

WINTER 2022

# cure<sup>®</sup>20<sup>TH</sup> *anniversary*

Cancer Updates, Research & Education<sup>®</sup>

## THE LASTING LEGACY OF ENVIRONMENTAL TOXINS

TOBACCO SMOKE, PESTICIDES, HERBICIDES AND CHEMICALS  
IN THE AIR ARE AMONG THE SUBSTANCES THAT  
ARE KNOWN TO INCREASE THE RISK OF GETTING SOME  
KINDS OF CANCER.

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The Discussion  
of Reconstruction  
Versus 'Going Flat'

#### LUNG CANCER

FDA Approves  
Combo Regimen  
With Chemo for  
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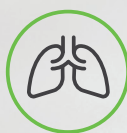
#### MYELOPROLIFERATIVE NEOPLASMS

Keeping Treatment  
Goals in Mind  
for Essential  
Thrombocythemia

curetoday.com

WINTER 2022 · VOL.21 NO.4

# KEYTRUDA IS A BREAKTHROUGH IMMUNOTHERAPY.



## FOR TODAY

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

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

## FOR THE FUTURE



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

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

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

### ➤ **KEYTRUDA + CHEMOTHERAPY, NONSQUAMOUS**

It may be used with the chemotherapy medicines pemetrexed and a platinum as your first treatment when your lung cancer has spread (advanced NSCLC) **and** is a type called “nonsquamous” **and** your tumor does not have an abnormal “EGFR” or “ALK” gene.

### ➤ **KEYTRUDA + CHEMOTHERAPY, SQUAMOUS**

It may be used with the chemotherapy medicines carboplatin and either paclitaxel or paclitaxel protein-bound as your first treatment when your lung cancer has spread (advanced NSCLC), **and** is a type called “squamous.”

### ➤ **KEYTRUDA USED ALONE, PD-L1 POSITIVE**

It may be used alone as your first treatment when your lung cancer has not spread outside your chest (stage III) and you cannot have surgery or chemotherapy with radiation, **or** your NSCLC has spread to other areas of your body (advanced NSCLC), **and** your tumor tests positive for “PD-L1” **and** does not have an abnormal “EGFR” or “ALK” gene.

### ➤ **KEYTRUDA AFTER CHEMOTHERAPY, PD-L1 POSITIVE**

It may also be used alone for advanced NSCLC if you have tried chemotherapy that contains platinum and it did not work or is no longer working **and**, your tumor tests positive for “PD-L1” **and** if your tumor has an abnormal “EGFR” or “ALK” gene, you have also received an “EGFR” or “ALK” inhibitor medicine that did not work or is no longer working.

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

## IMPORTANT SAFETY INFORMATION

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

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

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

*Important Safety Information is continued on the next page.*



**Teresa is a  
real patient**



**keytruda.com/lung**

#### **IMPORTANT SAFETY INFORMATION (continued)**

sleepiness; memory problems; changes in mood or behavior; stiff neck; balance problems; tingling or numbness of the arms or legs; double vision; blurry vision; sensitivity to light; eye pain; changes in eyesight; persistent or severe muscle pain or weakness; muscle cramps; low red blood cells; bruising.

- **Infusion reactions that can sometimes be severe or life-threatening.** Signs and symptoms of infusion reactions may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feeling like passing out, fever, and back pain.
- **Rejection of a transplanted organ.** Your health care provider should tell you what signs and symptoms you should report and they will monitor you, depending on the type of organ transplant that you have had.
- **Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with KEYTRUDA. Your health care provider will monitor you for these complications.

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

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

If you are pregnant or plan to become pregnant, tell your health care provider. KEYTRUDA can harm your unborn baby. If you are able to become pregnant, you will be given a pregnancy test before you start treatment.

Use effective birth control during treatment and for at least 4 months after your final dose of KEYTRUDA. Tell them right away if you think you may be pregnant or you become pregnant during treatment with KEYTRUDA.

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

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

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

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

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

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://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](http://www.merckhelps.com)**

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

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**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. **Rx ONLY**

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**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               | • dizziness                |
| • itching or rash                 | • feeling like passing out |
| • flushing                        | • fever                    |
| • shortness of breath or wheezing | • back pain                |

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

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

**Continued on next page.**



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

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

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

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

**Females who are able to become pregnant:**

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

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

**How will I receive KEYTRUDA?**

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

- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

**What are the possible side effects of KEYTRUDA?**

**KEYTRUDA can cause serious side effects. See “What is the most important information I should know about KEYTRUDA?”**

**Common side effects of KEYTRUDA when used alone**

**include:** feeling tired, pain, including pain in muscles, rash, diarrhea, fever, cough, decreased appetite, itching, shortness of breath, constipation, bones or joints and stomach-area (abdominal) pain, nausea, and low levels of thyroid hormone.

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

**Common side effects of KEYTRUDA when given with**

**certain chemotherapy medicines include:** feeling tired or weak, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, trouble breathing, fever, hair loss, inflammation of the nerves that may cause pain, weakness, and paralysis in the arms and legs, swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina, mouth sores, headache, weight loss, stomach-area (abdominal) pain, joint and muscle pain, and trouble sleeping.

**Common side effects of KEYTRUDA when given with**

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

**Common side effects of KEYTRUDA when given with axitinib**

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

These are not all the possible side effects of KEYTRUDA.

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

**General information about the safe and effective use of KEYTRUDA**

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

Based on Medication Guide usmg-mk3475-iv-2203r050 as revised March 2022.

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## Avoiding the Unavoidable

**IN OUR EVERYDAY LIVES**, we strive to avoid chemicals, air pollution and other toxins that may negatively affect our health. But what if we cannot escape their impact because it is a part of our occupation or even career?

Years later, people exposed to these toxins may have an increased risk for cancers, and the evidence is starting to build up. As more studies are

**“We need to learn more about how to potentially lessen (toxins’) effects on people’s lives.”**

examining the consequences of long-term exposure to toxins, we need to learn more about how to potentially lessen their effects on people’s lives.

In this seasonal issue of *CURE*®, we speak to a man who started a groundskeeper business in the late ‘70s and who, over a 12-year period, had daily exposure to a common herbicide. This may have played a role in his diagnosis of mantle cell lymphoma in 1991.

We also tell the story of a woman who, as a young child, would

wear her father’s jacket to do chores outside. This seems innocent and harmless, but her father worked in the construction industry and his jacket was often coated in white dust with asbestos, which was a result of the compound he mixed to hang drywall. Twenty-five years later, she received a diagnosis of mesothelioma, right after she gave birth to her baby.

Also in this issue of *CURE*®, we close out our yearlong series of stories commemorating our 20th anniversary with a feature on pediatric oncology advancements made over the past 20 years. We speak with doctors



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# publisher's note

WINTER • 2022

who played a critical role in advancing this field and the mother of a child who recently reaped the benefits of those developments, as she was treated for glioblastoma. We also learn about a woman who was treated for cancer as an adolescent during the early years of our publication, when she was part of a clinical study assessing the timing of chemotherapy treatments.

Other topics addressed in this seasonal issue are “going flat” after a mastectomy for breast cancer, caring for an ostomy pouch, a recent Food and Drug Administration approval in the lung cancer space and the importance of advocacy to increase awareness of certain cancers.

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

**MIKE HENNESSY JR.**  
President & CEO  
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## Cholangiocarcinoma: New Hope for a Rare and Aggressive Cancer

**CHOLANGIOCARCINOMA**, known more commonly as bile duct (or biliary) cancer, has several features that historically have made it difficult to treat. First, it is a rare cancer, so advances in treatment take longer because clinical trials are smaller and slower to complete. Second, it grows in a pattern along the bile ducts that are shaped like a tree or along the lining of the gallbladder, and therefore may not cause symptoms until late — usually when jaundice develops because of blockage of the main bile duct and at which time it is commonly inoperable. Additionally, it is usually resistant to what we have been using as a mainstay of cancer therapy, chemotherapy. While the last two decades have seen advances in newer biological cancer therapies, cholangiocarcinoma seemed to have been left behind.

“Good science, along with creativity in applying and testing it properly, can be successful against all odds.”

But recently, the tide seems to be turning. The systematic analysis of many tumor types with next-generation DNA sequencing — a much faster (and cheaper) way to decode the genomic aberrations that drive cancers — has illuminated dark secrets for many cancers. The analysis of proteins encoded by these altered genes can help cancer

biologists and chemists fashion customized treatments that disable the cancer machinery for that specific type of cancer. Some cholangiocarcinomas are now known to harbor fibroblast growth factor receptor 2 (FGFR2) gene fusions and other rearrangements that produce a hyperactive version of this growth factor that can result in malignant transformation. An inhibitor of all four of the FGFR receptors, *Lytgobi* (futibatinib) blocks the FGFR2 growth-inducing signal, leading to its therapeutic effect as demonstrated in a single-arm trial that enrolled patients who had progressed on prior therapy. This trial led to the drug's approval on September 30, 2022.

The revolution in cancer immunotherapy has extended to cholangiocarcinoma. We still are not fully certain of what makes particular cancer types or individual cases more “immunogenic” and likely respond to checkpoint inhibitors, the primary type of immunotherapy. The usual game plan in testing these therapies is to add them to standard chemotherapy, which, in the case of cholangiocarcinoma, for years, has been the combination of gemcitabine and cisplatin. The TOPAZ-1 randomized trial compared chemotherapy with or without the checkpoint inhibitor *Imfinzi* (durvalumab) and showed a statistically significant improvement in survival in patients with unresectable/advanced cholangiocarcinoma. This treatment was approved by the Food and Drug Administration on September 2, 2022 — amazingly in the same month and year as *Lytgobi*.

This incredible September story is hopefully a harbinger of things to come for rare and resilient cancers, showing that good science, along with creativity in applying and testing it properly, can be successful against all odds. 📺



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





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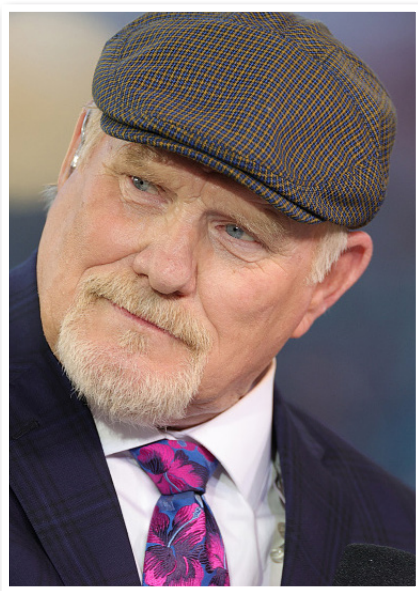
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compiled by BRIELLE BENYON

## NFL Hall of Famer and Analyst Terry Bradshaw Shares His Cancer Diagnoses



 **TERRY BRADSHAW**


**TERRY BRADSHAW**, a Hall of Fame quarterback and analyst on Fox's NFL pregame show, announced that he received a diagnosis of bladder cancer in November 2021 and underwent treatment at Yale University Medical Center in New Haven, Connecticut. While he said he is now bladder cancer free, he also announced that he received a diagnosis of Merkel cell carcinoma—a rare type of skin cancer—in March, which was treated with surgery at The University of Texas MD Anderson Cancer Center in Houston.

“Folks, I may not look like my old self, but I feel like my old self. I’m cancer free, I’m feeling great. And over time, I’m going to be back to where I normally am,” Bradshaw said during the pregame show. 

## Musician Mark Hoppus Will Write a Book About His Life Including Lymphoma

**MARK HOPPUS**, the bassist in the pop-punk band Blink-182, announced last year that he had received a diagnosis of stage 4 diffuse large B-cell lymphoma. In September 2021, Hoppus shared on Instagram that he was cancer free.

Now Hoppus, 50, is working on a memoir, he said in an interview with *The Hollywood Reporter*.

“We’re finalizing the deal and I’m really happy with the way that (it’s) coming together,” Hoppus said. “I’m excited to tell my story.” 




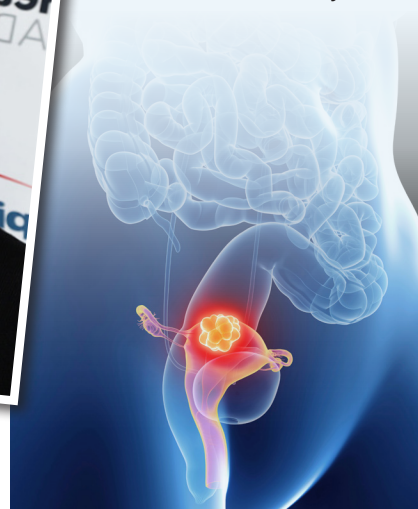
 **MARK HOPPUS**

## Chemicals in Hair-Straightening Products May Be Linked With Uterine Cancer

**WOMEN WHO USE** hair-straightening products known as relaxers may be at an increased risk for developing hormone-related uterine cancer, according to research from the National Institutes of Health.

