUMMER 2023
VOL.22 NO.2

KEYTRUDA IS A BREAKTHROUGH IMMUNOTHERAPY.

KEYTRUDA is approved to treat certain types of advanced non–small cell lung cancer (NSCLC) and to help prevent earlier stages of NSCLC (stage 1B and your tumor(s) is 4 cm or larger, stage 2, and stage 3A) from coming back after your lung cancer tumor(s) has been removed by surgery and you recieved platinum-based chemotherapy.

Talk to your doctor about KEYTRUDA today

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

- KEYTRUDA 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 may be used alone as a treatment in adults for your lung cancer to help prevent your lung cancer from coming back after your tumor(s) has been removed by surgery and you have received platinum-based chemotherapy, **and** you have stage IB and your tumor(s) is 4 cm or greater in size, stage II, or stage IIIA NSCLC.

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; 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.

Important Safety Information continued on the next page.

keytruda.com/lung

IMPORTANT SAFETY INFORMATION *(continued)*

- **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. Your doctor may treat you with corticosteroid or hormone replacement medicines. Your doctor 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 4 months after your last 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 last 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 4 months after the last 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 last 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, headache, stomach area (abdominal) pain, and low levels of white blood cells.

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-2303r054 as revised March 2023.

MERCK

CURE® Contents

SUMMER 2023

» Artist **STEPHENIE BLACK-GRANT** has been treated with immunotherapy for endometrial cancer.

» **LEE KEENEN** learned he had a gastrointestinal stromal tumor (GIST) shortly after completing a triathlon.

COVER ART: LUMAS RODRIGUEZ BY SHARON VANORNY; BLACK-GRANT BY JESSICA FRIEND; KEENAN BY ARIELLE GALLIONE

» **ZULMA ZORAIDA LIMAS RODRIGUEZ**, who only speaks a little English and received a diagnosis of breast cancer in 2014, says she "really didn't care whether the translators heard personal things. … I just wanted to live."

LIMAS RODRIGUEZ BY SHARON VINONY

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» IN THIS ISSUE:
Mindfulness Meditation
These techniques can make a big difference in the treatment experience of patients with cancer.

publisher's note

SUMMER 2023

Treating the Whole Patient

DURING A CANCER JOURNEY, it is vitally important to make sure the person, and not just their disease, is being cared for and treated. Mental and emotional well-being are crucial to a person's overall health, and they deserve plenty of attention from patients and providers alike.

In this seasonal issue of *CURE*®, we speak with a patient with cancer who has had to make her way through diagnosis, surgery and treatment — all while communicating through translators and not feeling connected to her fellow patients. She has since started volunteering to assist other patients so they don't experience that same sense of isolation.

"I didn't know any other patients who were going through this," Zulma Zoraida Limas Rodriguez, who speaks Spanish, told us through an interpreter as part of our story on non-English-speaking patients navigating cancer. "I didn't know what was going to happen in terms of the chemotherapy. And so now I volunteer to help women with cancer talk about the experience, and I'm very happy to be able to help them."

Also in this issue, we celebrate the honorees of CURE Media Group's 2023 Extraordinary Healer® awards, including a nurse who returned to support patients at the center where she received treatment for a brain tumor as a child.

We also share one patient's exploration of the complex emotions that come with receiving good news as someone with stage 4 cancer, look at the potential benefits of meditation practices for patients and speak with experts about the effect of depression on breast cancer treatment and survival.

"Sometimes for oncologists, their mindset is 'provide the best care for the patient.' But in the patient's mind, the best care may not be just survival," one study author tells us.

As always, we hope you find our stories inspirational and informative. Thank you for reading.

MIKE HENNESSY JR.
President & CO
MJH LIFE SCIENCES®

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The Emerging Importance of Immunotherapy in Endometrial Cancer

SOME CANCERS ARE MORE likely to be responsive to immunotherapy, but for different reasons. Endometrial cancer is now getting its time in the sun as several trials have matured to the point of showing clear benefits in patients with advanced cases already treated with chemotherapy

In this issue of *CURE*, you will learn why endometrial cancer may have unique sensitivity to immunotherapy and how this is transforming the treatment landscape. Genetic mutations are much more prevalent in tumor tissue compared with normal tissue as DNA repair abnormalities coupled with high cell division rates are seen in malignant cells. This results in abnormal proteins that are seen as "foreign" to the immune system and immune activation (known as making the tumor "hot"). This makes immunotherapy drugs like the checkpoint inhibitor Keytruda (pembrolizumab) more effective, as the immune system has already been "primed."

Because endometrial cancers can exhibit mismatch repair (MMR) deficiency, a type of DNA repair abnormality, this may explain why these cancers have been shown to respond to immunotherapy. Interestingly, the trials showed that even tumors that did not exhibit MMR defects benefit from the addition of immunotherapy. Such strategies are being moved in the first-line setting.

Researchers are looking for other ways to disrupt tumor cells in a way that better engages the immune system by exposing it to tumor antigens. This includes radiation and antiangiogenic drugs, both of which affect the tumor microenvironment in a pro-immunogenic direction. It is hoped that chemotherapy may even be omitted; this is being tested in ongoing clinical trials of immunotherapy with other biological drugs. The developments in endometrial cancer highlight the importance of understanding the details and nuances of how tumor cells interact with the immune "microenvironment" that surrounds and infiltrates tumors to variable extents.

Every day we learn more from basic science experiments and clinical trials for specific tumors that inform the next steps to being able to improve patients' outcomes.

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DEBU TRIPATHY BY MIKE KITADA; LUNG ART: JPGON / STOCK.ADOBE.COM

FIRSTLINE

compiled by BRIELLE BENYON

Jerry Springer, Talk Show Host and Former Politician, Dies of Pancreatic Cancer

JERRY SPRINGER

TALK SHOW HOST and former mayor of Cincinnati, Jerry Springer, died on April 27 of pancreatic cancer, according to his family's spokesperson, Jene Galvin. He was 79 years old.

"Jerry's ability to connect with people was at the heart of his success in everything he tried, whether that was politics, broadcasting or just joking with people on the street who wanted a photo or a word," Galvin said in a statement to The Associated Press. "He's irreplaceable and his loss hurts immensely, but memories of his intellect, heart and humor will live on."

Springer hosted his own talk show, "The Jerry Springer Show," from 1991 to 2018. Before the show, he was the mayor of Cincinnati for a year in 1977, then became an anchor and political reporter for Cincinnati's NBC affiliate for 10 years. Springer was also the host of "America's Got Talent" for seasons 2 and 3.

Steve Wilkos, who was a security guard on "The Jerry Springer Show," tweeted about the impact Springer had on his life. "Other than my father, Jerry was the most influential man in my life. Everything I have today, I owe to Jerry. He was the smartest, most generous, kindest person I've ever known. My wife and I are devastated. We will miss him terribly."

Maria Menounos Opens up About Pancreatic Cancer Diagnosis

MARIA MENOUNOS, AN actress and journalist who hosted "Extra" and "E! News" and was a correspondent for "Today" and "Access Hollywood," recently revealed that in January she received a diagnosis of stage 2 pancreatic cancer.

MARIA MENOUNOS

Menounos, who had a benign brain tumor removed in 2017 and delivered the keynote address at *CURE*'s third annual GBM Heroes event, underwent surgery to have a 3.9-cm tumor removed from her pancreas and urged others to take charge of their health.

"I need people to know there are places they can go to catch things early," she said in an interview with People. "You can't let fear get in the way. I had that moment where I thought I was a goner, but I'm OK because I caught this early enough."

Pennsylvania Governor Signs Bill to Provide Free Cancer Screenings

PENNSYLVANIA GOV. JOSH SHAPIRO signed a bipartisan bill requiring insurers to completely cover breast and ovarian cancer screenings for patients with high risk for the diseases. The legislation passed unanimously in the state House and Senate.

"This historic legislation is going to help women fight breast cancer and live healthier lives — and it would not have been possible without the courage, tenacity and bipartisan cooperation of Senate Pro Tempore Kim Ward and Speaker Joanna McClinton. I believe government can and should be a productive force for good – and this is a real example of the big things we can accomplish in the Commonwealth of Pennsylvania when we work together," Shapiro said in a statement.

PA VECTOR: ROBINSTARK/ STOCK.ADOBE.COM; JERRY SPRINGER: NEW YORK DAILY NEWS ARCHIVE VIA GETTY IMAGES; MARIA MENOUNOS: KEVIN MAZUR / GETTY IMAGES ENTERTAINMENT VIA GETTY IMAGES

‘The King of Chemo’ Is Cycling Across the Country

IAIN WARD, WHO received a diagnosis of stage 3 brain cancer in 2019 and is known on social media as “the King of Chemo,” is currently on a cross-country bike ride with his friend Adee Phelan to raise awareness and funds for mental health and cancer nonprofits. In addition to the ride from New York to Los Angeles, Ward hopes to break the world record for the most money raised by a single person running a marathon and run the fastest marathon dressed as a video game character, he told CNN Sports.

“I could get very upset about the bad poker hand that I’ve been dealt, but at the same time, it’s almost arrogant of me to not look at the other amazing poker hand that I’ve been dealt simultaneously,” he said.

As of April 23, Ward had made it approximately halfway through his journey before Phelan was hospitalized following a fall from his bicycle.

Ward, who has 4.8 million followers on TikTok, said his priority is to get as many followers as possible so companies will pay him to promote their products and that the proceeds will be donated to charity.

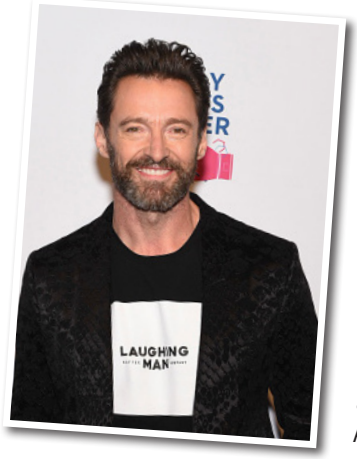
After Testing, **Hugh Jackman** Urges Others to Protect Themselves From Skin Cancer

HUGH JACKMAN, who is known for his role as Wolverine in the “X-Men” film series, recently underwent medical testing to determine whether a spot removed from his face was cancerous. The Australian posted a video on his Instagram account — which showed a bandage on his nose — urging others to protect themselves from the sun and to follow through with regular skin checks.

“Just to remind you, basal cell, in the world of skin cancers, is the least dangerous of them all,” he said in the video. “However, if I can just take this opportunity to remind you, summer is coming. … For those of us here in the Northern Hemisphere, please wear sunscreen.”

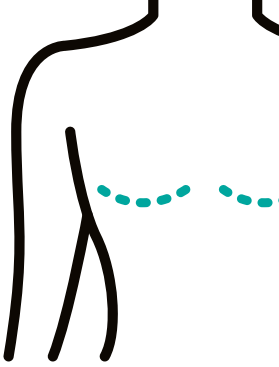
In 2013, Jackman had a basal cell carcinoma removed from his nose.

“It is just not worth it. No matter how much you want a tan. Trust me,” he said.



HUGH JACKMAN

FDA Issues Update on Cancer Found in Scar Tissue Around Breast Implants



ACCORDING TO A statement, the Food and Drug Administration (FDA) is aware of 19 cases of squamous cell carcinoma — a type of cancer that develops in the squamous skin cells — found in the capsule around breast implants. The agency noted that the disease is rare and the cause, incidence and risk factors remain unknown.

The FDA urged individuals who are considering breast implants to discuss the risks and benefits with their health care providers.

“The FDA continues to ask health care providers and people with breast implants to report cases of (squamous cell carcinoma), lymphomas or any other cancers around breast implants to the FDA. In addition, we continue to collaborate with other regulatory authorities, scientific experts, breast implant manufacturers and registries to gather all available information on cancers in the capsule around breast implants,” the FDA said.

Study Finds That Military Pilots and Crews Experience Higher Rate of Certain Cancers

THE PENTAGON STUDY of nearly 900,000 service members who flew on or worked on military aircraft between 1992 and 2017 found that pilots had a 24% overall higher rate of cancer than the general public. Specifically, there was an 87% higher rate of melanoma and a 39% higher rate of thyroid cancer. Men had a 16% higher rate of prostate cancer, while women experienced a 16% higher rate of breast cancer.

Ground crew members had a 19% higher rate of brain and nervous system cancers, a 15% higher rate of thyroid cancers and a 9% higher rate of kidney cancers. Women had a 7% higher rate of breast cancer. Overall, this group had a 3% increased rate for any cancer diagnoses than the general public.

Not all findings from the study were negative. Results also showed that ground and air crews in the military had lower rates of lung cancer and air crews had lower rates of bladder and colon cancer.

These findings “(prove) that it’s well past time for leaders and policy makers to move from skepticism to belief and active assistance,” retired Air Force Col. Vince Alcazar, a member of the Red River Valley Fighter Pilots Association, said in an interview with The Associated Press.