Findings showed that 1.64% of women who never used hair relaxers would receive a diagnosis of uterine cancer by aged 70 years, compared with 4.05% of those who were frequent users of the products.

“Because Black women use hair-straightening or relaxer products more frequently and tend to initiate use at earlier ages than other races and ethnicities, these findings may be even more relevant for them,” said Che-Jung Chang, a researcher on the study. 





## ‘Yellowstone’ Actor Barry Corbin’s Oral Cancer Almost Changed His Signature Voice



“YELLOWSTONE” ACTOR BARRY CORBIN, aged 82 years, received a diagnosis of oral cancer earlier in 2022 and underwent surgery for the disease, which he feared would impact his cowboy voice and signature look.

“(Clinicians) told me there was a possibility my vocal cords would be impacted and that would cause a big disruption in my business,” Corbin, who played Ross the cowboy, told “Today.”

“He did have some fear that he would not look the same when he returned to work after the surgery. He says he put his trust in the makeup people to make him presentable,” Barry’s wife, Jo Corbin, told *People*. “And if that wasn’t possible, he thought he might be written off the show.”

## Actor Dwayne ‘The Rock’ Johnson Records Message for Child With Brain Cancer

“BLACK ADAM” AND “Fast and Furious” actor Dwayne “The Rock” Johnson recorded a video message for Kayla Spangler, a patient with stage 4 glioblastoma, a type of brain cancer.

Spangler, of Franklin County, Indiana, has had cancer for two years.

“You have so many people in your corner who were trying so hard to get in contact with me and send me your information,” Johnson said in the video. “I finally got your information today. I was running from set. I wanted to send you this video.”

He encouraged her to keep going.

“Kayla, thank you for being a fan,” Johnson said. “I know that you’re fighting hard. Keep fighting. Keep inspiring everybody around you, including me now.”



▲ DWAYNE ‘THE ROCK’ JOHNSON

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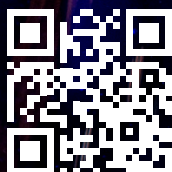
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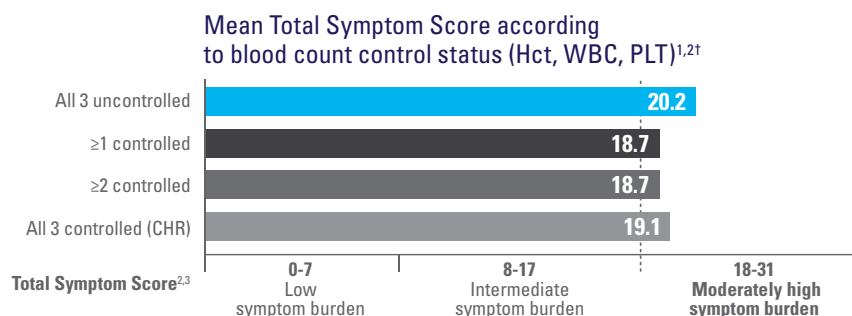




**In the prospective, observational REVEAL study, Patients with polycythemia vera had moderately high symptom burden regardless of blood count control<sup>1</sup>**

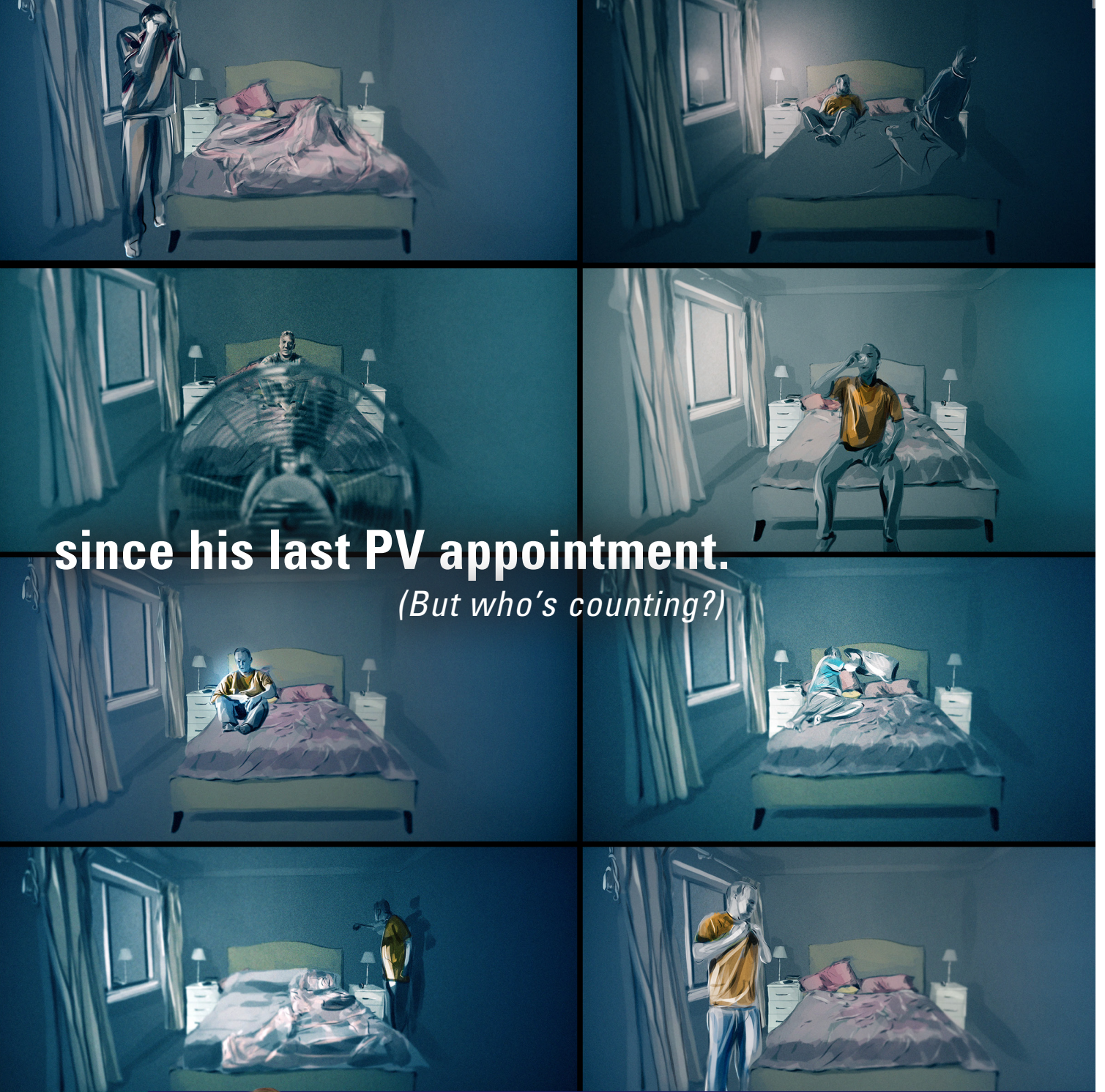
- Symptom burden in patients who achieved blood count control versus those who did not was analyzed among 1813 evaluable patients with PV<sup>1\*</sup>

Reprinted from *Clinical Lymphoma Myeloma and Leukemia*, Vol 19(9), Grunwald MR, Burke JM, Kuter DJ, et al, Symptom Burden and Blood Counts in Patients With Polycythemia Vera in the United States: An Analysis From the REVEAL Study, 579-584.e1, Copyright 2019, with permission from Elsevier.



CHR, complete hematologic remission; Hct, hematocrit; MPN-SAF TSS, Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score; PBT, phlebotomy; PLT, platelet; PV, polycythemia vera; WBC, white blood cell.





since his last PV appointment.  
(But who's counting?)



Robyn Scherber, MD, MPH

Your patients may have symptoms of polycythemia vera, such as night sweats, that are impacting their lives. Scan here or visit [PVnightswelts.com](https://www.pvnightswelts.com) to see how experts like Dr. Scherber assess for symptom burden in patients with PV.

Robyn Scherber, MD, MPH is an Asst. Prof. of Medicine at UT Health Science Center at San Antonio.



\*REVEAL was a prospective, observational study that collected contemporary data regarding burden of disease, clinical management, patient-reported outcomes, and healthcare resource utilization from adult patients with PV in the United States, and was sponsored by Incyte. A total of 2510 patients were enrolled over an approximate 2-year period (July 2014 to August 2016), with 2307 patients having completed the MPN-SAF TSS at enrollment. Of these, 1813 (72.2%) had a complete blood count within 30 days before completion of the at-enrollment MPN-SAF TSS and were evaluable. At the time of enrollment, most patients (n = 1714; 94.5%) were being managed with cytoreductive therapy; 1581 patients (87.2%) were managed with phlebotomy, hydroxyurea, or a combination thereof. CHR was defined as Hct <45%, WBC count <10 × 10<sup>9</sup>/L, and PLT count <400 × 10<sup>9</sup>/L; these same criteria were used to determine if Hct, WBC count, and PLT count were controlled.<sup>1</sup>

<sup>1</sup>A prospective study of 1334 patients with PV was conducted to assess baseline symptoms with certain disease features: known HU use (n = 499), known PBT (n = 646), palpable splenomegaly (n = 369), or all 3 features (n = 148), and compared to a control group of patients that lacked the specified feature. Assessment of MPN symptoms was performed by using the MPN-SAF TSS (MPN-10 TSS). All items were evaluated on a 0 (absent) to 10 (worst imaginable) scale. The MPN-10 TSS has a possible range of 0 to 100 with 100 representing the highest level of symptom severity. The TSS for each patient was analyzed to place the patient into the quartiles of low symptom burden (TSS, 0 to 7), intermediate symptom burden (TSS, 8 to 17), moderately high symptom burden (TSS, 18 to 31), or high symptom burden (TSS ≥32).<sup>2</sup>

**References:** 1. Grunwald MR, Burke JM, Kuter DJ, et al. *Clin Lymphoma Myeloma Leuk*. 2019;19(9):579-584.e1. 2. Geyer H, Scherber R, Kosiorek H, et al. *J Clin Oncol*. 2016;34(2):151-159. 3. Emanuel RM, Dueck AC, Geyer HL, et al. *Blood*. 2013;122:4067.

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## Caring for an Ostomy

As part of CURE®'s Heal at Home series, we offer a guide on ostomies following surgery and how patients can best care for their stomas.

By RYAN MCDONALD

*Will it smell? Is the ocean or a hot tub off limits? What about cleaning the pouch?*

These are just some of the questions that Stephanie S. Yates, a nurse practitioner who specializes in wound care at Duke Cancer Center Wound Ostomy Clinic in Durham, North Carolina, said she has heard over the past 40 years.

CURE® spoke with Yates to learn more about ostomies and educate patients with cancer on how to best care for themselves after receiving one.

### LOCATION, LOCATION, LOCATION

An ostomy is a surgical procedure that creates a new way for waste — mostly feces and sometimes urine — to leave a person's body. Not to be confused with an ostomy, the stoma refers to the opening created during the ostomy procedure.

As Yates noted, the type of stoma a patient with cancer receives depends on the location of their tumor. For instance, most patients with tumors near the anus need a permanent colostomy. In this

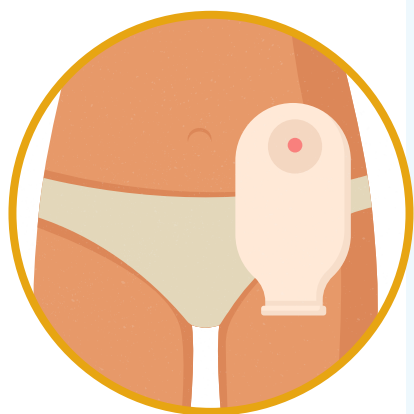
instance, an opening is made into the colon through the abdomen to allow fecal waste to bypass the part of the colon that was removed.

But, as Yates explained, fewer and fewer colostomies are being performed across the U.S. In fact, she said about 70% of the patients she sees have a temporary ileostomy, in which an opening is created in the small intestine through the abdomen. Surgery for these patients involves removing a section of the colon with

the intent of being able to reconnect it.