MASECTOMY LINE VECTOR: CHERNOUS / STOCK.ADOBE.COM; HUGH JACKMAN: LISA LAKE / STRINGER / GETTY IMAGES ENTERTAINMENT VIA GETTY IMAGES

'Gentleness And Kindness' in Patients' Lives

Mindfulness meditation can make a big difference in the treatment experience of patients.

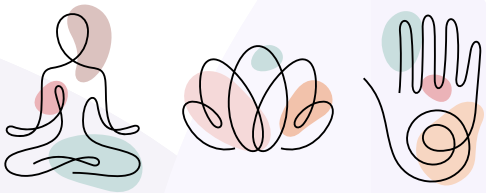
By ALEX BIESE

"MEDITATION IS REALLY placing your attention on something intentionally for a period of time," said Emily Herzlin, a certified mindfulness meditation and mindfulness-based stress reduction instructor. "Mindfulness has to do with being in the present, choosing to bring your attention to the present moment, with an attitude of nonjudgment or kindness. … So when we're mindful, we're trying to be with what's here in this moment with as much gentleness and kindness as possible."

Herzlin, who studied mindfulness-based stress reduction at UMass Medical School Center for Mindfulness in Worcester, Massachusetts, worked in the integrative medicine program at Memorial Sloan Kettering Cancer Center in New York and teaches in the integrative health and well-being program at Weill Cornell Medicine.

She was introduced to mediation as a teenager, while she was dealing with chronic health issues of her own and close family members were undergoing cancer treatment.

"I found it to be incredibly helpful, both in terms of my relationship with my own body as well as the cycle of worry and anxiety that comes up when people who you love are struggling or ill," Herzlin said. "It was a time of day where I could notice my thoughts, notice my anxieties and say, 'Thank you, (but) not right now.'"



WHERE to start

Meditation resources recommended by Herzlin include the following:

Apps such as Insight Timer and Headspace.

For people facing chronic pain, the writing of Vidyamala Burch, specifically "You Are Not Your Pain: Using Mindfulness to Relieve Pain, Reduce Stress and Restore Well-Being – An Eight-Week Program," co-written with Danny Penman.

Meditation videos and materials available on the integrative health websites at Weill Cornell Medicine (weillcornell.org) and Memorial Sloan Kettering Cancer Center (mskcc.org).

EGORVECTOR / STOCK.ADOBE.COM

HOW MEDITATION CAN HELP

Here are some of the areas where Herzlin said meditation can help patients:

Sleeplessness and anxiety

"The stream of worry and anxiety that can sometimes keep us up at night — meditative techniques can help to give the mind something else to pay attention to, to make a choice to shift the attention from the swirling thoughts of anxiety to something more neutral or calming, like the breath, or relaxing the muscles of the body, or phrases of lovingkindness, things you can say to yourself that are kind or gentle to yourself," Herzlin said.

Some prompts suggested by Herzlin include "May I be safe," "May I be peaceful," "May I be kind to myself" and "May I live with ease."

Treatments and Imaging

"When we practice mindfulness meditation, we usually choose an anchor for our attention, like the breath or the body, and then whenever our attention goes away from that anchor to thoughts about the past or the future, we try to pause and gently notice, stop and say: 'Oh, I got lost in something else. That's OK, let me come back to my breath or to the body,'" she explained.

Those same techniques can be used in doctors' offices while undergoing tests or coping with the stress and side effects of treatment, she said.

Pain

Meditation techniques for pain, Herzlin said, differ from person to person. The best practice for some is to shift the focus to something more soothing. For other individuals, it may be more helpful to face pain with compassion.

"A mindfulness technique is to actually be present with the pain, to allow the pain to be there, to not try to push it away, to even try to treat it with lovingkindness with friendliness," she said.

Mindfulness-based stress reduction courses, available online or in person.

The works of Sharon Salzberg, particularly "Real Happiness: The Power of Meditation: A 28-Day Program."

The hospital or medical center where they are receiving treatment may have mediation resources available, such as support groups or a teacher on staff.

The first and only Trop-2–directed ADC for mUC[1]

Elevate the Possibilities With TRODELVY®

mUC

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

WARNINGS AND PRECAUTIONS

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur and may require dose modification. Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6%. Neutropenic colitis occurred in 1.4%. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Administer G-CSF as clinically indicated or indicated in Table 1 of USPI.

Diarrhea: Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 35% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

Nausea and Vomiting: Nausea occurred in 64% of all patients treated with TRODELVY and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 35% of patients and Grade 3-4 vomiting occurred in 2% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Nearly 30% of patients responded, with ~5% experiencing complete response[1]

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

TRODELVY was evaluated in TROPHY, a Phase 2, single-arm, open-label, multicenter study (N=112) in patients with locally advanced or mUC who received prior treatment with a platinum-containing chemotherapy and either PD-1 or PD-L1 inhibitor

ORR*

27.7%

(95% CI: 19.6–36.9)
Complete Response (CR): 5.4%
Partial Response (PR): 22.3%
N=112

Median DOR*

7.2 months (range 1.4+, 13.7)

(95% CI: 4.7–8.6)
Number of responders: 31
+: denotes ongoing

See more data from the TROPHY study at **TRODELVYHCP.com**

*By IRA based on RECIST 1.1.

ADC=antibody-drug conjugate; CI=confidence interval; DOR=Duration of Response; IRA=independent review assessment; ORR=Objective Response Rate; RECIST=Response Evaluation Criteria in Solid Tumors.

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of Grade 3-4 neutropenia was 58% in patients homozygous for the UGT1A1*28, 49% in patients heterozygous for the UGT1A1*28 allele, and 43% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 21% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 9% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

ADVERSE REACTIONS

In the pooled safety population, the most common (≥25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (84%), decreased neutrophil count (75%), decreased hemoglobin (69%), diarrhea (64%), nausea (64%), decreased lymphocyte count (63%), fatigue (51%), alopecia (45%), constipation (37%), increased glucose (37%), decreased albumin (35%), vomiting (35%), decreased appetite (30%), decreased creatinine clearance (28%), increased alkaline phosphatase (28%), decreased magnesium (27%), decreased potassium (26%), and decreased sodium (26%).

In the TROPHY study, the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, any infection, alopecia, decreased appetite, constipation, vomiting, rash, and abdominal pain. The most frequent serious adverse reactions (SAR) (≥5%) were infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), and sepsis or bacteremia (5%). SAR were reported in 44% of patients, and 10% discontinued due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPHY study were reduced neutrophils, leukocytes, and lymphocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

Please see Brief Summary of full Prescribing Information, including BOXED WARNING, on the next page.

Reference: 1. TRODELVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; February 2023.

GILEAD | Oncology

Scan the QR code to watch a TROPHY study investigator discuss the data

TRODELVY® (sacituzumab govitecan-hziy) for injection, for intravenous use
Brief Summary of full Prescribing Information. See full Prescribing Information. Rx Only.

WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤ Grade 1 and reduce subsequent doses.**

[See Warnings and Precautions and Dosage and Administration]

INDICATIONS AND USAGE

*Also see **Clinical Studies***

TRODELVY (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with:

- Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- Unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.
- Locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

DOSAGE AND ADMINISTRATION

*Also see **Warnings and Precautions***

Do NOT substitute TRODELVY for or use with other drugs containing irinotecan or its active metabolite SN-38.

The recommended dosage of TRODELVY is 10 mg/kg administered as an intravenous infusion once weekly on Days 1 and 8 of 21-day treatment cycles. Continue treatment until disease progression or unacceptable toxicity. Do not administer TRODELVY at doses greater than 10 mg/kg. Administer TRODELVY as an intravenous infusion only. Do not administer as an intravenous push or bolus.

- First infusion: Administer infusion over 3 hours. Observe patients during the infusion and for at least 30 minutes following the initial dose, for signs or symptoms of infusion-related reactions
- Subsequent infusions: Administer infusion over 1 to 2 hours if prior infusions were tolerated. Observe patients during the infusion and for at least 30 minutes after infusion.
- Premedication: Prior to each dose of TRODELVY, premedication for prevention of infusion reactions and prevention of chemotherapy-induced nausea and vomiting (CINV) is recommended. Premedicate with antipyretics, H1 and H2 blockers prior to infusion, and corticosteroids may be used for patients who had prior infusion reactions. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist, as well as other drugs as indicated).

Dose Modifications for Infusion-related Reactions: Slow or interrupt the infusion rate of TRODELVY if the patient develops an infusion-related reaction. Permanently discontinue TRODELVY for life-threatening infusion-related reactions.

Dose Modifications for Adverse Reactions: Withhold or discontinue TRODELVY to manage adverse reactions as described below. Do not re-escalate the TRODELVY dose after a dose reduction for adverse reactions has been made.

Severe Neutropenia, defined as Grade 4 neutropenia ≥7 days, OR Grade 3-4 febrile neutropenia, OR at time of scheduled treatment, Grade 3-4 neutropenia which delays dosing by 2 or 3 weeks for recovery to ≤ Grade 1:

- At first occurrence, 25% dose reduction and administer granulocyte-colony stimulating factor (G-CSF). At second occurrence, 50% dose reduction and administer G-CSF. At third occurrence, discontinue TRODELVY and administer G-CSF.
- At time of scheduled treatment, if Grade 3-4 neutropenia occurs which delays dosing beyond 3 weeks for recovery to ≤ Grade 1, discontinue TRODELVY and administer G-CSF at first occurrence.

Severe Non-Neutropenic Toxicity, defined as Grade 4 non-hematologic toxicity of any duration, OR any Grade 3-4 nausea, vomiting or diarrhea due to treatment that is not controlled with antiemetics and anti-diarrheal agents, OR other Grade 3-4 non-hematologic toxicity persisting >48 hours despite optimal medical management, OR at time of scheduled treatment, Grade 3-4 non-neutropenic hematologic or non-hematologic toxicity, which delays dose by 2 or 3 weeks for recovery to ≤Grade 1:

- At first occurrence, 25% dose reduction. At second occurrence, 50% dose reduction. At third occurrence, discontinue TRODELVY.
- In the event of Grade 3-4 non-neutropenic hematologic or non-hematologic toxicity, which does not recover to ≤Grade 1 within 3 weeks, discontinue TRODELVY at first occurrence.

CONTRAINDICATIONS

*Also see **Warnings and Precautions***

TRODELVY is contraindicated in patients who have experienced a severe hypersensitivity reaction to TRODELVY.

WARNINGS AND PRECAUTIONS

*Also see **BOXED WARNING, Dosage and Administration, Contraindications, Clinical Pharmacology, Nonclinical Toxicology,** and **Use in Specific Populations***

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur in patients treated with TRODELVY. Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6% of patients. The median time to first onset of neutropenia (including febrile neutropenia) was 16 days and has occurred earlier in some patient populations. Neutropenic colitis occurred in 1.4% of patients. Withhold TRODELVY for ANC below 1500/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Dose modifications may be required due to neutropenia. Administer G-CSF as clinically indicated or indicated in Table 1 of full Prescribing Information.

Diarrhea: TRODELVY can cause severe diarrhea. Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of all patients treated with TRODELVY. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients. Withhold TRODELVY for Grade 3-4 diarrhea at the time of scheduled treatment administration and resume when resolved to ≤ Grade 1. At the onset of diarrhea, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment with TRODELVY (e.g., abdominal cramping, diarrhea, salivation, etc.) can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY treatment. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 35% of patients treated with TRODELVY. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%. Premedication for infusion reactions in patients receiving TRODELVY is recommended. Have medications and emergency equipment to treat infusion-related reactions, including anaphylaxis, available for immediate use when administering TRODELVY. Closely monitor patients for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

Nausea and Vomiting: TRODELVY is emetogenic. Nausea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 nausea occurred in 3% of patients. Vomiting occurred in 35% of patients. Grade 3-4 vomiting occurred in 2% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of CINV. Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to ≤Grade 1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of neutropenia and anemia was analyzed in 948 patients who received TRODELVY and had UGT1A1 genotype results. The incidence of Grade 3-4 neutropenia was 58% in patients homozygous for the UGT1A1*28 allele (n=112), 49% in patients heterozygous for the UGT1A1*28 allele (n=420), and 43% in patients homozygous for the wild-type allele (n=416). The incidence of Grade 3-4 anemia was 21% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 9% in patients homozygous for the wild-type allele. The median time to first neutropenia including febrile neutropenia was 9 days in patients homozygous for the UGT1A1*28 allele, 15 days in patients heterozygous for the UGT1A1*28 allele, and 20 days in patients homozygous for the wild-type allele. The median time to first anemia was 21 days in patients homozygous for the UGT1A1*28 allele, 25 days in patients heterozygous for the UGT1A1*28 allele, and 28 days in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on onset, duration, and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 enzyme activity.