"They have to divert the stool with an ileostomy in the small intestine for a short amount of time to allow it to heal before the stool has to go that way and pass through the anus," she said in an interview. "And that makes a big difference."

On average, patients who receive a temporary stoma have it in place for three to six months and are then able to return to using the toilet in a normal way, according to Yates.



### ASK QUESTIONS

Yates encourages patients to ask their care team questions about their stoma, especially whether it will be temporary or permanent.

"It makes a difference mentally in how you accept things (as well as) adjusting to what this new lifestyle is going to be about," she said.

But unfortunately, there are cases in which a concrete answer may not be available. Yates said this is because the tumor may be more aggressive than first believed, or certain types of treatment may prevent patients from undergoing additional surgery. Moreover, a patient may have hoped for reconnection in the future, but disease progression may take that option off the table.



## NAVIGATING LIFE WITH AN OSTOMY

One of the main concerns most patients have is whether they will smell, according to Yates.

“I’m usually able to easily inform them that they should not have smell because the pouches are made out of odor-proof material,” she said. “The only time you have smell (is when) you’re usually in your bathroom (caring for the pouch), but everybody else has smell (when in the bathroom).”

Additionally, she explained, people assume that they need to overhaul their diet.

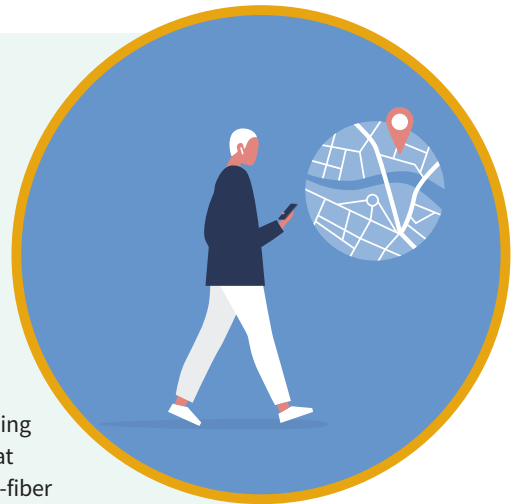
“A lot of people think, oh, there’s a colostomy diet,” she said. “But there really is not.”

If certain foods caused someone to experience stomach upset or have gas, that will likely continue after an ostomy. Yates suggested that patients pay more attention to items that cause gas — such as beer or beans — and choose how much and

when they consume those particular foods.

“Otherwise, there’s no absolute must eat or can’t eat,” she said. “We would encourage you to drink plenty of fluids and eat a variety of foods.”

But that advice changes slightly for patients who have received an ileostomy, according to Yates. She recommends that these patients maintain a low-fiber diet as too much fiber may upset their system and make it so they’re unable to pass their stool as easily. In this case, patients are advised to eat cooked vegetables, meats, breads and pastas.



## BASIC OSTOMY CARE

Washing with soap and water is one of the best ways to care for the area after an ostomy, according to Yates.

“If you think about it, (it’s) like (how) you take care of your bottom — clean and neat,” she said. “It doesn’t have to be sterile (and) it doesn’t

have (to include) any particular harsh cleaners.”

Depending on a patient’s preference, they may remove the pouch around the stoma in the shower, dispose of it and then place a new

adhesive and pouch over the stoma. Or they may feel more comfortable changing their pouch and cleaning the stoma area at the sink.

As for infections following a stoma, Yates noted that the risk drops significantly within a month of the procedure. The worst a person might experience is skin irritation around the stoma.

“That’s where the stool just sits against the skin typically and causes skin irritation,” she explained. “I think of that more like diaper rash. It’s a matter of using some products to just protect the skin better. Maybe adjusting the fit of the ostomy pouch

system. And then that way, usually that skin irritation takes care of itself.”

And if people were worried about having to consistently clean the pouch that holds their feces, that’s not much of a thing anymore. Most pouches are disposable and insurance covers them, according to Yates.

Also, she added, the pouches and adhesive are designed so as to hold up well in water.

“You can go into the swimming pool, the hot tub, the lake, the creek, the ocean — whatever kind of water you want to be in,” she said. ■



**SCAN THE QR CODE** to watch a video with **STEPHANIE S. YATES** discussing more helpful information about ostomies after colorectal cancer surgery.



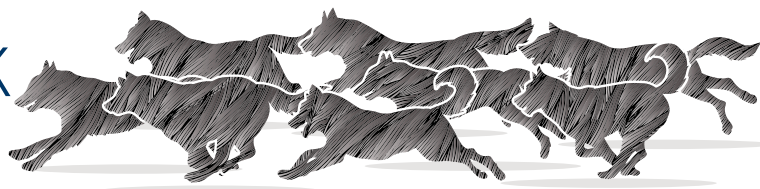
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# Embracing Pack Mentality

By MIRANDA LANKAS, M.A.



“We call ourselves the wolf pack. ... It is kind of tongue in cheek, but there is some seriousness behind how we view each other in terms of having each other’s backs,” said **Trevor Maxwell**, a stage 4 colon cancer survivor and the founder of Man Up to Cancer.

**IT’S A WARM** weekend at Camp Duffield in Delevan, New York. Men are hiking, swimming in the pond and congregating around a campfire. It’s a classic guys’ weekend called the Gathering of Wolves. The website advertising the event promises “a place of restoration, fun activities, great food, campfires and brotherhood.”

“There’s this American ethos or culture of rugged individualism that is not inherently bad, that has done a lot in this country,” says Trevor Maxwell, who conceptualized the event. “For a lot of stuff in life, being able to say, ‘No, I’m doing this independently’ is not necessarily a bad thing.”

The Gathering of Wolves is not celebrating masculinity for the sake of it, but encouraging men to get involved in a community of cancer survivors and caregivers.

Maxwell, founder of Man Up to Cancer, is a stage 4 colon cancer survivor who is adamant that masculinity should not be defined exclusively by rugged individualism, but should embrace community and relying on support systems. He and several other active members organized the outdoor retreat.

“We know that men who isolate during cancer, anyone who isolates during cancer, is more likely to die sooner, they are more likely to experience broken relationships, they’re more likely to have worse medical outcomes than people who are engaging in communities and support (groups),” Maxwell said.

Man Up to Cancer was founded in 2020, right before the COVID-19 pandemic forced the country into a very literal isolation. While quarantine drove people to physically isolate for their health, the resulting conversations about the mental toll of isolation and subsequent push to connect online helped Maxwell find other men searching for community after cancer diagnoses.

“The timing actually worked out great because there were a lot of guys out there who were looking for authentic supportive connections, who were stuck in their apartments or their houses, so we started having Zoom calls,” he said. “We’ve gotten to know each other really well as brothers in this fight over the past couple of years, but we’ve been limited to Zoom calls, Facebook interaction, phone calls. Some people would get together here and there.”

Maxwell’s pre-pandemic experiences with cancer support left something to be desired in terms of gender

inclusivity, though not by design. Maxwell described his “three-to-one rule” in co-ed cancer support spaces, where he’d see three women for every man accepting help, leading him to think: “Could I be the only guy who needs (this support)? I’m just a freak, and I’m struggling.”

While Maxwell may have been in the minority in seeking out cancer resources, he found his negative self-talk unfounded when talking with other men whose lives were impacted by cancer.

“There are many men in the Howling Place (Man Up to Cancer’s private male-only Facebook group) who don’t feel comfortable or who feel too vulnerable to share their fear, their pain, their struggles, in a co-ed environment,” Maxwell said. “That is often because a lot of men are concerned about being perceived as weak. They’re conditioned in our culture to man up, don’t talk about it, be tough. Handle it on your own.”

While men have been attracted to Man Up to Cancer’s website, podcast, Facebook group and now live events specifically to combat the mentality that they need to “handle it on (their) own,” the website proves they are far from alone. Smiling wives, daughters, sons, mothers, fathers and friends embrace and stand proudly in photos with the men they support. The website often follows statements about resources for men with the phrase “and the people who love them,” fostering connection to the people men already have instead of placing the entire burden of support exclusively on group members.

While the site and the community’s resources are open to women as well, Man Up to Cancer does keep some spaces just for the guys to eliminate the co-ed issues that lead them there in the first place. The inaugural Gathering of Wolves was male exclusive, with men with all cancer types from the United States and Canada (and one from Belgium) attending.

“We had an amazing group come together in person,” Maxwell said. “It was a magical weekend. It was really transcendent for myself and a lot of guys to build these relationships online for more than a couple of years. Then to come together in person and to get those hugs and to share our stories in person, to have fun, get away from cancer for a little bit, play games and just be guys together was a really positive experience for all of us.” ■



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## FDA Approves Imjudo With Imfinzi and Chemo for Metastatic NSCLC Without Certain Genetic Mutations

Imjudo, Imfinzi and chemotherapy improved overall and progression-free survival in certain patients with non-small cell lung cancer. By DARLENE DOBKOWSKI, M.A.



**THE FOOD AND DRUG** Administration (FDA) approved Imjudo (tremelimumab) in combination with Imfinzi (durvalumab) and platinum-based chemotherapy for the treatment of adults with metastatic non-small cell lung cancer (NSCLC) without epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

This FDA approval was based on findings from the POSEIDON study, which assessed the efficacy of Imjudo in patients with metastatic NSCLC who were not previously treated. In particular, the study analyzed the effectiveness of Imjudo, Imfinzi and platinum-based chemotherapy compared with platinum-based chemotherapy alone.

The groups also received some combination of maintenance chemotherapy. Patients received treatment until disease progression or

unacceptable side effects, according to a news alert from the FDA.


Imjudo plus Imfinzi and chemotherapy significantly improved overall survival (the time from treatment when a patient with cancer is still alive) compared with chemotherapy alone, with a median overall survival of 14 months in the combined treatment group and 11.7 months in the chemotherapy-alone group.

Progression-free survival (time after treatment when a patient with cancer lives with the disease without worsening) was also improved in the patients treated with Imjudo, Imfinzi and chemotherapy. In particular, the median progression-free survival was 6.2 months compared with 4.8 months in those treated with chemotherapy alone.

Patients assigned Imjudo, Imfinzi and chemotherapy had an overall response rate (percentage of patients with a partial or complete response to treatment) of 39% versus 24% in

patients assigned chemotherapy alone. The median duration of response (the time during which a patient achieves a complete or partial response to therapy) was 9.5 months in the combined treatment group compared with 5.1 months in the chemotherapy-alone group.

The most common side effects that occurred in at least 20% of patients included fatigue, nausea, musculoskeletal pain, decreased appetite, diarrhea and rash, according to the news alert.

Severe or life-threatening laboratory abnormalities that occurred in at least 10% of patients were anemia, neutropenia (low levels of neutrophils, a type of white blood cells), lymphocytopenia (low levels of white blood cells called lymphocytes), leukopenia (decrease in disease-fighting cells), hyponatremia (low levels of sodium in blood), increased lipase (potentially indicating acute pancreatitis) and thrombocytopenia (low platelet counts). 





# The potential to celebrate more of life's everyday moments.

Living longer could start with LIBTAYO.

LIBTAYO will not work for everyone.

Patient portrayal.

## What is LIBTAYO?

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

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

## Important Safety Information

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

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

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

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



In a study,  
**LIBTAYO was proven to help patients with  
advanced NSCLC live longer versus chemotherapy**



### Median overall survival (OS)\*

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

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

### More patients were alive with LIBTAYO compared with chemotherapy

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

### Individual results may vary.

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

## Important Safety Information (continued)

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

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

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

#### Females who are able to become pregnant:

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

- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO

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

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

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

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

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [fda.gov/medwatch](https://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

**REGENERON | SANOFI GENZYME** 

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**Explore what could be possible with LIBTAYO**  
Scan this QR code with your phone to learn more, or visit [LIBTAYO.com/NSCLC](https://LIBTAYO.com/NSCLC)



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

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

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

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### Lung problems.

- cough
- chest pain
- shortness of breath

### Intestinal problems.

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

### 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.

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

### Kidney problems.

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

### Skin problems.

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

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

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

**Infusion reactions that can sometimes be severe.** Signs and symptoms of infusion reactions may include:

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- chills or shaking
- itching or rash
- flushing
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- dizziness
- feel like passing out
- fever
- back or neck pain
- facial swelling

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- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barre syndrome
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Continued on following page



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

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

### How will I receive LIBTAYO?

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

### What are the possible side effects of LIBTAYO?

**LIBTAYO can cause serious side effects, including:**

- See “What is the most important information I should know about LIBTAYO?”

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

These are not all the possible side effects of LIBTAYO.

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

### General information about the safe and effective use of

**LIBTAYO.** Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about LIBTAYO, talk with your healthcare provider. You can ask your healthcare provider for information about LIBTAYO that is written for health professionals.

**REGENERON | SANOFI GENZYME** 

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This is a brief summary of the most important information about LIBTAYO. For more information, talk with your healthcare provider, call 1-877-542-8296, or go to [www.LIBTAYO.com](http://www.LIBTAYO.com)

## FEATURE environmental toxins







# THE LASTING LEGACY OF ENVIRONMENTAL TOXINS

**TOBACCO SMOKE, PESTICIDES, HERBICIDES AND CHEMICALS IN THE AIR ARE AMONG THE SUBSTANCES THAT ARE KNOWN TO INCREASE THE RISK OF GETTING SOME KINDS OF CANCER.**

*By* MARILYN FENICHEL

**D**ennis Barbee was a young man in 1979 when he started a groundskeeper business in Phoenix. Using Roundup to kill the weeds on various properties was just part of the job. For 12 years, Barbee had almost daily exposure to the common herbicide.

In 1991, Barbee moved to northern California. He was working in a different field in 2013 when he started experiencing severe gastrointestinal symptoms. After a series of tests, he received his diagnosis: mantle cell lymphoma, a type of non-Hodgkin lymphoma.

“It didn’t occur to me that Roundup had anything to do with my cancer,” Barbee recalls. “But then I saw in the news that it had been linked to non-Hodgkin lymphoma. Although none of my oncologists had suggested a link to Roundup, I suspected that it was the reason that I got cancer.” »





**DENNIS BARBEE's**  
daily exposure to  
Roundup may have been  
the cause of his mantle  
cell lymphoma.

In 2015, the International Agency for Research on Cancer (IARC), one of the agencies responsible for finding environmental toxins, also called carcinogens, identified the active ingredient in Roundup, glyphosate, as a probable cause of cancer.

Now 69 and living in Coeburn, Virginia, Barbee has paid a steep price for his long-ago exposure. After his diagnosis, he had intensive therapy, including chemotherapy, radiation and a stem cell transplant, which he tolerated well. He was in remission for three years but when the cancer came back in

2017, his treatment options had narrowed. He was prescribed a targeted therapy called Imbruvica (ibrutinib), which came with a host of side effects including extreme fatigue and neuropathy. "The fatigue was so intense that I could no longer do my job," Barbee says. "Not only did cancer cost me my health; it also sidelined my career and left me financially insecure."

The number of cancers linked to carcinogens is extensive. The National Toxicology Program (NTP), charged with compiling a list of carcinogens for the secretary of

the U.S. Department of Health and Human Services, has identified 256 substances, including eight added in 2021. In selecting substances for their lists, NTP and IARC consider environmental risks, including exposure to external toxins such as air and water pollution and chemicals, as well as lifestyle issues, such as smoking, alcohol and poor diet. Therefore, it's not surprising that the National Cancer Institute estimates that a substantial number of cancer cases can be linked to some form of exposure to these and many other substances.



Although determining the causes of various types of cancer can be challenging, some clear links have been established. “We know that tobacco smoke is a very powerful carcinogen, resulting in a 25-fold increased risk of lung cancer,” explains Dr. Jonathan Samet, dean of the Colorado School of Public Health in Aurora.

Dr. Edward S. Kim, physician-in-chief at City of Hope Orange County in California, concurs, adding, “Tobacco is the most notorious carcinogen of all. It doesn’t matter whether you’re a smoker or breathing in someone else’s smoke. At least 70 chemicals in tobacco are known to cause cancer.”

While active smoking can increase the risk of lung cancer by a factor of 15 to 30 (or a 1,500% to 3,000% increase in risk), second-hand smoke can increase it by a factor of 1.25 to 1.3 — or a 25% to 30% higher risk compared to a nonsmoker without smoke exposure.

## THE INTERPLAY BETWEEN CARCINOGENS AND GENES

The reason environmental toxins are so powerful is that they have the ability to damage DNA, and damaged DNA is instrumental in the processes that lead to a cancer diagnosis. Evidence of this phenomenon has emerged through the discovery of mutational signatures, composites of mutations associated with DNA damage and repair mechanisms. Dr. James Herman, co-leader of the cancer epidemiology and prevention program at UPMC Hillman Cancer Center and professor of medicine at the University of Pittsburgh, points out that work is underway to identify mutational signatures in genes driving the development of cancer. “Scientists have identified strong mutational signatures for tobacco and UV radiation in certain genes, verifying that the cancer was caused by exposure,” he explains.

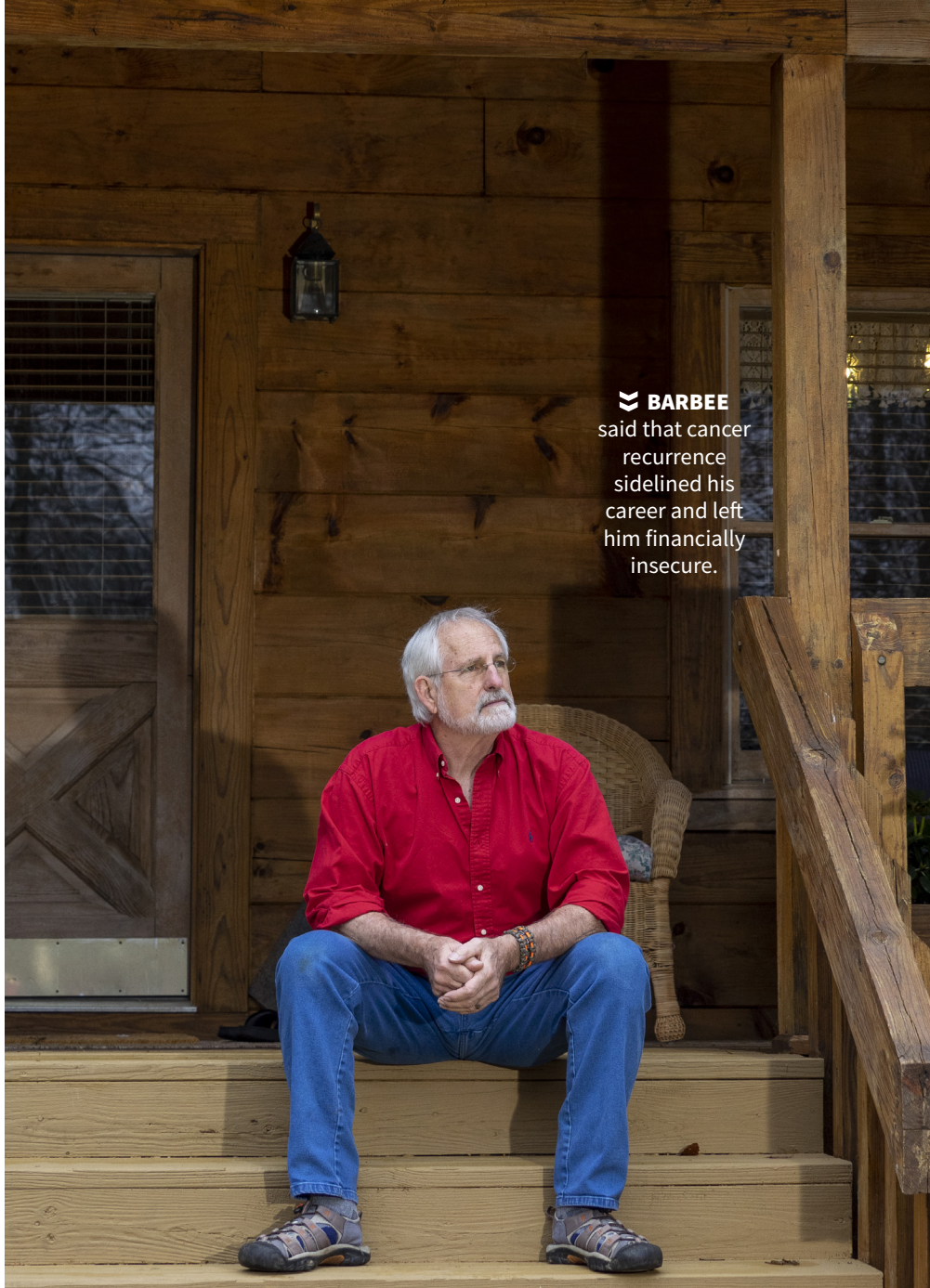
Developments in gene sequencing have led to greater understanding of why non-smokers often get non-small cell lung cancer. Many of those

cancers are caused by mutations in specific genes, with EGFR and KRAS among the most common. New research presented by Charles Stanton, chief clinician at the Francis Crick Institute in the U.K. at the 2022 meeting of the European Society for Medical Oncology, showed that normal lung cells can also have these mutations, probably a result of aging. According to Stanton, this research suggests that air pollution can then initiate lung cancer in cells with these mutations. This information is another piece of the puzzle and makes a strong case for limiting air pollution worldwide.

## ACTING ON EVIDENCE DOESN’T HAPPEN QUICKLY

Although doctors and researchers now acknowledge the link between environmental toxins and cancer, this realization took a long time to emerge. Recognition of asbestos as a carcinogen is a case in point. Doctors began suspecting a link between asbestos and mesothelioma, a rare cancer of the lining of many organs, including the lungs, abdomen and heart, in the 1940s, when they saw a jump in cases among people working in naval yards. By the 1960s, researchers had discovered that mesothelioma has a long latency »

**BARBEE**  
said that cancer recurrence sidelined his career and left him financially insecure.



## FEATURE

### environmental toxins

period, taking 15 to 70 years to develop following exposure.

When Heather von St. James, 53, of Minneapolis was 7 years old, her father worked in the construction industry. He was responsible for hanging drywall, mixing the compound that was full of asbestos, and sanding walls before they were painted.

"I remember my father coming home with his jacket covered in white, grayish dust," von St. James recalls, "but this didn't stop me from wearing it when I did chores outside. Little did I know that the exposure to asbestos would lead to a diagnosis of mesothelioma more than 25 years later, when I was only 36."

And the diagnosis couldn't have come at a worse time. "I had just given birth to my baby and I had never felt sicker," von St. James says. "I was anemic and my chest felt like a truck was sitting on it. After a CT scan and a biopsy, I received the diagnosis, but by then I already knew I had cancer."

The prognosis was grim. Von St. James was told that without treatment, she had 15 months to live. "That was not an option," she states. "Then my doctor told me about a surgeon, Dr. (David) Sugarbaker in Boston, who had pioneered surgery to treat the disease. Without blinking an eye, my husband said, 'Get us to Boston,' and 12 days later, we were sitting in Dr. Sugarbaker's office. I was cleared for surgery, an eight-hour procedure where the team removed my entire left lung, the lining of the lung or pleura where the tumor was located, the left half of my diaphragm, the lining of my heart and a rib. During the surgery, they did a heated "hyperthermic" chemotherapy wash, but I still needed four additional rounds of chemo and radiation. A year later, I was declared cancer free."

As von St. James entered the recovery phase, she began researching asbestos use in the United States and she discovered that it still hasn't been completely banned. In 1970, the Clean Air Act authorized the Environmental Protection Agency (EPA) to regulate its use. As a result, in 1989, a partial ban went into effect, prohibiting the manufacture, import and distribution of asbestos, and in 2019, a regulation was added prohibiting asbestos products that had left the market to return without EPA approval. While these regulations help, it is still legal to import and use asbestos in small amounts. As a result, many products still contain more than 1% of the mineral.

Like asbestos, Roundup is still in use in the United States. What's more, the EPA has not classified it as carcinogenic as long as users follow the directions on the label. However, with IARC designating of the chemical in Roundup as carcinogenic, many other countries have banned its use.

Regulations aside, for the legal community, enough evidence has emerged to hold the asbestos and Roundup industries accountable for the cancers their products have caused. Both von St. James and Barbee have been part of

lawsuits, and both have received settlements, 3M Corp. and Monsanto/Bayer, respectively. Yet the compensation can't erase the toll cancer has taken on their lives.

"I live with chronic pain, numbness and nerve damage, and at times, my voice is raspy and I feel short of breath. But I'm proud of the work I've done as a mesothelioma advocate and will continue to speak out until asbestos is finally banned," adds von St. James.

#### NEXT STEPS FOR ENVIRONMENTAL TOXINS STUDIES

As scientists work to solidify the role of environmental toxins on cancer risk, another variable has been thrown into the mix: climate change. Concern about the impact of climate change on health spurred the American Society for Clinical Oncology (ASCO) to form a task force charged with addressing this topic.