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

ADVERSE REACTIONS

*Also see **BOXED WARNING, Warnings and Precautions,** and **Clinical Studies***

The pooled safety population described in the Warnings and Precautions section reflect exposure to TRODELVY in 1063 patients from four studies, IMMU-132-01, ASCENT, TROPiCS-02, and TROPHY which included 366 patients with mTNBC, 322 patients with HR+/HER2- breast cancer, and 180 patients with mUC. Among the 1063 patients treated with TRODELVY, the median duration of treatment was 4.1 months (range: 0 to 63 months). The most common (≥ 25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (84%), decreased neutrophil count (75%), decreased hemoglobin (69%), diarrhea (64%), nausea (64%), decreased lymphocyte count (63%), fatigue (51%), alopecia (45%), constipation (37%), increased glucose (37%), decreased albumin (35%), vomiting (35%), decreased appetite (30%), decreased creatinine clearance (28%), increased alkaline phosphatase (28%), decreased magnesium (27%), decreased potassium (26%), and decreased sodium (26%).

Locally Advanced or Metastatic Triple-Negative Breast Cancer

The safety of TRODELVY was evaluated in a randomized, active-controlled, open-label study (ASCENT) in patients with mTNBC who had previously received a taxane and at least two prior chemotherapies. Patients were randomized (1:1) to receive either TRODELVY (n=258) or single agent chemotherapy (n=224) and were treated until disease progression or unacceptable toxicity. For patients treated with TRODELVY, the median duration of treatment was 4.4 months (range: 0 to 23 months). Serious adverse reactions occurred in 27% of patients, and those in > 1% included neutropenia (7%), diarrhea (4%), and pneumonia (3%). Fatal adverse reactions occurred in 1.2% of patients, including respiratory failure (0.8%) and pneumonia (0.4%). TRODELVY was permanently discontinued for adverse reactions in 5% of patients. These adverse reactions (≥1%) were pneumonia (1%) and fatigue (1%). The most frequent (≥5%) adverse reactions leading to a treatment interruption in 63% of patients were neutropenia (47%), diarrhea (5%), respiratory infection (5%), and leukopenia (5%). The most frequent (>4%) adverse reactions leading to a dose reduction in 22% of patients were neutropenia (11%) and diarrhea (5%). G-CSF was used in 44% of patients who received TRODELVY. The most common (≥25%) adverse reactions including lab abnormalities were decreased hemoglobin (94%), decreased lymphocyte count (88%), decreased leukocyte count (86%), decreased neutrophil count (78%), fatigue (65%), diarrhea (59%), nausea (57%), increased glucose (49%), alopecia (47%), constipation (37%), decreased calcium (36%), vomiting (33%), decreased magnesium (33%), decreased potassium (33%), increased albumin (32%), abdominal pain (30%), decreased appetite (28%), increased aspartate aminotransferase (27%), increased alanine aminotransferase (26%), increased alkaline phosphatase (26%), and decreased phosphate (26%).

Locally Advanced or Metastatic HR-Positive, HER2-Negative Breast Cancer

The safety of TRODELVY was evaluated in a randomized, active-controlled, open-label study (TROPiCS-02) in patients with unresectable locally advanced or metastatic HR+/HER2- breast cancer whose disease has progressed after the following in any setting: a CDK 4/6 inhibitor, endocrine therapy, and a taxane; patients received at least two prior chemotherapies in the metastatic setting (one of which could be in the neoadjuvant or adjuvant setting if progression occurred within 12 months). Patients were randomized (1:1) to receive either TRODELVY (n=268) or single agent chemotherapy (n=249) and were treated until disease progression or unacceptable toxicity. For patients treated with TRODELVY, the median duration of treatment was 4.1 months (range: 0 to 63 months). Serious adverse reactions occurred in 28% of patients, and those in >1% of patients included diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting (each 2%). Fatal adverse reactions occurred in 2% of patients, including arrhythmia, COVID-19, nervous system disorder, pulmonary embolism, and septic shock (each 0.4%). TRODELVY was permanently discontinued for adverse reactions in 6% of patients. The most frequent (≥0.5%) of these adverse reactions were asthenia, general physical health deterioration, and neutropenia (each 0.7%). The most frequent (≥5%) adverse reaction leading to treatment interruption in 66% of patients was neutropenia (50%). The most frequent (>5%) adverse reactions leading to dose reduction in 33% of patients were neutropenia (16%) and diarrhea (8%). G-CSF was used in 54% of patients who received TRODELVY. The most common (≥25%) adverse reactions including lab abnormalities were decreased leukocyte count (88%), decreased neutrophil count (83%), decreased hemoglobin (73%), and decreased lymphocyte count (65%); diarrhea (62%), fatigue (60%), nausea (59%), alopecia (48%), increased glucose (37%), constipation (34%), and decreased albumin (32%). Other clinically significant adverse reactions in TROPiCS-02 (≤ 10%) include: hypotension (5%), pain (5%), rhinorrhea (5%), hypocalcemia (3%), nasal congestion (3%), skin hyperpigmentation (3%), colitis or neutropenic colitis (2%), hyponatremia (2%), pneumonia (2%), proteinuria (1%), enteritis (0.4%).

Locally Advanced or Metastatic Urothelial Cancer

The safety of TRODELVY was evaluated in a single-arm, open-label study (TROPHY) in patients (n=113) with mUC who had received previous platinum-based and anti-PD-1/PD-L1 therapy. Serious adverse reactions occurred in 44% of patients, and those in >1% included infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), sepsis or bacteremia (5%), diarrhea (4%), anemia, venous thromboembolism, and small intestinal obstruction (3% each), pneumonia, abdominal pain, pyrexia, and thrombocytopenia (2% each). Fatal adverse reactions occurred in 3.6% of patients, including sepsis, respiratory failure, epistaxis, and completed suicide. TRODELVY was permanently discontinued for adverse reactions in 10% of patients. The most frequent of these adverse reactions was neutropenia (4%, including febrile neutropenia in 2%). The most common adverse reactions leading to dose interruption in 52% of patients were neutropenia (27%, including febrile neutropenia in 2%), infection (12%), and acute kidney injury (8%). The most common (>4%) adverse reactions leading to a dose reduction in 42% of patients were neutropenia (13%, including febrile neutropenia in 3%), diarrhea (11%), fatigue (8%), and infection (4%). G-CSF was used in 47% of patients who received TRODELVY. The most common (≥25%) adverse reactions including lab abnormalities were decreased leukocyte count (78%), diarrhea (72%), decreased hemoglobin (71%), decreased lymphocyte count (71%), fatigue (68%), decreased neutrophil count (67%), nausea (66%), increased glucose (59%), decreased albumin (51%), any infection (50%), alopecia (49%), decreased calcium (46%), decreased sodium (43%), decreased appetite (41%), decreased phosphate (41%), increased alkaline phosphatase (36%), constipation (34%), vomiting (34%), increased activated partial thromboplastin time (33%), increased creatinine (32%), rash (32%), decreased magnesium (31%), abdominal pain (31%), increased alanine aminotransferase (28%), increased lactate dehydrogenase (28%), decreased potassium (27%), increased aspartate aminotransferase (26%), and decreased platelet count (25%). Other clinically significant adverse reactions (≤15%) include: peripheral neuropathy (12%), sepsis or bacteremia (9%), and pneumonia (4%).

DRUG INTERACTIONS

*Also see **Warnings and Precautions** and **Clinical Pharmacology***

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY

USE IN SPECIFIC POPULATIONS

*Also see **Warnings and Precautions, Clinical Pharmacology,** and **Nonclinical Toxicology***

Pregnancy: TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Lactation: There is no information regarding the presence of sacituzumab govitecan-hziy or SN-38 in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 1 month after the last dose of TRODELVY.

Females and Males of Reproductive Potential: Verify the pregnancy status of females of reproductive potential prior to initiation. TRODELVY can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose.

Males: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

Infertility: Based on findings in animals, TRODELVY may impair fertility in females of reproductive potential.

Pediatric Use: Safety and effectiveness of TRODELVY have not been established in pediatric patients.

Geriatric Use:

Of the 366 patients with TNBC who were treated with TRODELVY, 19% of patients were 65 years and 3% were 75 years and older. No overall differences in safety and effectiveness were observed between patients ≥ 65 years of age and younger patients.

Of the 322 patients with HR+/HER2- breast cancer who were treated with TRODELVY, 26% of patients were ≥ 65 years and 6% were ≥ 75 years. No overall differences in effectiveness were observed between patients ≥ 65 years of age and younger patients. There was a higher discontinuation rate due to adverse reactions in patients aged 65 years or older (14%) compared with younger patients (3%).

Of the 180 patients with UC who were treated with TRODELVY, 59% of patients were ≥ 65 years and 27% were ≥ 75 years. No overall differences in effectiveness were observed between patients ≥ 65 years of age and younger patients. There was a higher discontinuation rate due to adverse reactions in patients aged 65 years or older (14%) compared with younger patients (8%).

Hepatic Impairment: No adjustment to the starting dose is required when administering TRODELVY to patients with mild hepatic impairment. The safety of TRODELVY in patients with moderate or severe hepatic impairment has not been established, and no recommendations can be made for the starting dose in these patients.

761115-GS-007 Feb 2023

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cure® Extraordinary HEALER® 2023

‘Our Connection With Patients Runs So Very Deep’

CURE welcomed over 500 attendees in person and hundreds virtually during the hybrid Extraordinary Healer event.

By DARLENE DOBKOWSKI, M.A.

CURE MEDIA GROUP recognized **Abbey Kaler, M.S., APRN, FNP-C, CMSRN**, as the winner of its 2023 Extraordinary Healer award, which honors nurses in the cancer community who dedicate their lives to make a difference in the lives of patients and their loved ones.

“The … thing I learned is that my connection with our patients runs so very deep,” Kaler said upon receiving the award. “It’s so much more than I ever imagined it could be. I’m so thankful for the opportunity to love and care and pour into our patients every single day.”

Essays were submitted by colleagues, patients and family members identifying Kaler, two other finalists and 40 other Extraordinary Healer nominees, all detailing the noble acts of oncology nurses, including being a “safe harbor in a stormy sea” during a cancer diagnosis and treatment, as »

DIANA CHAVEZ

KRISTIE L. KAHL, vice president of content of MJH Life Sciences, the parent company of CURE Media Group, from left, with **GINNY T. KIRKLIN, M.P.H.**, honoree **ABBEY KALER, M.S., APRN, FNP-C, CMSRN** and **ALEXANDRA FRENZEL**, patient advocate and metastatic breast cancer patient of The University of Texas MD Anderson Cancer Center and keynote speaker Shannon Miller, Olympic gymnast and ovarian cancer survivor, at the CURE Media Group Extraordinary Healer award event on April 26 in San Antonio, Texas.

one nominator described her hero, and planning events for hospital patients undergoing treatment.

The Extraordinary Healer award event, sponsored by Janssen Oncology and Incyte, took place April 26 during a hybrid celebration held in conjunction with the 48th Annual Oncology Nursing Society Congress in San Antonio, Texas.

Abbey Kaler, M.S., APRN, FNP-C, CMSRN, left, won CURE Media Group's 2023 Extraordinary Healer award, and patient Alex Frenzel, right, helped draft the nomination.

> I love talking with my patients and helping to educate them on their current situation.
>
> **–ABBEY KALER**

The evening featured a keynote address from Shannon Miller, Olympic gymnast and ovarian cancer survivor. Miller earned seven Olympic medals and is the only female athlete to be inducted into the U.S. Olympic Hall of Fame twice. In January 2011, Miller received a diagnosis of a rare form of ovarian cancer and underwent surgery to remove a baseball-sized tumor. She also underwent an aggressive chemotherapy regimen.

Miller reminded the audience to reflect on the good times as well as the struggles they may face, as both can teach important lessons.

"We look back and think about the highlights, the good times, maybe those golden medal moments, but I do feel like it's important to remind myself of the struggles along the way — the falls, the injuries, the moments where I just want to give up," Miller said. "Because I know it's in those moments, it is in the mistakes and the challenges, the falls and failures that I learned how important it is to get back up, to keep going."

Miller is currently cancer-free and strives to be a strong advocate for awareness, early detection, research and survivorship.

At the end of her keynote address, Miller shared her gratitude to all oncology nurses.

"For our oncology nurses here tonight and so many that are not, I want to thank you for what you do," she said. "It is amazing. It is not an easy road you've chosen. You are there at some of the most heart-wrenching moments of a person's life. But you're also there at some of the most hopeful and wonderful moments. I hope that you feel that thank you each and every day not just from your patients, but their caregivers, their loved ones and family."

'I'm Part of Their Team'

Kaler, an advanced registered nurse practitioner navigator at the Advanced Breast Cancer Clinic at The University of Texas MD Anderson Cancer Center (MD Anderson) in Houston, was nominated by Ginny Kirklin, M.P.H., on behalf of the Advanced Breast Cancer Program steering committee, advocates and patients at MD Anderson.