» HEATHER  
VON ST. JAMES  
was exposed to  
asbestos by her  
father's work  
jacket, which she  
wore as a child.







### VON ST. JAMES

is a patient advocate for others with mesothelioma and aims to speak out until asbestos is banned by regulatory agencies.



“There’s no question that climate change has accelerated interest in the role of air pollution in cancer risk,” says Dr. Eric H. Bernicker, a medical oncologist with Houston Methodist Cancer Center. “In fact, it is hard to decouple the discussion of air pollution from climate, largely because both are driven by the same factors, such as the burning of fossil fuels. In addition, climate change shines a light on health disparities, starkly showing that the worst air tends to be in poorer areas, and these areas also have higher rates of cancer.”

The ASCO Climate Change Task Force will begin its work by developing a policy statement about how climate change is affecting wellness and health and the strain it will put on the health care delivery system in the years ahead. The task force will

then most likely make the suggestion that ASCO turn its attention to two broad areas of research: modeling the risks of climate change to cancer and whether a warming planet will result in an increase in certain carcinogenic viruses and cancers already linked to environmental toxins.

“We’ve already seen the effect of wildfires, floods and other major weather events on health,” Bernicker says. “For example, after Hurricane Harvey, the radiation cancer center at Houston Methodist Hospital was flooded with water, causing us to scramble to get patients treated elsewhere. We’ve fixed that problem but the experience provoked discussions on how to help patients and caregivers become more resilient.”

A big part of the push for resilience involves driving home the

importance of prevention. That includes advocating for smoking cessation and less consumption of alcohol and red meat.

“We’re not trying to scare people but we do need to educate them so that they make good choices,” Bernicker adds. “They don’t need to buy a fancy treadmill to be more active; they can simply take a walk. Gaining control of what we can in our lives and avoiding exposure to toxins when possible are steps we as individuals can take. In the meantime, the scientific community will continue to do its part.”



**SCAN THE QR CODE** to hear more about Heather von St. James’ cancer journey.



# BUYING MORE TIME

BILIARY DUCT CANCER, OR CHOLANGIOCARCINOMA, HAS ALWAYS BEEN KNOWN AS A DIFFICULT-TO-TREAT DISEASE, BUT IMMUNOTHERAPIES MAY MAKE AN IMPACT ON PATIENTS' LIVES.

By ANDY POLHAMUS

**T**ina House should have been relieved when she went to her doctor to discuss a lump she found on her skin. At first, the news seemed good: The lump was only an ingrown hair. During her appointment, she and her physician agreed to have some routine bloodwork done. House soon got a phone call asking her to return to the doctor. The testing indicated that there was something wrong with her liver

enzymes. House's doctor referred her for a sonogram. Shortly after, House learned that she was about to begin fighting for her life.

"I was blissfully enjoying my retirement," House recalls. She and her husband, formerly of Texas, had retired to Spruce Pine, a small town near Asheville, North Carolina. They hiked regularly in the mountains around their town and bowled together in two leagues. »





**TINA HOUSE**'s visit to her doctor for a lump on her skin turned into the beginning of her biliary tract cancer journey.





**HOUSE's** oncologist treated her cholangiocarcinoma with Imfinzi, which shrank her tumors by 10% to 20%.

"I really didn't have any symptoms," says House. "I've always been a very healthy person. I had in mind from my adulthood that I was going to live to be in my mid-90s."

Besides bowling and hiking, House liked to take her dog on long walks. She'd been a member of Weight Watchers for more than 35 years. But not long after her sonogram in April 2022, when House was 65, her doctor took time out of a vacation to deliver urgent news: House had advanced biliary tract cancer, a rare and deadly disease.

She walked over to her husband, who was on the phone, and wrote "cancer" on a Post-it note.

"I felt like the whole floor had just been pulled out from under me," House remembers. "We hung up the phone, stared at each other and both started bawling."

House, like most people with biliary tract cancer, had no symptoms beyond some minor fatigue and a little weight loss. The National Cancer Institute says

the majority of patients with the disease don't experience symptoms until the tumor grows large enough to cause jaundice and itching in addition to less specific symptoms like weight loss due to abnormal function that drains the bile it produces through the biliary tract into the intestines. Despite the minimal symptoms, House was in grave danger. Without treatment, she learned, she would live only six months. And although one surgeon initially thought she could remove House's tumor, her care team soon determined that the cancer had metastasized to nearby lymph nodes, rendering the disease inoperable.

Months earlier, a 53-year-old Indiana entrepreneur Marshall Morris had received a similar diagnosis. In the summer of 2021, Morris was doing yardwork at home in Indiana when he began to feel itchy. He initially thought it was poison ivy.



"The itching just continued to get worse for the whole month of June to the point where I couldn't sleep," Morris says. "Imagine the worst kind of itching you get from poison ivy, but underneath the skin."

He visited his doctor for some tests, at which point he found out that the "numbers" for his liver function were unusual.

"I'm not all rainbows and unicorns. 'Just tell it to me like it is, Doc,'" Morris remembers saying. "The doctor was this older guy. I don't think he looked more than a minute and then he goes, 'There's a 75% chance this is cancer.'"

Like House, Morris soon learned that his cancer was unresectable because of the tumor's location

surrounding the portal vein, which drains blood from the digestive tract. And just as in House's case, Morris's disease was incurable.

Cholangiocarcinoma is famously difficult to treat, as it usually presents at advanced or inoperable stages and does not respond very well to most cancer drugs.

"One of the struggles we've had in managing biliary tract cancer is that it really is three separate diseases," says Dr. Flavio G. Rocha, professor of surgery in the division of surgical oncology at Oregon Health & Science University and physician-in-chief of the Knight Cancer Institute.

These three diseases are intrahepatic cholangiocarcinoma, in which the tumor develops in the bile duct inside the liver, and two different kinds of extrahepatic cholangiocarcinoma (hilar and distal), which occur outside the liver. Gallbladder cancer can also fall under the broad category of biliary tract cancer.

Historically, cholangiocarcinoma has been known as an aggressive disease with a poor prognosis, especially in its later stages.

"They tend to be more aggressive malignancies," Rocha adds. "They tend to metastasize early, which makes (patients) ineligible for surgical resection, which is really to date the only potentially curative treatment."

Furthermore, Rocha continues, it is very difficult to screen patients for

cholangiocarcinoma, meaning that "it may or may not be too late" to offer curative treatment by the time people are diagnosed.

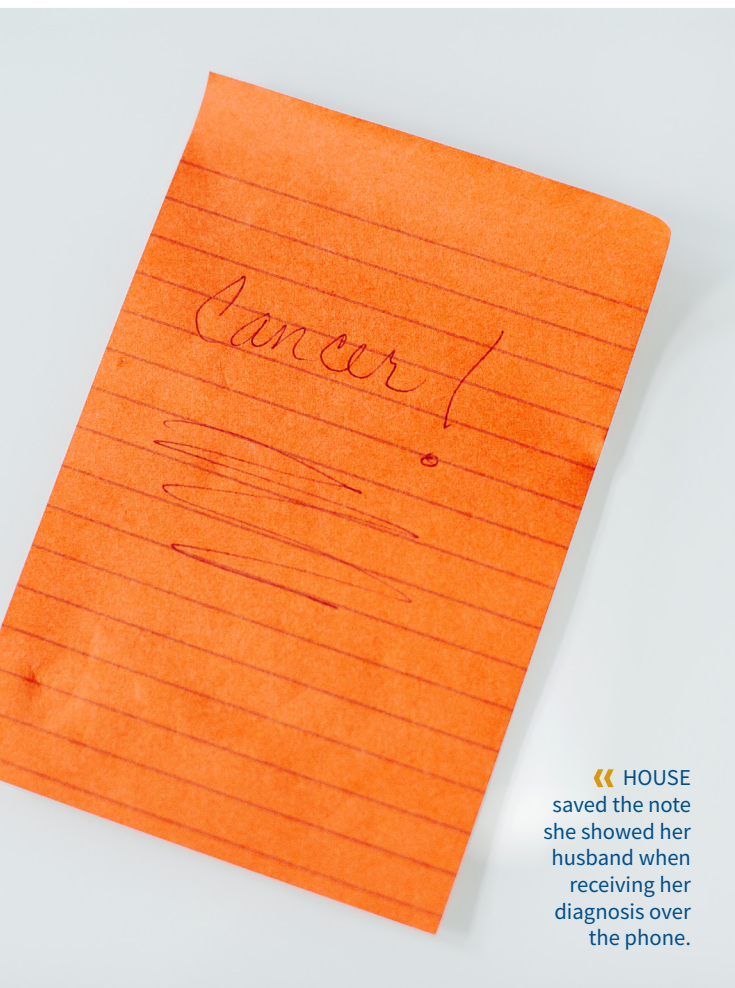
The American Cancer Society estimates that the five-year survival rate for people with intrahepatic biliary tract cancer is just 9% across all disease stages. For extrahepatic disease, the estimated five-year survival rate is 10% across all stages. Survival rates for advanced disease are dismal. Until recently, treatment options for unresectable cholangiocarcinoma have been limited, relying on a combination of the chemotherapy drugs cisplatin and gemcitabine for what Dr. Aiwu Ruth He calls "palliative systemic therapy."

"This combination has been the standard of care for the past decade," explains He, a medical oncologist at Georgetown University Medical Center in Washington, D.C., and a researcher in liver and biliary tract cancer.

More recently, additional treatment options have become available. In September 2022, the Food and Drug Administration (FDA) approved the immunotherapy drug Imfinzi (durvalumab) combined with the chemotherapy drugs cisplatin and gemcitabine, to treat patients with metastatic or locally advanced biliary tract cancer.

"(Imfinzi) changes the fundamental approach by which we treat anyone with a new diagnosis of biliary tract cancer," says Dr. Douglas Robinson, assistant professor of medicine at Harvard Medical School in Boston and a medical oncologist specializing in gastrointestinal cancers.

Robinson said the past decade's reliance on gemcitabine and cisplatin came from a 2010 trial that showed the two drugs together improved survival from about 8.4 months to just under a year, a significant improvement over gemcitabine alone. The two »



« HOUSE saved the note she showed her husband when receiving her diagnosis over the phone.

## FEATURE

### biliary duct cancer

drugs had comparatively mild side effects, which also made them an attractive choice.

“It’s a meaningful improvement, but I think it speaks to just how much further we had to go with this disease,” Robinson says. “Whenever we have encouraging but certainly not phenomenal results, and we have modest toxicity, there’s a constant interest: Is there a way to intensify therapy, to add a third drug to the mix to improve outcomes?”

This is where Imfinzi comes in. The FDA based its approval upon the phase 3 TOPAZ-1 trial, which was designed to evaluate the efficacy of the drug combination in nearly 700 patients who had either untreated metastatic or inoperable biliary tract cancer, or who had previously treated recurrent disease. Imfinzi had already been approved for use in certain types of lung and bladder cancers.

“Over the last 10 years, many treatments have been tested, but this is the first positive phase 3 trial,” He says.

Dr. He was one of the investigators in TOPAZ-1. She says patients treated with the previous chemotherapy-only approach lived for a median of less than one year.

Researchers working on the trial randomly assigned patients to receive the combination chemotherapy with either Imfinzi or placebo.

Overall, 26.7% of patients assigned to the Imfinzi plus chemotherapy treatment regimen reportedly showed either a partial or complete response to the treatment, while those assigned to the placebo and chemotherapy showed an objective response rate of 18.7%. At first glance, that may not seem like much of an improvement, but consider the number of patients whose lives were extended by Imfinzi. The combination of Imfinzi and chemotherapy more than doubled the two-year survival rate, the investigators reported: At 24 months, the overall

survival rate for patients who were assigned Imfinzi plus chemotherapy was 24.9% compared with 10.4% for those who were assigned to chemotherapy and placebo.

I was spending 10 days a month in the hospital. ... Since we’ve taken the chemo away, I feel phenomenal.

—MARSHALL MORRIS

Imfinzi, like all cancer drugs, comes with side effects. What’s more, the two chemotherapy drugs in the approved combination carry their own side effects. The two types of therapy in the TOPAZ-1 trial were roughly similar in how safe they were for the patients taking them: Among patients assigned to Imfinzi and chemotherapy, 75.7% of patients experienced grade 3 or grade 4 side effects, compared with 77.8% of those assigned to chemotherapy and placebo. The most common side effects in the study were rash, fatigue, abdominal pain, nausea, constipation, decreased appetite and fever.

Dr. He acknowledges that although this is progress, there is still a long way to go.

“With the addition of (Imfinzi), there is an increase in landmark survival measurements (such as the survival rate at 18 months, 24 months and so on), but median overall survival is still not so good,” she says.

Even so, He continues, TOPAZ-1 represents a breakthrough because it shows that immunotherapy can be effective in treating cholangiocarcinoma. Researchers are already looking into how they can improve on this success.

“There are many more studies testing immunotherapy in combination with chemotherapy,” she says.

Additionally, because cholangiocarcinoma is a heterogeneous group of cancers, He says it is possible that some patients may respond better to the combination of chemotherapy and immunotherapy than others.

Another therapy has begun to scratch the surface of this heterogeneity. Robinson points out that the biological drug Lytgbobi (futibatinib) was approved at the end of September 2022 for a subset of patients with previously treated, unresectable cholangiocarcinoma who have alterations in the FGFR2 gene that encodes a growth factor that is activated when altered in certain ways. In the future, he says, targeted therapies for specific gene mutations will become more important in treating this group of cancers.

“What we’re seeing in many GI (gastrointestinal) cancers is, we really lack genetic targets,” he says. “The deeper we look into the cholangiocarcinoma genome and the specific mutations that are in our cholangiocarcinoma patients’ tumors, we often find mutations for which we either have drugs or have clinical trials exploring drugs that may be able to target those tumors. Maybe we’ll be able to find the driver that’s making the tumor grow and divide, block that driver and really impact that patient’s prognosis.”

*continued on page 34*





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*continued from page 32*

House's oncologist in North Carolina had only limited experience treating cholangiocarcinoma but was up to date on emerging treatments. He'd heard about the TOPAZ-1 trial and decided to give House the study therapy, which was still pending FDA approval at the time.

"He said, 'It's shown that (Imfinzi) can really help these other two chemotherapy drugs,'" says House.

She started treatment with Imfinzi, gemcitabine and cisplatin on June 23, 2022. Two months later, in August, a scan showed that all of her tumors had shrunk by 10% to 20%.

"It was really, really encouraging," House says.

Next, with the advice of her local oncologist, House traveled to get a second opinion from The University of Texas MD Anderson Cancer Center in Houston. She decided that while she was in the area, she would visit family in Dallas with her husband and her dog, calling the first leg of the trip the "Farewell to Tina Tour." Her mortality was still foremost on her mind.

"I didn't know when I would get to see my family again, if ever," she remembers. "You just don't know."

An oncologist at MD Anderson said her disease appeared to be stable and advised her not to "mess with success."

Morris began treatment with chemotherapy alone but later received the combination of Imfinzi, cisplatin and gemcitabine.

"It helped slow down the progression of the cancer, but they sat with me in the beginning of January and said, 'Hey, (you have) maybe six months,'" Morris recalls. "So July 8 became my expiration date, so to speak."

Chemotherapy with Imfinzi didn't stop the disease, so Morris' care team tried radiation on top of

Imfinzi, which appeared to stabilize his disease. A metastasis that had taken over the right side of his liver disappeared after radiation therapy, and the main tumor shrank slightly, as did tumors on some lymph nodes.

Morris has since transitioned to being treated only with Imfinzi. He started an organization called Dying Defiantly, which offers emotional and psychological support for people with terminal illnesses. He funds the group himself with money he earned from selling some business interests after learning of his own terminal illness and wants other people with terminal diagnoses to live life to the fullest while they still can.

"Cancer doesn't have to define you," he says. "You can keep moving."

House underwent a CT scan mid-November of this year and says that all of her tumors continue to shrink, and that the other masses "appear subjectively smaller in size with decreasing enhancement," she told *CURE*®. There are also no new masses seen on the scan.

It may be possible that if her tumors continued to shrink, she will be able to stop taking the chemotherapy drugs, which have come with hair loss and fatigue, and instead simply receive an injection of Imfinzi alone once a month as long as there was no evidence of cancer progression.

"It's all worth it if I can get these tumors taken care of and live longer," House says.

Morris says he feels "amazing" on monotherapy with Imfinzi, though he warns people who tell him he doesn't look sick not to "judge a book by its cover." His main side effect is a rash that appears on his skin after infusions. Chemotherapy, he says, was "poison" to him and the side effects made him specifically request to stop

gemcitabine and cisplatin altogether.

"I'm a quality-of-life person, not a quantity-of-life person," he says. "I was spending 10 days a month in the hospital from getting infections. Since we've taken the chemo away, I feel phenomenal."

Morris is emphatic that he still has a life to live. He travels, spends time with family and friends and competes in an ax-throwing league.

"For a guy that's four months past when they said he was going to be here, I feel pretty amazing," he says.

House adds that her doctor thinks she will be able to live for several years with her disease, although her life will still likely be cut short by cancer. She has ordered an urn to someday hold her ashes, gotten her life insurance policy in order and broken the news to family and friends, including her two grown daughters.

"Cholangiocarcinoma is a bad cancer to have," says House. "It's rare. It's vicious. It's like playing a sophisticated game of whack-a-mole because you can get rid of some of it and then a year later, it comes back. And it'll come back in a weird place, like (your) neck, or hip, or brain."

House has become active in the patient community, volunteering with the Cholangiocarcinoma Foundation, and chose to share her story because "there are no warning signs."

"Had I not gone to that doctor's visit and said, 'Do you think we need to draw labs?' I would be dead right now," says House. "I'm angry that my life is not going to last as long as I thought it would. ... I know that this is probably what I'm going to die from, but the (Imfinzi) has given me hope. The Imfinzi has given me time, which is the most precious thing to me right now." ■





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The inaugural trek of Sole 2 Soul for MPN will take place with teams across Canada and the United States trekking through Waterton Lakes National Park in Canada which borders Montana's Glacier National Park. Team members are currently raising funds to fuel research and to amplify the voices of those living with an incurable blood cancer. These life-changing experiences offer participants an opportunity to redefine what's possible during a MPN diagnosis while joining a welcoming team that challenges their personal preconceived limits and widens their circle of support.

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# SCRATCHING THE SURFACE

The treatment and support that children with cancer receive has advanced over the past 20 years, but more progress to improve the cure rate is on the horizon.

By DARLENE DOBKOWSKI, M.A.

**I**n 2003, Megan Piotrowicz was a typical 12-year-old girl, an age when aesthetics become more important and hobbies like playing basketball consume more after-school time. She was one of five children in an incredibly supportive family.

Then she was diagnosed with Ewing sarcoma in her skull. This was a rare place for this bone cancer to occur, as it often appears in patient's legs and arms.

Piotrowicz was treated at Children's Hospital of Philadelphia, an institution her

family considers a "jewel that lies in our backyard." She was enrolled in a clinical trial that compared a two-week and three-week rest period between chemotherapy treatments. She was assigned the shortened amount of rest period between the three rounds of chemo she received.

"I look back at my time as a patient and I truthfully consider myself lucky," Piotrowicz says. "I didn't get sick. I didn't have those throw-up bouts at home, anything like that. I think I just got sick on my first treatment, and then I was good." »









## MEGAN PIOTROWICZ

was 12 when she was treated for Ewing sarcoma. At 31, she pays it forward by working at the center where she received care.

hematology-oncology, director of the Cancer and Blood Disease Institute and the Alfred E. Mann Family Foundation Chair in Cancer Research at Children's Hospital Los Angeles. "We were brought into one large cooperative group in North America so we could become even more integrated, systematic, organized and coordinated in our approach to developing and studying new therapies for children with cancer."

This led to research focused on the arsenal of therapies available to oncologists, including drugs, but also radiation, surgery, supportive care and chemotherapy, and assessing how best to combine them in newer and safer ways. Better coordination leads to better scientific design of the trial, and more collaboration leads to larger and more informative trials that reach accrual and final analysis more quickly — both critical elements in advancing care.

That's not to say there was no collaboration in pediatric oncology research before this time. In fact, the community of pediatric oncologists have always worked together through cooperative groups like the Children's Oncology Group, experts say.

"The National Cancer Institute basically provides an infrastructure grant to fund 220-plus centers across North America so that if you are a child with newly diagnosed leukemia and you walk into any pediatric cancer center, you will probably be offered the same clinical trial, whether you're in Houston, Seattle or Los Angeles," adds Dr. Susan Blaney, director of Texas Children's Cancer and Hematology Center.

Her tumor shrank from the size of a tennis ball to the size of a golf ball in three months, then she underwent a tumor resection surgery to remove it. The surgery went so well, according to her neurosurgeon, that she reconstructed her skull at the same time, which would typically occur during a separate surgery. After the eight-hour surgery, she was in the intensive care unit overnight and was home the next day to celebrate her mom's and aunt's birthdays. She was deemed cancer free on December 13, 2003.

Piotrowicz is grateful that she and her family opted to participate

in a trial that provided evidence to further the pediatric oncology space, especially because she had a great outcome from her treatment.

### COLLABORATION IN THE AREA

Looking back 20 years, one of the biggest changes made in the pediatric cancer space was the National Cancer Institute's merger of four clinical trial groups into one.

"That was a huge transformation. Since that merger, all of the pediatric oncology experts in the country have worked together," says Dr. Alan S. Wayne, chief of the division of



## TREATMENT ADVANCEMENTS

Researchers have also learned more about the molecular genetics of cancer specifically in children, which has allowed physicians to risk-stratify patients and determine which patients are better suited for certain treatments.

“Those things we can do today with sequencing are almost unfathomable compared to what we could do 20 years ago,” says Dr. Stephen P. Hunger, chief of the division of oncology, director of the Center for Childhood Cancer Research and the Jeffrey E. Perelman Distinguished Chair in the Department of Pediatrics at Children’s Hospital of Philadelphia. “That’s improved our understanding of cancer. It’s identified potential therapeutic targets but it’s also been incorporated into routine patient care so you’re better able to pick out who are the patients at highest risks and how do we treat them differently? And conversely, who are the patients with extremely good risk that we ought to see how maybe we could either dial things back a bit or at least not further intensify therapy?”

This has also opened the doors to the use of precision medicine and cellular immunotherapy in these patients, including the use of CAR T-cell therapy in children.

Wayne was the clinical director of pediatric oncology at the National Cancer Institute in 2013 when he helped lead the development of a collaborative study to assess the use of CAR T-cell therapy in children with highly resistant acute lymphoblastic leukemia, the most common childhood cancer. Results from this phase 1 trial of CD-19-targeted CAR T cells were published in *The Lancet* in 2014. Of the 20 children with leukemia in the study, 14 went into remission with a single dose of the cells. Research like this led to the 2017 U.S. Food and Drug Administration’s approval of Kymriah (tisagenlecleucel),

To see a child discharged, go home to play and return to school, needless to say, it’s what we live and work for.

—DR. ALAN S. WAYNE

the first commercially approved gene therapy.

CAR T-cell therapy has also been used for other blood cancers, says Dr. Will Parsons, deputy director of Texas Children’s Cancer and Hematology Center, who specializes in precision medicine research.

“There’s cases where I think one of the first patients treated (with CAR T-cell therapy) about 10 years ago now, and they’re still doing quite well today,” he adds. “And that’s a patient whose cancer had received every possible treatment they could get. We would normally expect the life expectancy to be weeks, months ... so really amazing progress in precision oncology and immunotherapy.”

Assessing the genetics of each patient and their tumor has also been helpful in potentially preventing the overtreatment of children. Precision oncology allows cancer teams to aid in decision-making to identify the optimal treatments and avoid unnecessary toxic ones to potentially improve a patient’s outcomes.

An example of this being utilized is for medulloblastoma, a common malignant brain tumor in children. Previously, children with medulloblastoma — a cancer that occurs in the back of the brain and the cerebellum — would undergo surgery to remove as much of the affected area as possible, then chemotherapy and/or radiation depending on how well the

surgery went. Now physicians focus on reducing the toxic effects of those treatments based on results from pathology, including genomic analysis.

That’s what Eugenia Chong’s daughter, Florence, underwent when she received a diagnosis and was treated for stage 4 medulloblastoma in the summer of 2020 when she was 23 months old. Florence was throwing up in the morning and would crawl instead of walk, which Eugenia, who is a nurse, thought was associated with changes in everyday life from the COVID-19 pandemic. As the symptoms persisted, Eugenia took Florence to her pediatrician and other specialists and eventually to the emergency department at Children’s Hospital Los Angeles, where a CT scan showed that Florence had a very large tumor. This began her 40-day hospital stay, which included inserting a drain into the ventricle of Florence’s brain to offload some of the fluid that caused her symptoms. Florence then underwent surgery to remove the mass and pathology reports determined her diagnosis, after which chemotherapy was started.