Kirklin referred to Kaler's diagnosis of juvenile pilocytic astrocytoma, a rare benign brain tumor, at 9 years old, which drove Kaler to pursue a medical career to care for and support patients.

DIANA CHAVEZ

In fact, she returned to the center where she received care as a child to become a nurse.

"That was my goal: to return to the institution that had cared for me and my family at such a vulnerable time," Kaler said in an interview with CURE. "I wanted to provide the same level of care in my work that was shown to us."

Kaler uses the voices of the patients she sees every day and creates initiatives around them, such as supportive programs to help patients with metastatic breast cancer, caregivers and health care providers, among others in the community.

"I love talking with my patients and helping to educate them on their current situation," she said. "I enjoy being part of their support structure and creating a relationship – knowing I'm part of their team and will always be there to support them."

The other finalists for the Extraordinary Healer award are Kerry O'Neil, B.S.N., RN, OCN, nursing manager at City of Hope in Newport Beach, California; and Mary Colasuonno, B.S.N., RN, BMTCN, registered nurse at City of Hope National Medical Center in Duarte, California.

A Noteworthy Nursing Career

O'Neil was nominated by Cynthia Powers, D.N.P., M.S.N., RN, CPHQ, of Irvine, California. In her essay, Powers noted O'Neil's 40 years as an oncology nurse and supervisor, which allowed her to impact the lives of thousands of patients with cancer and their families.

That impact stands the test of time. In the nomination, Powers wrote about a time O'Neil was walking her dog when she was approached by a woman and her daughter, who recognized her as her "mom's favorite nurse 30 years ago." The patient made O'Neil a Christmas ornament, which reminds her of that woman every year.

In an interview with CURE, O'Neil mentioned how important it was to her to maintain relationships with patients as she entered a management position at her institution.

"Generally, when you get into a management position, you're no longer working in the clinical arena," O'Neil said. "I'm a little unusual in that I still give patients their chemotherapy, have relationships with them, and I'm still on the floor with the other nurses. I like having that patient interaction; I don't think I could do it if I didn't have that, because that's where my heart is — it's why I got into nursing in the first place."

Making Every Interaction Count

Colasuonno was nominated by Lesley Han, M.S.N., M.S.H.A., RN, EBP-C, of Duarte, California, who wrote how throughout her career as a nurse, Colasuonno "always made a conscious effort to make every interaction count." Han noted Colasuonno's determination to bring positivity to others in an effort to foster healing.

In her nominating essay, Han said the impact Colasuonno has on patients also reaches her team: She leads them to seek out excellence in patient outcomes and to do so with empathy and understanding of how patients and their families may feel.

Colasuonno told CURE that patients can learn from nurses, but nurses can learn from their patients as well. She recalled a patient who was so sick as a child that her parents thought she had died, but the patient told Colasuonno that she knew it wasn't her time yet. Since then, Colasuonno has taken every day as a gift.

"She's not the only patient with those kinds of stories," Colasuonno said. "Moments like that with my patients really make me feel I was meant to be a nurse."

Victories and Setbacks of a Cancer Journey

Kristie L. Kahl, vice president of content at MJH Life Sciences, the parent company of CURE Media Group, emphasized the importance of honoring oncology nurses at events like Extraordinary Healer, especially after reading essay nominations throughout the years, and noted the relentless work they do for patients and their families.

"We appreciate all of you here this evening, our oncology nurses, who stand by our patients, holding their hands through the victories and the setbacks, the good and the bad, day in and day out during what can be one of the scariest and most overwhelming experiences a patient and their loved ones can face," she said.

Jackie Keehne-Miron, national director of the oncology clinical educator team at Janssen Pharmaceutical Companies, reflected on her time as an oncology nurse in the 1980s, at a time when there were many changes to practice that made it more personal.

"Delivery of nursing care is based on human touch, it's based on emotion, it's based on caring, it's based on advocacy," she said. "And it's really based on knowing when to take those gloves off and fight for your patient and be their advocate. This is the difference between a nurse and the extraordinary healer. And this is the heart of nursing. The science and knowledge (are) vital. However, it's the delivery that says: 'I care. I'm here for you. I understand.' This is where the magic comes in, which you all do every single day."

It is that caring and compassion for patients with cancer that make oncology nurses extraordinary, said Erik Lohrmann, vice president of CURE Media Group, who shared his connection with cancer during the event and the connection his late uncle experienced with his own nurse.

"Previously, I talked about perspective and how what all of you do, events like this provide perspective, a reminder of how cancer touches us all," he said. "But for me, there is another message here, kind of in the characteristics and traits that you all possess and what you bring to patients on a daily basis: hope, compassion, connection. That's a real gift that you offer." C

CURE® Extraordinary HEALER® 2023

THANK YOU FOR AN *Extraordinary Evening!*

Congratulations to ABBEY KALER, M.S., APRN, FNP-C, CMSRN, of The University of Texas MD Anderson Cancer Center in Houston, who received ***CURE*'s 2023 Extraordinary Healer** award at a celebration on April 26 in San Antonio, Texas, before more than 500 of her nursing peers. Kaler was nominated by Ginny T. Kirklin, M.P.H., Alexandra Frenzel, and on behalf of the Advanced Breast Cancer (ABC) Program steering committee, advocates, and patients at MD Anderson.

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

Mary Colasuonno, B.S.N., RN, BMTCN
City of Hope National Medical Center
Nominated by Lesley Han, M.S.N., M.S.H.A., RN, EBP-C

Kerry O'Neil, B.S.N., RN, OCN
City of Hope
Nominated by Cynthia A. Powers, D.N.P., M.S.N., RN, CPHQ

Congratulations to All Nominees

Sobha Akkar, B.S.N., RN, OCN
Duarte, California

Anica Bausch, B.S.N., RN, OCN
Madison, Wisconsin

Missy Bean-Tanner, RN
New Orleans, Louisiana

Patricia Jo Beaty, M.P.H., RN
Canton, Ohio

Gailine Boice, RN, OCN
Mesa, Arizona

Kelly Bryant, RN
Orange Park, Florida

Mary Colasuonno, B.S.N., RN, BMTCN
Duarte, California

Beatriz "Betty" Cortes Garcia, RN
Eureka, California

Afton Dickerson, M.S.N., RN, ACNP-BCP
Houston, Texas

Pam Dowling, B.S.N., RN
St. Louis, Missouri

Myra Escudero, M.S.N., RN
New York, New York

Terry Fogaren, NP
Boston, Massachusetts

Melissa Fuentes, RN, OCN
Deland, Florida

Marcia Gaulke, B.S.N., RN, OCN
Atlanta, Georgia

Caitlyn Geer, B.S.N., RN, CNII
Commack, New York

Linda Giamalva, B.S.N., RN-BC, NC IV
Galveston, Texas

Sheila Goodwin, CMA (AAMA)
Kettering, Ohio

Kirstin Hettinger, B.S.N., RN, OCN
Columbus, Ohio

Traci Jakovljevic, B.S.N., RN
Mayfield Heights, Ohio

Abbey Kaler, M.S., APRN, FNP-C, CMSRN, Ph.D. Student
Houston, Texas

Amanda Kelm, B.S.N., RN, OCN
Charlotte, North Carolina

Danielle Kyrillidis, B.S.N., RN, OCN
East Hills, New York

Joan Livingstone, B.S.N., RN, OCN
Detroit, Michigan

Deborah Lorick, M.S.N./MHA, CMSRN, OCN
Lancaster, California

Carrie McMichael, RN, OCN, CRNI
Oceanside, New York

Kristen Mitchell, A.D.N.
Pittsburg, Kansas

Tiffani Morgan, B.S.N., RN
Roseville, California

Kerry O'Neill, B.S.N., RN, OCN
Irvine, California

Jennifer Pagan-Negron, RN
Elyria, Ohio

Anthony "Tony" Reynolds, RN
Hazard, Kentucky

Mayori A. Rodriguez, B.S.N., RN
Doral, Florida

Kimberly Rosencrance, B.S.N., RN, OCN
New York, New York

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

Kathy Shine, B.S.N., RN
Chandler, Arizona

Georgia Smith, M.S.N., FNP-BC
Durham, North Carolina

Jessica Smith, B.S.N., RN, OCN
Columbus, Ohio

Michelle Taylor, NP
Phoenix, Arizona

Rachel Thatcher, RN
Cleveland, Ohio

Sara White, APRN-CNS, AOCNS
Tulsa, Oklahoma

Carrie Williams, M.S.N./Ed, RN
Newport Beach, California

CURE® magazine would like to thank everyone who attended the 2023 Extraordinary Healer® award celebration!

Depression Can Impact Treatment and Survival

Depression reduces the likelihood of receiving recommended treatment, which can affect survival, according to a Kentucky-based study. *By* ALEX BIESE

PATIENTS WITH BREAST CANCER who have depression were found to be less likely to receive recommended courses of treatment and saw lower rates of survival, according to a recent study. Experts told *CURE* that these findings are consistent with the need for attention to mental health to be part of cancer care.

"There's no question that there is a high degree of depression in patients with cancer, and I do think that depression affects the course of cancer care delivered and outcomes," Dr. David Silver, a gynecologic psychiatrist with UPMC with 15 years' experience as a gynecologic oncologist, said in an interview with *CURE*.

A study of more than 6,000 patients who received a diagnosis of primary invasive breast cancer at age 20 or older (median age, 70) between 2007 and 2011, published in the journal *Cancer*, found that 4.1% (246), 3.7% (221) and 6.2% (375) of patients had persistent depression, depression pre-diagnosis only and depression post-diagnosis only, respectively.

Nearly a third (1,770, or 29.2%) of patients did not receive guideline-recommended cancer treatment, and the odds of receiving recommended treatment were 75% lower for patients with depression pre-diagnosis. There was no change in likelihood of treatment for patients with post-diagnosis or persistent depression.

Patients with depression pre- or post-cancer diagnosis were significantly more likely to see worse survival rates than patients with no depression, according to the study.

There was no significant difference in survival found between patients with persistent depression and those without depression. Those findings surprised the study's authors.

"After further investigation, we understand it's because the depression condition is often under-reported, under-diagnosed and under-managed," said co-author Bin Huang of the division of cancer biostatistics, department of internal medicine, at the University of Kentucky.

The survivorship rate, Huang said, "is actually a strong indicator that a patient's depression condition was well managed. And because they are well managed, that's why we do not see a clear difference between those patients with consistent depression and those patients without depression at all."

While the study was focused on patients with breast cancer in Kentucky, Huang said he would like to see similar studies regarding mental health conducted among other patient populations.

"As we all know, one study is not (comprehensive) — you cannot be provided your conclusive answer just based on one population-based study," he said. "Maybe this study (would) only work for this segment of (the) population, maybe just this breast cancer. We certainly need to look at more studies in

a much bigger scale and for a wider population."

Depression, Silver said, is a "sorely underrated part of the cancer patient's care, not unlike mental health care in general."

"When we're talking about patients with cancer, I think there's such a high likelihood for distress, depression, anxiety and other disorders that, if attended to during a patient's cancer care, will make their cancer care that much more palatable, that much more feasible," he said. "Because sometimes it's not even possible to get a patient through their cancer care.

Symptoms of depression include inability to motivate oneself as well as difficulty focusing, concentrating and completing tasks, Silver explained.

"When you think about what a cancer patient is up against, you realize that there are so many steps that a patient is put through in such a short period of time," he said. "There is so much pressure to be at the hospital at a certain time, to be at the infusion room at a certain time, to tolerate toxic treatments that will benefit their cancer (that are) at the same time giving them side effects that are uncomfortable.

"If a person has depression, they may have trouble getting to things on time, they may not want to leave their house. And first that can get in the way of them getting breast cancer care. … And then conversely, having cancer is a huge stressor, and a huge stressor like that will bring out more symptoms in people who have underlying diagnoses of depression and anxiety or other mental health issues."

For patients with a history of depression or mental health concerns, Huang urged discussion with care providers.

"The best approach is just to talk to their primary care physicians and work with mental health providers to come up with a plan to get better management for their depression conditions," he said.

"And also, (they should) talk to their oncologist as well, because sometimes this helps the oncologist understand the patient's decision-making. Because sometimes for oncologists, their mindset is 'provide the best care for the patient.' But in the patient's mind, the best care may not be just survival."

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

Treatment Is 'All About Precision Medicine'

Patients, Meanwhile, Need to Advocate for Themselves to Receive the Best Care

Dr. Jyoti Malhotra, who discussed targeted therapies as part of *CURE*'s Educated Patient® Lung Cancer Summit, explains how patients can make sure they receive specific, up-to-date care. *By* ALEX BIESE

WITH DEVELOPMENTS CONSTANTLY happening in the field of targeted therapies for patients with lung cancer, it's up to patients to make sure they are receiving up-to-date, precision care.

"There are a lot of new treatments targeting mutations in the tumor (that) have been approved, but the key point here is that every patient who is diagnosed with lung cancer needs to get a whole panel of mutation testing on the tumor," Dr. Jyoti Malhotra, associate professor in the department of medical oncology and therapeutics research and director of thoracic medical oncology for City of Hope Orange County, told *CURE*.

Specific mutated genes and proteins that help cancer cells survive and grow are targeted by drugs known as targeted therapies, Malhotra explained during a talk on the topic as part of *CURE*'s Educated Patient Lung Cancer Summit.

"The field of lung cancer treatment has really transitioned," Malhotra told *CURE*. "Now it's all about precision medicine, meaning it's all about understanding each patient's tumor and know(ing) precisely what changes have happened in that patient's tumor so that we can tailor our treatments not for lung cancer in general, but (for) what every patient's tumor has, and be very precise in our treatment approach."

Malhotra advises patients to try to get the work-up analysis of their cancer finished as soon as possible so treatment can be started quickly and to receive a thorough assessment of their disease and tumor using sequencing and genetic testing.

Then, she said, patients should seek expert opinions and consider enrolling in a clinical trial for access to novel treatments.

"It's very important to be an advocate for yourself, asking for better treatments, starting treatment quickly and learning as much about the tumor as possible," she said.

Erlotinib – an epidermal growth factor receptor type 1/epidermal growth factor receptor (HER1/EGFR) tyrosine kinase inhibitor – made waves when it was approved by the Food and Drug Administration in 2004 to treat locally advanced or metastatic non-small cell lung cancer.

"That was really the first time when we started seeing these great responses with using targeted therapy," Malhotra said.

Targeted therapies have been on the table for nearly 20 years but their growth has expanded rapidly more recently.

"In the last five years or so this has really accelerated," she said. "Because in the first 15 years … maybe there were two different types or groups of targeted therapies approved. But in the last five years, there are more than eight to 10 different targets for which appropriate treatments are now approved and more to come within the next year."

WHAT WAS THE DRIVER BEHIND THAT RAPID EXPANSION?

"It was really about awareness as we started seeing the improvement in outcomes because targeted treatments are better than the other standard-of-care treatment options such as chemotherapy, they have fewer side effects, (are) better tolerated, have longer and more durable clinical benefit," Malhotra said. "And as molecular testing is getting more and more accessible to patients, we are seeing more and more patients using these treatments, which has made a significant improvement. The overall survival from lung cancer has gone up in the last decade, which is very encouraging."

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Non-English-Speaking Patients

With Cancer Face Big Barriers to Care in the U.S., But Help Is Available

For patients who don't speak English, there can be additional obstacles during their cancer journey. Resources, family, care providers, fellow patients and the law are on their side.

By ALEX BIESE

During his cancer journey, Lin Qiao felt "very, very safe" thanks to one particular member of his care team: his daughter, Sabrina.

In the spring of 2016, Lin was hospitalized for an aortic dissection while Sabrina was a freshman at the University of Pennsylvania. A follow-up CT scan that August revealed a mass on his kidney. He received a diagnosis of renal cell carcinoma and he underwent a partial nephrectomy the following June.

Lin, a Chinese immigrant living in Pennsylvania, was one of the approximately 145,000 people with limited English proficiency (LEP) who receive a cancer diagnosis in the United States each year, according to a study published in *JAMA Network Open*. Sabrina, who was 19 at the time of her father's cancer diagnosis, served as the interpreter between him and his care team.

Speaking with *CURE* via email, Lin says Sabrina's involvement in his experience with cancer was important. "My daughter's knowledge and help about medicine made my experience easier and made me feel that I was in better hands," he said. »

AGNE SOPYTE

SABRINA QIAO served as an interpreter for her father, who received a diagnosis of renal cell carcinoma in 2016.

> *It was extremely emotionally taxing in terms of just the fear and the general worry.*
> — *Sabrina Qiao*

Sabrina, who was familiar with the medical system as she had dealt with autoimmune disease in high school and had routinely translated documents for her parents, says she slipped into the role of her father's medical interpreter easily.

"After my father got sick, and it was a terrible, very traumatic thing for our family, this was just such a natural kind of overflow into how we would go about doing things," she says.

'NO ONE'S DOING A PATIENT *a favor*'

English-speaking and non-English-speaking patients reported having experienced similar barriers to care — including long times to schedule care appointments, confusion over whom to contact for after-hours medical issues and difficulty accessing specialists because of costs — in a study of colorectal cancer survivors published by *BMC Primary Care*.

But that same study found that non-English-speaking participants described additional difficulties, including uncertainty about treatment as well as knowing where and when to seek follow-up care, perceived discrimination and reluctance to impose on interpreters' time.

Patients with limited English proficiency, according to a study published in the *Clinical Journal of Oncology Nursing*, experience delayed cancer diagnoses and often receive inadequate treatment, have limited understanding of the medical system and are not relayed information in their language about their cancer and treatment.

"From the moment a patient is interacting with the check-in staff, the nurse or physician to the calls they receive for appointments and scheduled procedures, having somebody not understand the language adequately can be a big barrier. The problem also falls with the health care system if they don't have staff that can communicate with the patient properly," says Dr. Cesar Rodriguez Valdes, associate

AGNE SOPYTE

professor of medicine at the Icahn School of Medicine at Mount Sinai and in 2022 the inaugural recipient of *CURE*'s Multiple Myeloma Health Equity Hero award.

That language barrier, he explains, extends beyond the patient's direct interactions with their provider.

"We need to keep in mind that language can also be a barrier for making appointments, (speaking to) answering services, (coordination of) ancillary care, and financial, social worker and other departments within the health care system that should be equipped to have either somebody fluent in that language or a translating service that can help assist," he says.

Federal law, however, is on patients' side.

"What is important is that patients understand their rights regarding medical interpreters. No one's doing a patient a favor by bringing an interpreter into the room; that provider or medical system is not able to provide a reimbursable service without providing clear communication via interpreter services for LEP individuals," says Dr. Estelamari Rodriguez, associate director of community outreach-thoracic oncology at the University of Miami Sylvester Comprehensive Cancer Center and 2022 recipient of *CURE*'s Lung Cancer Heroes® award.

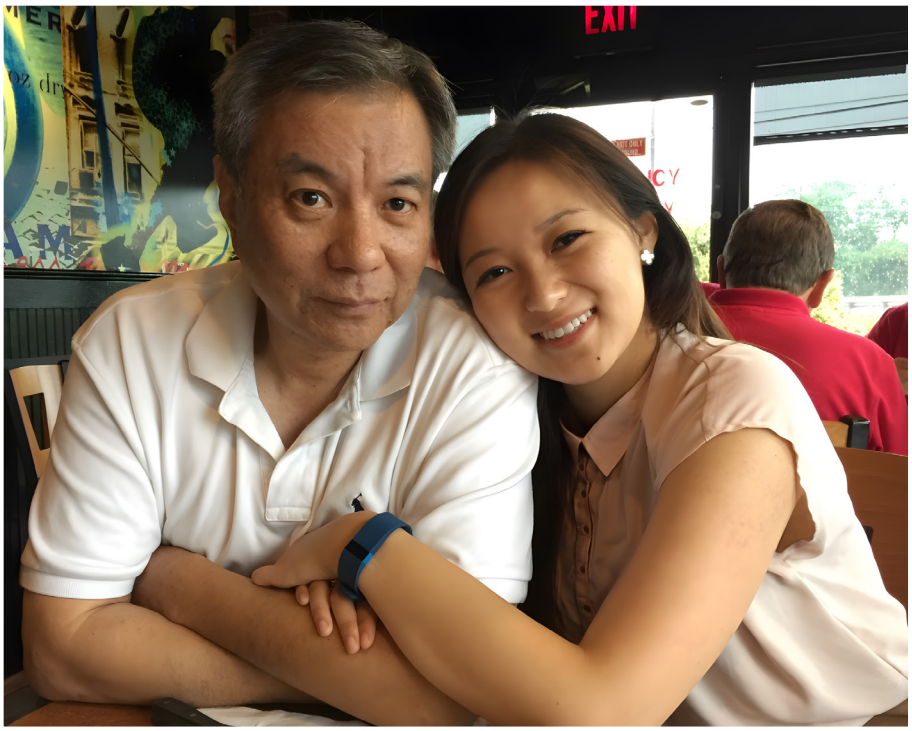
Title VI of the Civil Rights Act of 1964, as the *Clinical Journal of Oncology Nursing* study explained, mandates that interpretation services be provided to patients with limited English proficiency and that health care providers receiving federal funding provide equal care access for those patients.

The United States Department of Health and Human Services' National Culturally and Linguistically Appropriate Services Standards mandate that health care organizations offer language assistance at no cost to patients, while the Affordable Care Act recommends linguistically appropriate patient education documents and signage and offers funding for hospitals to provide qualified interpreters, according to the study.

"I would hope patients will have someone in their family who will demand interpreter services when needed," Rodriguez says. "Because you might see the clinic struggling to set it up, but that's a systems problem if the hospital is not set up to provide free-of-charge medical interpreters or have the technology to provide it by phone or computer. They have to fix that — and you have to call them on it."

Additionally, there are patient advocacy organizations such as Global Resource for Advancing Cancer Education, which provides informational videos in English, Spanish and Mandarin, as well as Latinas Contra Cancer, which offers Spanish-language services such as support groups and patient navigation. Various translation services are accessible online and there is multilingual information on the websites of the National Cancer Institute, the Centers for Disease Control and Prevention and the American Cancer Society.

"There are resources with translators online, (such as) using videoconferences that you can do (in) real time and they will translate for you," Rodriguez Valdes says. "There are also translators by phone that are located in either other parts of the country or other parts of the world that can translate real time. And then there's a lot of new apps and gadgets that can help you translate on the spot, whether it be text, or give you words in a different language. These are great resources, »



TURNING TO FAMILY FOR HELP

"My daughter's knowledge and help about medicine made my experience easier and made me feel that I was in better hands," says Lin Qiao.

PHOTO PROVIDED BY SABRINA QIAO

ZULMA ZORAIDA LIMAS RODRIGUEZ volunteers with the UW Health Breast Center Patient Survivor Advocates program.

and that's really helped facilitate the care to patients who do not speak English – but they still have their limitations."

Factors such as interruptions due to interpretation or differences in dialect can affect the information exchanged between patient and provider, he says.

ENLISTING THE HELP *of* FAMILY MEMBERS?

Lin, now 65, said he believes his daughter's role in his cancer journey brought them closer together.

"I never doubted that my daughter translated the wrong thing," he says.

He can't recall any frustrations caused by relying on his daughter for medical interpretation and says he would tell other patients with cancer that children who can do so "are the best bet in terms of translating."

The doctors *CURE* spoke to, however, say that enlisting family members to serve as

I am afraid. But I do try to be positive and to help other people.

— Zulma Zoraida Limas Rodriguez

ONLINE RESOURCES ARE AVAILABLE

FOR NON-ENGLISH-SPEAKING PATIENTS AND THOSE WITH LIMITED ENGLISH PROFICIENCY.

Global Resource for Advancing Cancer Education
provides informational videos in English, Spanish and Mandarin
» cancergrace.org

Latinas Contra Cancer
offers Spanish-language services such as support groups and patient navigation
» latinascontracancer.org

The National Cancer Institute's
website is available in both English and Spanish
» cancer.gov

The Centers for Disease Control and Prevention
is available in both English and Spanish, with information accessible in several additional languages
» cdc.gov

The American Cancer Society
website is available in both English and Spanish, with informational PDFs in several additional languages
» cancer.org

medical interpreters is generally not providers' preferred route, for multiple reasons. Certified interpreters are also required in certain settings, limiting some people, including family members or friends, from performing those duties.

"At the at the end of the day, it comes down to patients feeling empowered to demand that a translator is in the room," Rodriguez says. "Patients can choose to bring a family member in the room to help with translation but that can be problematic in some cases. When we are discussing sensitive issues like prognosis, sexual history, end-of-life care, patients may not be comfortable with the family members in the room. "So we don't really rely on family members to be medical interpreters. It's not the right thing to do."

Relying on family members for interpretation during a cancer journey also takes its toll on the loved one doing the interpreting, as Sabrina, now a Manhattan-based writer, can attest.

"It was extremely emotionally taxing in terms of just the fear and the general worry," she says.

"I really structured my entire days around my father," Sabrina explains, "not necessarily just the running to appointments in between classes … but just the mental toll it would take, to be in class and know that OK, well, he has a scan next week or he has a scan tomorrow and then what do we need to prepare? Am I going to be prepared to interpret these findings afterward and am I going to be able to relay the information to him?