“(The hospital stay) was obviously very, very scary. It was frightening,” Eugenia recalls. “I was also four months pregnant at the time with my son. ... It was challenging that only one parent was allowed at a time to stay with her.” »



**EUGENIA CHONG** and her husband, **RICH**, supported their daughter, **FLORENCE**, when undergoing cancer treatment, all while expecting their second child, **TRUMAN**.

with cancer, but also in the support that children, their parents and caregivers receive throughout the cancer journey. This includes the care needed for children as they receive toxic therapies. This, in turn, may improve survival rates for children, experts say.

During her hospital stay, Florence was visited by child-life specialists who provided services to distract her from painful procedures and engaged her to communicate her needs and fears at an age-appropriate level.

“They provided a type of presence that was nonclinical, which actually created a less scary environment for a child,” Eugenia says. “They also provided support for me, giving me breaks so that I could just leave the room for a little bit.”

In addition, there is more supportive care for patients as they enter the survivorship phase.

“We didn’t used to have a science really called survivorship because we didn’t have enough survivors,” Blaney says. “But it’s very important.”

As survival rates have improved from 20% to 80% over the past few decades, cancer teams have learned more about survivorship and the short- and long-term side effects of treatment, including effects to the brain, heart, lungs and fertility.

Piotrowicz froze her eggs as an adult because the treatment she had undergone increased her risk for early menopause.

“My doctors made sure that (they asked), ‘Do you want a family? Is that important to you? This is what you need to think about,’” she recalls. “They asked me when I was 18, and my mom was like, ‘Let’s get her through college.’ It’s not something



Despite the COVID-19 restrictions at the hospital, Eugenia tried to make light of the difficult situation with her husband, Rich.

“(We) had a conversation where we said, if our child was to be neutropenic and not have a defense, this actually might be the best

time where people are distancing, washing their hands and wearing masks,” she said. “So I would say there was a silver lining.”

#### **SUPPORTIVE CARE**

Not only have advancements been made in the treatment of children



that my mom or my dad (were) thinking about.”

Services such as Passport for Care, which was developed with the Children’s Oncology Group, are available at all pediatric institutions and allow childhood cancer survivors and their physicians to access information about treatment the patient underwent when they were too young to remember the technical names of treatments. It also provides patients with updated guidelines on what monitoring to undergo based on the treatment they received when they were younger.

### MOVING FORWARD

Although significant advancements have been made in how children with cancer are treated, there are unmet needs that persist.

“We are not far enough along; we’ve got so much more to do,” Wayne says. “I feel like we’re just scratching the surface despite all the progress.”

Wayne added that more focus is needed to make therapies safer, more effective, less demanding and less expensive.

In addition, more money is needed to dedicate to pediatric cancer research, a cause that Piotrowicz has been involved with over the past six years at the institution where she received her cancer care. Now aged 31, she is starting a new role at Children’s Hospital of Philadelphia as a major gift officer for the neuroscience center.

“I take (this) very seriously,” she said. “I think that’s the best part of my job — making (contributors) feel really good. There’s no way to pay these doctors back, so this is their way of doing it and making them feel good about it is something that I feel is really special.”

Making cancer treatment less expensive and more accessible may also impact the disparity that persists. Although many big cities have centers of excellence for pediatric cancer, the travel alone can be a

According to a data brief released by the Centers for Disease Control and Prevention, from **1999 to 2014**:

The cancer death rate for children and adolescents (aged 1 to 19 years) declined

**20%**

Brain cancer replaced leukemia as the most common cause of cancer-related deaths in children.

According to the American Cancer Society,

**85%**  
of children with cancer

now will survive at least five years compared with

**58%**  
in the **mid-1970s**.

burden on a family. This burden may also persist for people who live in the same city as these centers.

“The kids in inner-city Northeast Philadelphia, which is five to seven miles from here — that can be a world of difference,” Hunger says. “It’s not so much the distance; it’s the barriers of knowledge, access, dealing with the struggles of life. If you’re from a family that is worrying about how to put food on the table, it’s a little hard to manage the intricacies of tertiary care of pediatric cancer, although we work very hard to support them.”

As researchers and physicians continue to push the area of pediatric cancer forward, they often look back on the past 20 years and how much progress has been made.

“Every time we see one of these new therapies help a child, it truly is miraculous,” Wayne says. “And to see a child discharged, go home to play and

return to school, needless to say, it’s what we live and work for.”

Both Piotrowicz and Florence have been cancer free since they underwent treatment, which is a testament to the advancements that have been made over the last two decades.

“(Florence) started preschool,” Eugenia says. “I just got her preschool photos back, so she’s made friends and she’s gained a lot of independence. Her words have exploded and her personality has really developed. She’s just wonderful. You would not be able to know that she’s gone through cancer treatment.”



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## Ask Questions to Avoid Confusion Around Tumor Testing

As part of *CURE*®'s four-part gastrointestinal cancers webinar series, a panel of experts recently answered questions and offered advice around different types of testing. By RYAN MCDONALD

**BIOMARKER TESTING HELPS GUIDE** cancer treatment decisions, but there's no hiding that the field is complex and often difficult for patients to understand, according to an expert.

According to Dr. Christopher Lieu, co-director of gastrointestinal medical oncology at University of Colorado Cancer Center in Aurora, general discussions around biomarkers, genetics and proteins can overwhelm patients.

Lieu and Drs. John Marshall and Elizabeth Montgomery led a panel discussion as part of a gastrointestinal cancers webinar series held by *CURE*® and in partnership with the GI Cancers Alliance to address patient questions and concerns about testing methods in gastrointestinal cancers.

### ASK QUESTIONS

One of the main ways patients can ease their concerns and ensure they're not as overwhelmed, according to Lieu, is to ask their provider a set of questions.

He suggested that patients with gastrointestinal cancers ask if their tumor has been tested for biomarkers, and if it has not, patients should ask if it will be why it hasn't been done.

Sometimes, Lieu explained, the testing may be considered unnecessary.

"The answer might honestly be as simple as, 'You have stage 1 cancer. I could order the testing, but it'd be a gigantic waste of money because it won't influence our decision,'" he said.

Lieu explained that it's reasonable to ask how the results will affect their treatment. But if the provider says there are no actionable — or targetable — options, Lieu said patients should not become discouraged.

The benefit, he said, is that the testing has been done and that patients have the information gleaned from it. Lieu said several clinical trials and treatments may be on the horizon that could help those patients.

Or the results of the testing may inform providers enough to explain to patients that even though they may be on a certain treatment, there are other options if the drug stops working.

"That's exciting," he said. "That's what we want to offer more (to) our patients."

### REPEAT TESTING

The panel discussed the possibility of needing repeat needle biopsies of tumors to detect cancer or potential spread of the disease.

For example, there may be an instance where a patient's pathology report indicates there was no evidence of cancer but the biopsied area appears to be PET positive or "lit up on a scan." A PET scan measures the metabolic activity of the cells in the body. In this instance, there may be evidence to suggest there's abnormal tissue, but it's not concrete enough to say it's cancer.

Montgomery said the needle may have missed the tumor, and then a second biopsy would be needed to get a better sample of the tissue to determine whether the tumor is cancerous. Or there could be scar tissue or inflammation from past infections that causes the scan to light up, but in the end is insignificant.

"Sadly, if you're in a position in which somebody thinks you could have cancer from a scan, and a tiny biopsy is done and no cancer is found, you really need to consider the possibility that the darned needle just didn't quite get what it was supposed to get," said Montgomery, a gastrointestinal and soft tissue pathologist at University of Miami Health System. ■



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# Keeping Treatment Goals in Mind

Treatment of patients with essential thrombocythemia is currently focused on reducing the risk for blood clots and improving symptoms. However, new therapies in development may help address unmet needs. By DARLENE DOBKOWSKI, M.A.

**SOME OF THE MAIN** goals of treatments for essential thrombocythemia (ET) include reducing disease progression and blood clots while improving symptom burden, but more treatments may be on the horizon focused on specific targets, an expert said.



DR. DOUGLAS A. TREMBLAY

Dr. Douglas A. Tremblay, assistant professor of medicine at the Icahn School of Medicine at Mount Sinai in New York, spoke about the current and future options of ET during the CURE® Educated Patient® MPN Summit. He also discussed the treatment landscape with CURE® and the importance of telling care teams about any symptoms that may be present.

## Q: What are the current treatment options for patients?

**A:** The current treatment options for patients with (ET) are largely shared with patients with polycythemia vera. They include antiplatelet agents, most commonly aspirin in almost all patients, but select patients may not get aspirin.

In patients who are high risk ... we talk about employing cytoreductive (lowering the numbers of abnormal cells) therapy, which commonly includes hydroxyurea or pegylated interferon. These have been used for decades to reduce the amount of blood cells and decrease the risk of thrombosis (blood clots), which is the primary goal for patients who have (ET).

There's also one agent that's not used in polycythemia vera but is used in (ET), and that's a selective platelet

inhibitor called Agrylin (anagrelide). This treatment reduces the platelet counts but doesn't have impacts on the red blood cell or white blood cell numbers.

## Q: Have there been any changes in the past 10 years to current treatment options?

**A:** Truthfully, the current treatment options for (ET) have not changed in the last decade. However, we've learned more about optimal use of these agents. For instance, we now know more about the use of interferon in this disease through a number of different clinical investigations and trials. We've learned more about the use of (Agrylin) in the second-line setting in this disease as well. And importantly, through better risk stratification, we have learned which patients may benefit the most from cytoreductive therapy and which patients it may not be necessary. We've also learned more about intervening to improve symptoms. Even though they may have one of the more indolent versions of myeloproliferative neoplasms, significant and potentially debilitating symptoms can occur. So how do these current drugs really stack up to each other in terms of their ability to reduce symptoms and improve symptoms for patients? This is something we are beginning to learn more about.

## Q: What are some of the things that are on the horizon to address some unmet needs?

**A:** High-risk (ET) patients on cytoreductive therapy can still have blood clots, so treatments are needed that can even more effectively reduce the risk of thrombosis. There's also inadequate control of symptoms with standard therapy.

But perhaps most importantly, do any of these drugs prevent the disease from progressing to more aggressive forms of myeloproliferative neoplasms like myelofibrosis or acute myeloid leukemia (termed MPN blast phase)? For a lot of the current therapies, it's really unclear. And it's probably unlikely that they significantly reduce the risk for progression. So how would these new therapies employ to accomplish those goals?

## Q: Are there any treatments in the pipeline that are currently being studied, or is there more work needed to be done before we get to that?

**A:** There's a number of agents that are in the pipeline. One is ropeginterferon, which is recently FDA (Food and Drug Administration) approved, called Besremi (ropeginterferon alfa-2b-njft) for polycythemia vera. That's being evaluated in several clinical trials to see if that »



can improve outcomes in patients who have had resistance or intolerance to hydroxyurea, so trying to test that into that disease group. It's also looking at the rates of thrombotic events in that group as well.

But perhaps a more exciting strategy is LSD1 (lysine-specific demethylase 1) inhibition. This protein is important for the transition of stem cells in the bone marrow to megakaryocytes, which make platelets. There's a lot of other factors that go into its ability to reduce inflammatory cytokines which are contributing to the symptoms of the disease, as well as these

different growth factors which may impact bone marrow fibrosis. And so LSD1 inhibition is a target of a drug, called bomeademstat, which is being developed for both myelofibrosis and (ET). Preliminary clinical data in ET patients suggest that it is very successful at reducing platelet counts and it also normalizes white blood cell count, which is another feature as well. But it keeps hemoglobin counts pretty much stable, which is unique among other cytoreductive therapies, which reduce all counts.

It may also improve the burden of ET-related symptoms, especially fatigue

that patients with ET can experience. And importantly, it does look at the amount of mutation burden that someone has, which we think may be a surrogate for progression, although it hasn't fully been established.

And then the other drugs that are in development for ET include Jakafi (ruxolitinib), which is approved for polycythemia vera after (progression on) hydroxyurea and approved for myelofibrosis. (Jakafi) has been evaluated in several studies, and data suggest that it may have a particular benefit in symptom control as well as lowering platelet counts. ■

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This summit will provide patients, survivors and caregivers with the latest research and information on standards of cancer care, emerging therapies, and general wellness.