"Because at a certain point also I remember having a conversation with my mom where she was like, 'I know that you are scared. But every time he sees you worried, it worries him.' And (I was) trying to regulate that as well, which I could understand but it was also extremely difficult for me not to worry."

'I JUST WANTED TO *LIVE*'

Zulma Zoraida Limas Rodriguez speaks only a little English. But when she received a diagnosis of breast cancer in 2014, she didn't »

SHARON VANORNY

ZULMA ZORAIDA LIMAS RODRIGUEZ received a diagnosis of breast cancer in 2014. Her mother died of cancer, and she said her father, who has cancer, is "beyond recovery."

SHARON VANORNY

care that she had to speak to her care team through a Spanish-to-English interpreter.

"I just wanted treatment," Rodriguez tells *CURE* through an interpreter. "I really didn't care whether the translators heard personal things because, of course, it's a very personal thing. I just wanted to live so I didn't care about what I had to do."

Rodriguez, who lives in Wisconsin, underwent surgery to have both breasts removed, followed by chemotherapy in 2015, as a patient of UW Carbone Cancer Center.

Now 51, she has a family history of cancer.

"I am afraid, and there are times when I am overcome with fear because my mother died of cancer and my father has cancer. He is beyond recovery," she says. "And every time I see a person who is ill with cancer, I am afraid. But I do try to be positive and to help other people."

She is now offering fellow patients the sort of help — and companionship — she wishes she'd had when beginning her cancer journey nearly a decade ago. She now volunteers with the UW Health Breast Center Patient Survivor Advocates program.

"I did have a problem in that I didn't know any other patients who were going through this," she says. "I didn't know what was going to happen in terms of the chemotherapy. And so now I volunteer to help women with cancer talk about the experience and I'm very happy to be able to help them."

Vital support, it turns out, can come from connections between patients, especially if they have common bonds.

"Sometimes, by going to support group meetings, (patients) may be able to meet a friend that you know is bilingual, and may help them also navigate the process," says Dr. Cecil Benitez, who works in the radiation oncology department of UCLA Health.

"But I always think it's a good idea to — just because you don't know the language, it doesn't mean you can't speak up for yourself — find someone who will listen and ask for those resources," Benitez says.

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After a single treatment of Keytruda for endometrial cancer, **STEPHENIE BLACK-GRANT** was able to breathe better, didn't need morphine for pain and was able to lie down again.

JESSICA FRIEND

TREATMENT *BREAKTHROUGHS*

Immunotherapy Comes *for* Advanced Endometrial Cancer

Treatments have progressed and improved with the use of immunotherapy with chemotherapy.

By KATHERINE MALMO

In November 2021, **Stephenie Black-Grant**, a 50-year-old artist who lives in Orlando, Florida, was in Iowa caring for her father when she found a lump at the base of her neck near her collarbone. She soon learned she had a recurrence of the endometrial cancer that had been diagnosed years before. Her doctors planned to start this round of treatment with radiation followed by the immunotherapy drug Keytruda (pembrolizumab).

But the medical center's radiation department was running behind and while it was able to map her egg-sized tumor, it couldn't schedule her treatments. Finally, her doctor decided to start Keytruda while they waited.

"Before my second (Keytruda) treatment," Black-Grant says, "the doctor comes into the exam room, she's on her laptop while asking me questions about how I'm feeling. And me and the nurses are grinning because you can barely see the lump in my neck. So I was just waiting. She finally looks up and she almost falls off the freaking stool. It was hilarious. And I'm laughing. And when I laugh really hard, I still cough. So we are all just laughing and coughing and laughing." »

Before my second (Keytruda) treatment, the doctor comes into the exam room … and me and the nurses are grinning because you can barely see the lump in my neck.

— *Stephanie Black-Grant*

Black-Grant was already able to breathe a bit better, didn't need morphine for her pain and was able to lie down again. She knew that at the very least, they'd have to remap the tumor if they planned to do radiation because it was much smaller. This was all from a single treatment of Keytruda.

Black-Grant's experience is the result of some exciting new drugs and studies that are bringing about a shift in how doctors treat advanced endometrial cancer.

SYMPTOMS, DIAGNOSIS *and* TREATMENT

According to Dr. Linda R. Duska, gynecologic oncologist and professor of obstetrics and gynecology at the University of Virginia in Charlottesville, endometrial cancer is the most common gynecological cancer and is almost always symptomatic. It's usually caught in the early stages by bleeding, staining or vaginal discharge in postmenopausal women and heavier bleeding or intermittent bleeding in premenopausal women. Cancers confined to the uterus can almost always be cured with surgery and radiation therapy.

Dr. Brian Slomovitz, director of gynecologic oncology at Mount Sinai Medical Center in Miami Beach, Florida, and professor at Florida International University, and the Uterine Cancer Clinical Trial Lead for GOG Foundation/GOG Partners, says symptoms of

JESSICA FRIEND

advanced disease can include pelvic pain, abdominal swelling and an early sense of satiety or fullness.

An endometrial cancer diagnosis usually includes a uterine biopsy or sampling from a dilation and curettage procedure. Then the doctor may recommend scans to determine whether tumors have spread outside the uterus. If so, these patients receive a diagnosis of advanced disease.

Advanced and recurrent endometrial cancer cases have historically been treated with chemotherapy – combination carboplatin/paclitaxel – and in some patients, trastuzumab and hormonal therapy.

Black-Grant's story started 21 years earlier, in 2000, when heavy menstrual bleeding led to a diagnosis of uterine polyps that were treated with a dilation and curettage (D&C) procedure and progesterone tablets.

Then in 2017, Black-Grant began having pelvic discomfort and abdominal pressure. She started spotting, but her periods were still regular so she brushed it off. In 2020, her gynecologist performed a hysterectomy and removed three fibroids and a sizable uterine tumor. She received a diagnosis of stage 3, grade 3 advanced endometroid adenocarcinoma and had six months of chemotherapy as well as internal and external radiation that she described as painful and hard on her body.

THE FINDINGS

According to Dr. Ramez N. Eskander, gynecologic oncologist and associate professor at the University of California San Diego, things began to change in uterine cancer research in 2013 when scientists began to understand the various subtypes of endometrial cancer. Among the discoveries, they found that certain tumors were categorized as hypermutated or mismatch repair deficient (dMMR) while others were less mutated or mismatch repair proficient (pMMR). Approximately 30% of endometrial cancers are dMMR, according to a study published in the journal *Cancers*.

In 2015, Eskander says Dr. Dung Le of Johns Hopkins Medicine presented a pivotal study that showed a type of immunotherapy medication called a checkpoint inhibitor (Keytruda) worked well on colon cancer tumors that were dMMR. Researchers hypothesized that these same checkpoint inhibitors would be effective for women with dMMR endometrial tumors.

In 2017, Keytruda received Food and Drug Administration approval for use on dMMR tumors found in any part of the body. This was big news, but what about people with tumors that were pMMR?

Duska says dMMR tumors that are hypermutated can be thought of as "hot" and pMMR tumors with fewer mutations as "cold", implying that the higher number of mutations and resulting protein alterations can better stimulate the immune system and make immunotherapy more effective. Since we know that Keytruda works on hot tumors, we need to make cold tumors hot so that Keytruda works.

"There are different ways you can make a cold tumor hot," Duska says. "You could do it with anything that disrupts the tumor's microenvironment (the neighborhood of cells in which the tumor lives). So that can be radiation, chemotherapy or you could do it with a tyrosine kinase inhibitor, which is what lenvatinib (Lenvima) is."

LENVIMA PLUS KEYTRUDA

Dr. Vicky Makker, medical oncologist at Memorial Sloan Kettering Cancer Center in New York, was the lead author on the KEYNOTE-775 trial for patients with advanced endometrial cancer who had experienced a recurrence after prior chemotherapy.

Half these patients received additional chemotherapy alone and the other half received Keytruda and Lenvima without chemotherapy. Overall, Keytruda plus Lenvima reduced the risk of disease progression by 44% and the risk of death by 38%. This worked for patients with dMMR or pMMR tumors.

According to Slomovitz, this shows that immunotherapy can be used in all patients with endometrial cancer as a second-line treatment after progressing on prior chemotherapy. "Based on these studies, we need to investigate whether, at least in some patients, if immunotherapy can be moved to the first line," he says.

KEYTRUDA *plus* CHEMOTHERAPY

In March 2023, the results of the NRG-GY018 trial, led by the National Cancer Institute with Eskander as lead author, were released. In the study of patients with advanced-stage endometrial cancer, one group started chemotherapy plus placebo. The other group received chemotherapy plus Keytruda.

The study found that 30% of the patients had dMMR tumors and of that group, 74% who received Keytruda were alive without progression of their cancer 12 months later while only 38% of the placebo group could say the same. But that wasn't all. They also looked at the results for patients with pMMR tumors.

"Not only did we see a paradigm shift in the (dMMR) patients with that 70% reduction," Eskander says, "but even in the (pMMR) patients, we saw statistically significant and »

clinically meaningful improvement in progression-free survival with a 46% reduction in the risk of disease progression or death."

Around the same time, the RUBY study results were released at the European Society for Medical Oncology Virtual Plenary. This similar study found that using immunotherapy and chemotherapy for the treatment of advanced endometrial cancer previously treated with chemotherapy significantly improved progression-free survival (the time during and after treatment when a patient with cancer lives with the disease without worsening).

Eskander says the next step is to incorporate immunotherapy with chemotherapy-naive patients at initial diagnosis.

THE TREATMENT SHIFT

"Both RUBY and GY-018 were game-changing trials," Slomovitz says. "Statistically, the results are some of the most convincing that we have seen in gynecologic cancers, ever. Not only were the results presented at major conferences on the same day, but they were also published in *The New England Journal of Medicine* simultaneously. As far as medical breakthroughs go, you can't get better than that. We're looking forward to FDA approval to incorporate immunotherapy in the first-line management for women with endometrial cancer."

Trials such as LEAP-001 will determine if doctors can use a combination of Keytruda and Lenvima instead of chemotherapy for first-line management.

> *Both RUBY and GY-018 were game-changing trials. Statistically, the results are some of the most convincing that we have seen in gynecologic cancers, ever.*
>
> *—Dr. Brian Slomovitz,*

THE FUTURE

One study Slomovitz is watching is the LEAP trial that will determine whether Keytruda and Lenvima, the combination that is approved in the second-line setting, works better in a first-line setting than chemotherapy. Researchers are also investigating whether patients with dMMR tumors can be treated with Keytruda alone in the first-line setting and whether there are any biomarkers that would indicate who benefit from such treatment.

Duska expresses some caution. "We were all very excited about the results from these trials," she says. "It's wonderful news for the MMR-deficient group for sure. In the MMR-proficient group, I think we still need to wait for the mature overall survival (the time from treatment until death of any cause) data from RUBY. I think we need to wait to see what things look like when we move immunotherapy into the front line instead of chemo. And then we need to think carefully about how we're going to use immunotherapy in the second line if we've already used it in the first line."

SIDE EFFECTS *of* IMMUNOTHERAPIES

Black-Grant said the Keytruda did make her extremely tired, and she had frequent nausea, which was new for her. She also had some digestive and bowel issues that weren't unusual but had become more bothersome. One side effect she really struggled with was itchy rashes.

"The side effects for immunotherapies, the checkpoint inhibitors, are well tolerated," Slomovitz says. "Sometimes they can cause immune-related types of side effects like colitis, diarrhea or thyroiditis or cystitis, but in general they're pretty well tolerated."

Valerie Smith, a pseudonym to protect her privacy, was diagnosed with stage 3 clear cell advanced endometrial cancer in 2019 when she was in her late 50s, after years of symptoms and illnesses that required frequent doctors' visits and painful procedures. She had surgery in February 2020 and underwent six chemotherapy treatments in the early days of the COVID-19 pandemic.

"It was overwhelming," Smith says. "With mandatory isolation I was stripped of my ability to socially engage. I was experiencing isolation and a life-threatening event. It was traumatic."

Smith says chemotherapy brought the usual side effects and hit her with nausea and vomiting that was hard to control even with antinausea meds.

Then she had 28 rounds of radiation that left her with the "most horrendous UTI (urinary tract infection) I've ever experienced." She couldn't even stand up to get to the medical center to provide a sample.

THE UNMET NEEDS

The one group that continues to be difficult to treat is women with high-risk histologies including uterine serous cancers and carcinosarcomas, Slomovitz says.

"Even though we're getting better in the first-line management of all women with endometrial cancers," Slomovitz says, "We still have very limited treatment options for those women with the aggressive histologies. And we find those types of histologies are more likely to affect Black women. That may be one of the reasons why, in fact, Black women are more likely to die of this disease. We are committed to finding better treatment options for all women and to overcome disparities in our treatment options."

Smith is one of these women. "No, the immunotherapies are not warranted in my case if there is a recurrence," Smith says.

Finding out why Black and Hispanic women are more likely to receive a diagnosis of advanced or recurrent stage disease with high-risk histologies is something that Duska believes researchers need to explore further and understand so they can address the disparities. This is most likely to be done by helping Black and Hispanic women enroll in clinical trials.

Supporting OTHER WOMEN

Black-Grant never needed radiation the second time around. These days, she sees her oncologist a few times a year for scans that show she is still clear of disease.

Both women, Black-Grant and Smith, are active with the Endometrial Cancer Action Network for African-Americans (ECANA) and part of the Sister Study, which provides peer support to African-American women in treatment for endometrial cancer. Black-Grant is also on the ECANA board.

Smith is doing her best to recover physically, emotionally and financially. She wants all women to know that a cancer diagnosis isn't anyone's fault and that they should make sure they are receiving the best care possible.

"Because I didn't know what I was doing at the onset," Smith says. "And this was a total, total surprise. I did not receive the best care at the onset, so I had to become my own advocate, which is not an easy task."

Lining Up New Options

Patients with GIST have more treatment options than ever, with others currently under development.

By SONYA COLLINS

On a summer Sunday in 2011, **Lee Keenan** competed in the Pleasant Prairie Triathlon in Wisconsin. At 42 years old and having completed numerous triathlons, he was in fighting shape. This time around, he decided not to focus on speed and instead just to have a good time. And that he did.

Back at home that afternoon, just over the state line in Illinois, he had energy left to man the grill at a cookout.

"It was a great day. I enjoyed the race and had a lot of fun," says Keenan, now 54.

But Monday morning, he woke up with such intense abdominal pain that he thought he had torn something in the race. Over the next couple of hours, the pain only got worse. He got in to see his doctor that day. After an ultrasound, the doctor sent Keenan to the hospital for a CT scan. That was when they found a mass. »

«

Former triathlete **LEE KEENAN** has been treated for gastrointestinal stromal tumors (GIST) with Qinlock for more than a year.

PHOTOS BY ARIELLE GALLIONE

"Do I have cancer?" "I didn't even know what an oncologist was," Lee Keenan says of when he received his diagnosis. "My wife and I looked up the word 'oncologist' on our phones. When he came back into the room, I asked him, 'Do I have cancer?'

> *A lot of the medicines I've taken weren't even available when I first got GIST. The last three didn't even exist at that time.*
>
> — *Lee Keenan*

Doctors took a biopsy, told Keenan it was benign and scheduled a surgery to take it out. As he lay in the hospital recovering from the removal of the mass, an oncologist came into the room and introduced himself.

"At this point in my life, I didn't even know what an oncologist was. My wife and I looked up the word 'oncologist' on our phones. When he came back into the room, I asked him, 'Do I have cancer?'"

He did. Keenan had a gastrointestinal stromal tumor, or GIST, but the doctor explained that his prognosis was great. This cancer typically did not metastasize. Keenan would take medication, go in for annual scans to ensure the cancer hadn't returned and live a long life, the doctor told him.

ARIELLE GALLIONE

The next three years on Gleevec (imatinib), the treatment doctors typically prescribe first for GIST, were uneventful, Keenan says. He had no side effects from the drug and his routine scans were clear – until a scan revealed a new tumor.

After another surgery to remove the tumor, he remained on Gleevec for a few more years, until he had to have another tumor removed. Keenan's doctor, Dr. Mark Agulnik, section chief of sarcoma medical oncology at City of Hope in Duarte, California, then put him on Sutent (sunitinib), which he remained on until a new growth required another procedure. From there, he qualified for a clinical trial that compared Ayvakit (avapritinib) to Stivarga (regorafenib). He started on Stivarga then moved on to Ayvakit. After progressing on Ayvakit, Keenan started taking Qinlock (ripretinib).

"A lot of the medicines I've taken weren't even available when I first got GIST. The last three didn't even exist at that time," Keenan says.

The many options that have been available to Keenan reflect the dramatic advances that have taken place in GIST treatment over the last decade. This progress has been possible, in large part, because the role that driver mutations play in GIST is among the most well understood of solid tumors and one of the first that was amenable to a dramatic anti-cancer treatment effect from drugs designed to specifically target the mutations.

Over the last 10 years, five options have been added to the treatment arsenal, including new drugs and additional indications for existing drugs. This decade of progress culminated with two new drug approvals in 2020. Qinlock earned approval from the Food and Drug Administration (FDA) for inoperable or metastatic GIST after progression on the three existing GIST drugs Gleevec, Sutent and Stivarga. Ayvakit also got the nod from the FDA, which made it the first therapy for patients with the multidrug-resistant PDGFRA D842 mutation.

"Each additional option we have for treatment of these cancers adds time that we are able to control the growth and spread of these tumors, which buys people more time," says Dr. Andrew Brohl, a medical oncologist who treats patients with GIST at Moffitt Cancer Center in Tampa, Florida.

TYROSINE KINASES – THE KEY TO GIST TREATMENT

Targeting tyrosine kinase has long been the approach to treating GIST. First-line therapies Gleevec, Sutent and Stivarga are kinase inhibitors.

Tyrosine kinases are chemical messengers that control how cells grow and divide. Doctors often liken them to an on-off switch for the process of cell growth and division. When they are on, the cell divides and produces another cell.

"Normally, in GIST, the kinase is mutated. That is, it's always turned on," says Dr. Margaret von Mehren, chief of sarcoma medical oncology at Fox Chase Cancer Center in Philadelphia and an investigator on the INVICTUS trial, which led to FDA approval of Qinlock.

A metabolite called ATP (adenosine triphosphate) flips the switch on by attaching — or "binding" — to the kinase. The three kinase inhibitors for GIST bind to the kinase where ATP is supposed to latch on. In effect, the drug molecules take ATP's spot and prevent it from flipping the switch on.

Doctors typically start patients on Gleevec, switch them to Sutent if needed and then Stivarga.

WHEN TUMORS FIND A **WORKAROUND**

These first- through third-line kinase inhibitors work for a time, but eventually cancer cells come up with a way to outsmart them.

"Once people progress on Gleevec, Sutent or Stivarga, we find they have developed additional, secondary mutations that alter the structure of the kinase and prevent these other drugs from binding," von Mehren says.

These secondary mutations – that is, new mutations that develop in the tumor as it becomes resistant to a drug – are typically in the KIT or PDGFRA genes located on what's called the activation loop of the kinase. Simply put, the activation loop allows the kinase to put itself in the on position.

Qinlock and Ayvakit have a different structure that allow the drug to target the altered kinases encoded by gene mutations that make the tumors resistant to first-line drugs. By acting on the activation loop, these drugs prevent the cancer-promoting kinases from getting into the position that would allow the kinase to switch to on.

QINLOCK TARGETS *TWO* COMMON RESISTANCE MUTATIONS

Qinlock targets both KIT and PDGFRA mutations. Based on the results of the INVICTUS trial, the drug earned FDA approval for people who had progressed on three or more prior kinase inhibitors.

In the trial, the drug extended progression-free survival (the time during and after treatment when a patient lives with the disease without worsening) by a median 6.3 months compared with one »

After eight months on Ayvakit, **BRIAN GILHOOLY** was ready for surgery.

ARIELLE GALLIONE

month on placebo. The overall response rate (the percentage of patients with a partial or complete response to treatment) was 9% and overall survival (the time from treatment until death of any cause) was just over 15 months compared with about six months in the placebo group.

"Ripretinib is a very good drug for many types of GIST tumors as it affects a broad spectrum of mutations," von Mehren says.

Qinlock seems able to block some mutations that other drugs do not: KIT mutations in two distinct locations on the gene – exons 17 and 18.

After progressing on numerous other drugs, Keenan has been taking Qinlock for almost 16 months. "I feel very lucky," Keenan says. "It's been effective at reducing the size of the growths. It's been very good."

He's scheduled for another scan in June to ensure that the drug continues to do its job. In the meantime, the former triathlete continues to live an active life. "Like a lot of people in my group of friends, I put the running shoes away around age 47 and biking is now my main way to exercise."

AYVAKIT BEATS A TOUGH MUTATION

While Keenan has always had another drug to move on to, for one particular group of patients, no drug seemed to work.

"A primary PDGFRA mutation known as D842V was resistant to all the drugs from the get-go," says Dr. Michael Heinrich, a professor of medicine at Oregon Health & Science University Knight Cancer Institute in Portland. "We tried different things but none of them ever worked, so we had to go back to the test tube."

In the development of Ayvakit, intended to be a KIT inhibitor, researchers learned that it seemed to block this less common mutation as well. Expanding the search for trial participants to sites around the world, the NAVIGATOR trial, which included Heinrich as an investigator, began to enroll patients with the D842V mutation.

In the clinical trial, most patients with a PDGFRA mutation on exon 18 responded to the drug. The highest response rate was among people with a D842V mutation.

Shortly after 53-year-old **Brian Gilhooly** received a diagnosis of GIST in October 2021, he learned he had this once-drug-resistant mutation. His doctor at Loyola Medicine in Maywood, Illinois, told him he wouldn't respond to first-line Gleevec and that he would be taking Ayvakit instead.

But Gilhooly didn't like the sound of this new drug.

"They say it can affect your brain — your memory and cognition," Gilhooly says.

Gilhooly traveled to Portland to get a second opinion from Heinrich, who agreed that Ayvakit was the best option.

"The key to managing these neurocognitive side effects is early recognition of them, modifying the dose, and doing dose interruptions," Heinrich says.

> *(Ayvakit) was harsh, but it killed off the tumor.*
>
> — *Brian Gilhooly*

It was decided. Gilhooly would take the drug until it shrank his tumor enough for surgery. In the end, he never had to worry about cognitive problems. After eight months on the drug, he was ready for surgery.

But Gilhooly did still get his fair share of side effects. The whites of his eyes turned yellow because of elevated bilirubin, a yellow substance the body produces during the breakdown of old red blood cells. His red blood cell count plummeted, too.

"The drug was harsh, but it killed off the tumor," he said. "When they removed it, they said it was 90% necrotic, only 10% viable."

The surgeon managed to remove the entire tumor and Gilhooly was up and walking the same day. Now, more than 18 months later, his first two post-surgery scans showed no evidence of disease. He'll continue to get scans every four months. His next one is scheduled for July.

THE *WAY* FORWARD

As the treatment arsenal for GIST expands, researchers are learning the nuances of each. Not only do the current drugs target specific gene mutations, but each seems »

LOOKING FORWARD: More than 18 months later, Brian Gilhooly's first two post-surgery scans have shown no evidence of GIST.

to be more effective against mutations at different locations in the tumor's DNA.

Sutent, for example, works especially well in patients whose tumors develop resistance mutations in KIT on exons 13 and 14. Qinlock, on the other hand, does its best work in people who have primary mutations at exon 11 and secondary ones at 17 and 18.

This knowledge may drive changes in how doctors make treatment recommendations.

"We are moving toward being able to choose which option we use for a patient based on the genetics of their tumor as some drugs are more or less effective depending on the genetic characteristics of the tumor," Brohl says.

The deeper understanding of these molecular differences is driving further research, too.

Deciphera, the maker of Qinlock, is planning a trial for patients who have developed resistance to Gleevec. They will be treated with Qinlock or Sutent based on their tumor's DNA.

"This is the first biomarker-driven study we've ever done in GIST," Heinrich says. "I expect patients would be very interested in this." At the same time, he adds, "Another approach is to try to be more holistic by inhibiting mutations in either 13/14 or 17/18. Currently our drugs can inhibit one class but not the other – for example, 13/14 but not 17/18 or the other way around."

Cogent Biosciences is sponsoring the phase 3 PEAK trial for patients who are resistant to Gleevec. It will compare second-line Sutent, which blocks mutations on exons 13 and 14, with and without a new drug called bezuclastinib, which is expected to inhibit mutations at 17 and 18. The trial's crossover design will eventually allow all patients access to the combination therapy if it gets positive results.

As most patients with GIST eventually become resistant to their treatment, the newest drugs available and in the pipeline will have a significant impact. They offer patients yet another option after resistance develops. But the persistent problem of resistance shines a light on the need for additional treatment approaches.

"There's still resistance to these drugs because they are all tyrosine kinase inhibitors that partially overlap in their mechanism of action and primarily affect the same pathways within the cell," Brohl says. "Alternate ways to enhance treatments or avoid those shared resistance pathways are still very much needed."

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'It's OK to Feel Safe'

A survivor discusses how continued minimal residual disease negativity made her feel more confident about coming off maintenance therapy. *By* BRIELLE BENYON

AFTER UNDERGOING TREATMENT — including a stem cell transplant — for multiple myeloma, Tiffany Williams was put on maintenance Revlimid (lenalidomide) to prevent the disease from coming back. After six years of Revlimid, she was able to come off the drug because minimal residual disease (MRD) testing showed that she had no traces of cancer in her body.

"Over time, I realized that it's OK to breathe. It's OK to feel safe," Williams, a 55-year-old retired nurse practitioner and mother of two, said in an interview with *CURE*. "I started to feel like it was OK to enjoy time off of meds."

> Over time, I realized that **it's OK to breathe.**
>
> –TIFFANY WILLIAMS

MRD testing is a process in which clinicians look at either blood or bone marrow cells to see if there are any leftover traces of cancer. For Williams, who received the myeloma diagnosis in November 2013, MRD testing was part of a scheduled bone marrow biopsy while she was on maintenance therapy.

The results from the procedure can lend insight to long-term outcomes for patients with blood cancer. Those who test positive for MRD may be more likely to experience cancer growth or recurrence than those with MRD negativity.

However, coming off maintenance treatment, which is offered only to patients with myeloma who underwent a stem cell transplant, can bring its own stressors. In fact, after Williams' first test came back MRD negative, she stayed on Revlimid for another year.

"For the first (MRD testing) I had, (my negative status) was a reason to celebrate and be joyful. But at the same time, I wasn't sure if I wanted to come off therapy," she said. "I had reassurance of being on (maintenance therapy.)"

When the MRD status came back as negative again a year later, Williams felt more reassured that her cancer was gone for good and that it was OK for her to stop taking Revlimid. "It was definitely a psychological process of coming to a readiness and that it's OK to feel safe, and I don't have to be so afraid," she recalls.

Now, even though she's no longer on maintenance therapy, Williams still follows up with her health care team every three months and still undergoes bone marrow biopsies to test for MRD and other signs of myeloma. She said she will have her next one this summer.

Williams encourages others on maintenance therapy to talk with their doctors about MRD testing and whether it could change their treatment trajectory.

"I think the peace of mind it provided for me might not be for everyone," she said. "But I would encourage people to explore it, talk to their doctor about it. … If you choose to get MRD testing, the results can help you better understand the disease in total."

DAVID A LITMAN / STOCK.ADOBE.COM; PHOTO PROVIDED BY TIFFANY WILLIAMS

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Earlier Jakafi Treatment Shows Encouraging Outcomes

Sooner treatment with Jakafi showed promise in improving both survival and symptom burden in certain patients with myelofibrosis, but physicians often delay the treatment.

By BRIELLE BENYON

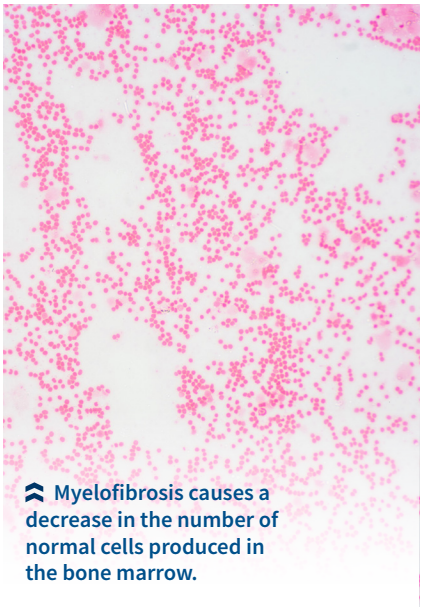
A HIGHER PERCENTAGE OF patients with intermediate-2 and high-risk myelofibrosis who were introduced to Jakafi (ruxolitinib) within a year of receiving a diagnosis saw improved survival and reduced symptom burden compared with those who were given the drug later or not at all, according to recent research published in the journal *Cancer*.

Researchers analyzed data from two clinical trials (COMFORT-I and COMFORT-II), which included a total of 525 patients with myelofibrosis, a type of myeloproliferative neoplasm.

In this patient population, 84 patients received Jakafi within 12 months of diagnosis while 216 received the drug at or after 12 months from diagnosis. Additionally, 66 patients received placebo plus best available therapy within 12 months and 159 patients received placebo plus best available therapy after 12 months.

Myelofibrosis causes a decrease in the number of normal cells that are produced in the bone marrow. As a result, the spleen starts to produce these types of cells and often becomes inflamed, indicating potentially worsening disease and putting patients at risk for infections.

"Patients with myelofibrosis, a bone marrow cancer, often do not live as long as the general population. These patients may also have an enlarged spleen and difficult symptoms such as fatigue," the researchers wrote.



Myelofibrosis causes a decrease in the number of normal cells produced in the bone marrow.

Study findings showed that at week 48, patients who received Jakafi earlier had a higher rate of spleen volume response (meaning that their spleen shrank) than those who were not exposed to the drug within a year of treatment (44% versus 26.9%, respectively).

Additionally, at a 240-week follow-up, 63% of patients who were given Jakafi early were still alive compared with 57% of those who were given the drug a year or later after diagnosis. At this time, 49.4% of patients who received placebo plus best available therapy within 12 months were alive, and 40.7% of those given placebo/best therapy at or after 12 months were alive.

The researchers also noted that on average, patients given Jakafi — regardless of whether it was within or after 12 months from diagnosis — tended to live longer than those prescribed placebo plus best available therapy.

The Food and Drug Administration approved Jakafi for intermediate- or high-risk myelofibrosis more than a decade ago, and it is recommended to be the first therapy offered for patients with the disease. However, as the study authors pointed out, Jakafi is often not the first drug given or it is not given soon after diagnosis.

"The National Comprehensive Cancer Network guidelines for myeloproliferative neoplasms recommend (Jakafi) as a first-line treatment for patients with higher-risk (myelofibrosis)," study authors wrote. "There is a compelling rationale to treat patients with intermediate- or high-risk (myelofibrosis) with (Jakafi). Despite this, real-world treatment patterns indicate that many physicians delay or avoid (Jakafi) treatment, often in favor of hydroxyurea or watchful waiting."

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Good News or Guilt: Living With Stage 4 Cancer

Is it always one or the other? Can good news in one person's cancer experience do good for the community? *By* MARTHA CARLSON

MARTHA CARLSON

I HAVE CALLED myself "lucky" too many times to count because it fills a space where there are no answers.

Why me and why not you?

To paraphrase an oncologist I respect, my living so long and so well with metastatic breast cancer is not a matter of luck, but simply a matter of biological processes.

That may be true, but it doesn't change the fact that while I am sitting over here with good news, my friends with similar or even identical diagnoses are not getting the same news. Their news, in fact, can be the exact opposite of mine.

I have been with dying friends, watched as treatment after treatment fails to deliver, heard the words "we're just watching and waiting" so many times that they reverberate in my mind.

Saying my good fortune is just a matter of biological processes is like ice to me. It minimizes the emotional depth of living with cancer and takes away hope in ways more profound than acknowledging that I am, in this one respect at least, lucky.

I didn't do anything to have this response, and you didn't do anything to not have it.

Anyone with stage 4 cancer can tell you that this diagnosis gives cancer free rein over all the mind games. There's an impolite slang term for that experience the Oxford Language Dictionary defines as "a disturbing or extremely confusing experience, in particular one that is caused by deliberate psychological manipulation."

Cancer working deliberate psychological manipulation sounds right to me. Does it sound right to you?

One of the ways it does this is through the difficult interplay between my good news and my guilt that hearing it will sting the hearts of others. Good friends have told me that hearing my experience with stage 4 cancer brings hope, and I hear that sentiment echoed on social media, too. I know there is truth to those words. But there is also truth to the pain other friends feel because our paths are so utterly different.

As I said, psychological manipulation.

There have been many times over my past eight years with stage 4 cancer that I've been silent about good scans. There have been times when someone can't see my pain because it isn't the same as theirs.

How do we share good news even when it is challenging? Should we share good news?

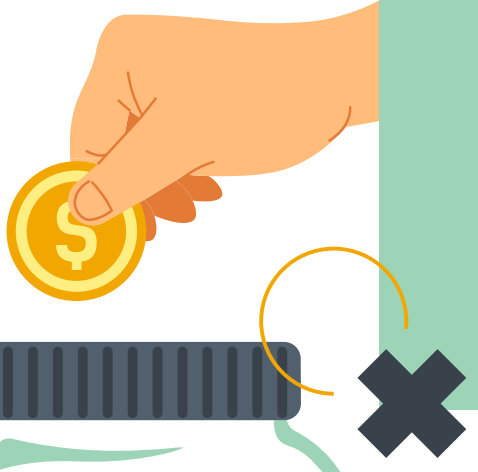
Turns out there's an easy-to-read essay by professor/author Zachary White about how sharing good news creates and strengthens community. This idea makes sense to me: "Your good news is no longer yours. It's no longer theirs. This kind of collective intimacy makes it possible for us to know that the breadth of what we are experiencing—the good and bad—is not just a reporting of what is happening, but a reminder that, though others may not be physically with us, they are always co-authors shaping what we see and notice and appreciate in ways that can sustain us during the most difficult parts of our experiences."

I want to live up to the truth of these words. I think it will probably be hard and require breathing room, this learning to both give and receive good news and bad. I have had times when I can't bear to see some people because I know they can't grasp my loss, so I think it's unfair to urge people to hear good news and simply be happy for someone else.

But for me, most simply, it's a reminder that my good news contains more than my own guilt. It may be a source of connection in a world that too often keeps us apart.

ANNI'S ILLUSTRATION BY RAY PELESKO

Pointers *for the* **Patient**



TRIAGE CANCER

A cancer advocate has tips and tricks for patients on navigating their medical bills, from insurance coverage to out-of-pocket costs and appealing denials. By KRISTIE L. KAHL

FINANCIAL TOXICITY IS A common effect that follows a cancer diagnosis; however, there are ways patients can more easily navigate their medical bills, according to Monica Fawzy Bryant, Esq.

As part of *CURE*'s "Speaking Out" video series, Fawzy Bryant, co-founder and chief operating officer of Triage Cancer, a nonprofit organization providing free legal and practical information to patient with cancer and their caregivers, offered advice for managing medical bills during a cancer journey.

Q: After receiving a diagnosis, why is it important for patients to understand their benefits? What should they look for in particular?

A: First and foremost, what people need to understand is the network of providers that are included in their health insurance policy because their coverage is really going to differ depending on if they're seeing in-network providers.

The other major piece people need to understand is their out-of-pocket maximum. Most health insurance policies have a cap on the amount that they're to pay out of pocket. And the way you get to that cap is by generally adding up everything you're paying toward your deductible, toward your co-payments and toward your coinsurance. And once you've met that out-of-pocket maximum, the insurance company is supposed to pick up 100% of costs moving forward.

Q: What are some tips for patients who have to appeal any insurance denials?

A: The one thing I'd love everyone to walk away with is the idea that they don't have to take no for an answer. So if someone receives a denial from their health insurance company, the very first thing they should do is understand how to appeal that denial. … Generally speaking, there's going to be at least two levels of appeals.

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The first is an internal appeal. And that's where you go back to the insurance company and ask them to reconsider. So maybe it's about adding more information or providing additional documentation or evidence. But even if someone does not get the approval at the internal phase, then they have the right to do what's called an external appeal. And that's where you go to an independent entity in your state. And that independent entity looks at all the evidence, looks at the plan, looks at the medical circumstances and decides if that service or prescription drug is medically necessary. And whatever that independent entity decides is binding.

Of the 200 million claims that are denied each day … we know that generally 99.9% of denied claims are never appealed. We also know that when people do appeal, about 50% of the time the decision is in favor of the patient. So it's hard, because appealing is this extra thing that we're asking people to do while they're also coping with their cancer diagnosis and the rest of life; however, it is almost always in their best interest to at least try to appeal because the insurance company may have gotten it wrong.

Q: How can patients negotiate for and advocate for themselves with insurance?

A: Asking a lot of questions is really important. It can be hard, from the patient and caregiver perspective, to understand what is their responsibility … so I think certainly asking a lot of questions. And if you don't get the answer that you need, keep asking.

The other piece and it is to stay organized. There's potentially going to be explanation of benefits and bills and tons of paperwork coming from the provider side, from the insurance company. If someone has to go through an appeal, there's going to be more paperwork. And so being really organized is going to be important in the process … because it can get a little bit overwhelming to do all of this.

The last piece … is particularly around the appeals process. People should know that at the end of the day, it is their responsibility to ask for prior authorizations and to appeal those denials. … At the end of the day, it is in fact the patient's responsibility.

Q: Do you have any financial assistance programs our patients can look into?

A: At Triage Cancer, we provide free education on all the legal and practical issues that can arise after a diagnosis, including health insurance, employment and finances. On our website, we have our resources broken down by topic and by location because sometimes where you live can impact what you have access to. So if someone goes to our resources page and goes to health insurance, for example, they will see all of our health insurance appeals information. We have videos, quick guides, checklists and tracking forms. And all of that can be downloaded on our website. We also have a number of educational events where someone can come learn live, so you can join from the comfort of your own home and the dates and registration are all available on **triagecancer.org**.

Transcription edited for clarity and conciseness.