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# Keytruda as Initial Treatment Provides Survival Benefit in High-Risk Melanoma

Results from the phase 2 SWOG S1801 study show that patients given Keytruda in the neoadjuvant setting had a significant event-free survival benefit compared with those who received adjuvant Keytruda. *By CONOR KILLMURRAY*

**THE USE OF KEYTRUDA** (pembrolizumab) improved survival for patients with high-risk (stage 3 or 4) resectable melanoma when given as initial therapy compared with administration after primary treatment, according to results from a recent study.

At a median of 14.7 months, there were 104 event-free survival (the time after cancer treatment that a patient is free from complications or events that the treatment was meant to delay or prevent) events recorded; in the neoadjuvant (treatment given as a first step to shrink the tumor) group, event-free survival was observed to be significantly longer. The two-year event-free survival rate was 72% compared with 49% in the adjuvant (additional treatment after primary treatment) group.

In the neoadjuvant arm, 8% of patients had disease progression (cancer that grows or spreads) that precluded surgery and 6.5% of patients had residual disease (cancer cells that remain after attempting to remove the cancer) or developed a metastasis prior to adjuvant therapy. Comparatively, 11% of patients in the adjuvant arm experienced residual disease or developed metastasis prior to starting therapy. Moreover, there were fewer tumor-related events, such as disease progression or recurrence, seen in 20% of patients in the neoadjuvant arm versus 40% of the adjuvant arm.

“The administration of anti-PD-1 blockade as therapy before surgery in the neoadjuvant setting induces an immune response from a larger population of T cells that reside in the bulk of the tumor,” Dr. Sapna Patel explained in a presentation of the data at the European Society of Medical Oncology (ESMO) Congress 2022 in Paris.

The phase 2 randomized trial assigned 345 patients to either the adjuvant group (159 patients) or to the

neoadjuvant group (154 patients), which determined when patients would receive treatment with Keytruda.

Keytruda in the neoadjuvant arm also benefited event-free survival in all key subgroups compared with the adjuvant group. These groups included patients 66 years or older, men, patients with stage 3C disease and those with BRAF-mutated disease.

Nine participants in the neoadjuvant arm achieved a complete radiographic response (disappearance of all signs of cancer on imaging) and 59 had a partial response (decrease in tumor size or the extent of cancer in the body from treatment) to therapy. Forty-two patients had an increase in their target lesions but 30 of those patients were still able to receive surgery. One of the patients with a complete response declined surgery and had not had a recurrence of disease after 31.5 months of follow-up.

According to Patel, there were no new safety signals for Keytruda observed in this study and rates of severe or worse side effects were similar between the study groups. The most common side effects in both groups was infection in the skin or wound or a rash. Researchers also saw that Keytruda given in the neoadjuvant setting did not increase side effects during the perioperative period.

As of the time of the presentation, 41 patients in the adjuvant arm were still on therapy along with 43 patients in the neoadjuvant arm. Fewer patients discontinued treatment in the neoadjuvant arm than in the adjuvant arm, at 59 versus 71 patients, respectively. ■



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

**LIBTAYO works with your immune system to help treat advanced CSCC**

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

**46%**  
**63 out of 137 patients**

saw an improvement in their advanced CSCC.

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

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

**41%**  
**23 out of 56 patients**

saw an improvement in their advanced CSCC.

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

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

\*Patients were dosed by body weight.

†LIBTAYO 350 mg over a 30-minute infusion every 3 weeks.

CSCC=cutaneous squamous cell carcinoma.

**LIBTAYO may not work for everyone.**

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

## What is LIBTAYO?

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

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

## Important Safety Information

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

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

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

- **Lung problems:** cough, shortness of breath, or chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual, stools that are black, tarry, sticky or have blood or mucus, or severe stomach-area (abdomen) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), or bleeding or bruising more easily than normal
- **Hormone gland problems:** headache that will not go away or unusual headaches, eye sensitivity to light, eye problems, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, feeling more hungry or thirsty than usual, urinating

more often than usual, hair loss, feeling cold, constipation, your voice gets deeper, dizziness or fainting, or changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

- **Kidney problems:** decrease in your amount of urine, blood in your urine, swelling of your ankles, or loss of appetite
- **Skin problems:** rash, itching, skin blistering or peeling, painful sores or ulcers in mouth or nose, throat, or genital area, fever or flu-like symptoms, or swollen lymph nodes
- **Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with LIBTAYO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:** chest pain, irregular heartbeat, shortness of breath or swelling of ankles, confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs, double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight, persistent or severe muscle pain or weakness, muscle cramps, low red blood cells, or bruising
- **Infusion reactions that can sometimes be severe.** Signs and symptoms of infusion reactions may include: nausea, chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, back or neck pain, or facial swelling

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



## Meet Dave.

### Husband, father, and music lover.

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

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

*—Dave, living with locally advanced CSCC*

**Actual LIBTAYO patient.  
Individual responses may vary.**

To learn more about Dave and other patient stories, visit [MeaningfulStories.com](https://www.MeaningfulStories.com)

## Important Safety Information (continued)

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

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

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

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

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

**Females who are able to become pregnant:**

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

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

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

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](https://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

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

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

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

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

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### Lung problems.

- cough
- chest pain
- shortness of breath

### Intestinal problems.

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

### Liver problems.

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

### Hormone gland problems.

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

### Kidney problems.

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

### Skin problems.

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

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

- chest pain, irregular heartbeat, shortness of breath or swelling of ankles

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

**Infusion reactions that can sometimes be severe.** Signs and symptoms of infusion reactions may include:

- nausea
- dizziness
- chills or shaking
- feel like passing out
- itching or rash
- fever
- flushing
- back or neck pain
- shortness of breath or wheezing
- facial swelling

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

Continued on following page



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

### Females who are able to become pregnant:

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

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

### How will I receive LIBTAYO?

- Your healthcare provider will give you LIBTAYO into your vein through an intravenous (IV) line over 30 minutes.
- LIBTAYO is usually given every 3 weeks.

- Your healthcare provider will decide how many treatments you will need.
- Your healthcare provider will do blood tests to check you for side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

### What are the possible side effects of LIBTAYO?

**LIBTAYO can cause serious side effects, including:**

- See “What is the most important information I should know about LIBTAYO?”

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

These are not all the possible side effects of LIBTAYO.

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

### General information about the safe and effective use of

**LIBTAYO.** Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about LIBTAYO, talk with your healthcare provider. You can ask your healthcare provider for information about LIBTAYO that is written for health professionals.

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This is a brief summary of the most important information about LIBTAYO. For more information, talk with your healthcare provider, call 1-877-542-8296, or go to [www.LIBTAYO.com](http://www.LIBTAYO.com)



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# kidney cancer

## Side Effects With Kidney Cancer Therapies

During the International Kidney Cancer Symposium, Kiran Virdee outlined best practices in kidney cancer symptom management. *By LINDSAY FISCHER*

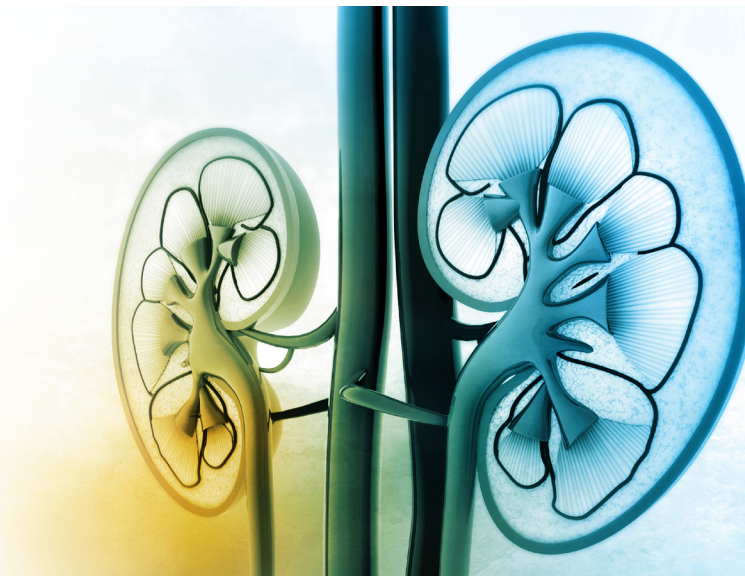
**IN RESPONSE TO THE** growing number of treatment options available, side effect management in kidney cancer has become nuanced, according to Kiran Virdee, a registered nurse at Memorial Sloan Kettering Cancer Center.

During a presentation at the 2022 International Kidney Cancer Symposium, Virdee discussed which side effects have been linked to what drug classes at her clinical practice. For instance, in patients receiving tyrosine kinase inhibitor therapy, common side effects have included hypertension, diarrhea, skin irritation, inflammation of the mouth (mucositis), fatigue and nausea. With immunotherapy, the most common side effects have been colitis (inflammation of the inner lining of the colon), skin irritation, itching, lung tissue inflammation, endocrinopathies (diseases of the endocrine gland) and inflammation of the heart muscle. With radiotherapy, fatigue, pancytopenia (deficiency of red cells, white cells and platelets), skin irritation, swelling and nausea are the most frequently observed side effects, and with surgery, they are primarily pain, wounds and fatigue.

She also said that, although the list is not comprehensive, in her experience the side effects with which patients tend to have the most difficulty day-to-day are high blood pressure, diarrhea, skin irritation, mucositis, fatigue and decreased appetite. She recommends the following strategies for mitigating those toxicities.

### HIGH BLOOD PRESSURE

Taking routine, accurate blood pressure readings and keeping a daily log of measurements.



### DIARRHEA

Here, Virdee stresses the importance of recording baseline bowel movements to gauge the extent to which diarrhea is indeed a problem during treatment. Those who experience diarrhea should try modifying their diet, taking antidiarrheal medication and routine stool sample collection.

### SKIN IRRITATION

For dermatitis, patients should consider daily skin checks, emollient-based creams, topical steroids and consultations with a dermatologist.


### MUCOSITIS

A review of patients' oral care routine may be required if they are experiencing mucositis. Steroid rinses and diet modifications are useful for side effect management.

### FATIGUE

Prioritizing activity is a key component of reducing fatigue, Virdee noted. In addition, patients should maintain a well-balanced diet, limit naps and engage in relaxing activities.

### DECREASED APPETITE

Finally, many patients receiving kidney cancer therapy will experience a decrease in appetite. Small but frequent meals, preplanning meals and snacks and replenishing caloric intake with fluids are all good strategies to deal with the side effect. Collaborating with nutritionists can also help patients manage this toxicity. 





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Research Foundation




A team of patients,  
caregivers, myeloma  
nurses and loved ones  
hiked Mount Washington  
in New Hampshire.



## Hiking to Raise Awareness and Research Funds

**IN THE SUMMER OF** 2022, a team assembled by Moving Mountains for Multiple Myeloma, a partnership between CURE® and Multiple Myeloma Research Foundation (MMRF), hiked Mount Washington in New Hampshire, the highest peak in the northeastern United States and the most prominent peak east of the Mississippi at 6,288 feet above sea level. Known for its extreme weather and popularity in the hiking world, it was an exclusive opportunity to climb as a team and raise funds for the MMRF.

The team consisted of patients, caregivers, nurses and loved ones who were chosen for this challenge, demonstrating the recent advancements made in multiple myeloma that have helped patients live longer with a higher quality of life. The hikers took the Tuckerman Ravine Trail, which offers breathtaking views while trekking upward on an exhilarating hike. Members of the team gained over 4,000 feet in elevation to reach the summit, then spent the night in Lakes of the Clouds Hut. The next morning featured the descent and a celebration of the epic hike. 





# HOUSE CALL BREAST CANCER



## Reframing the Discussion for Surgical Options after Breast Cancer — Women are Choosing to ‘Go Flat’

After undergoing a mastectomy, women can either proceed with reconstruction or ‘go flat,’ but one expert says that the correct decision is what’s best for the patient. *By DR. CAROLYN BHAKTA*

**NO DOUBT ABOUT IT:** A breast cancer diagnosis can be devastating. Thankfully, breast cancer treatment has advanced. Many women are living longer and with greater quality of life and we are seeing higher cure rates than ever before.

But when the focus is on survival, sometimes the last thing on a patient’s mind after undergoing surgery are cosmetic outcomes.

As providers, it is crucial that we approach cancer treatment with the whole patient in mind. Equally important, treatments for both body and mind are essential to a patient’s recovery and restoration of self.

Even after cancer treatment and surgical intervention, patients are left with the scars of their past. As a surgeon, if I can somehow better a person’s cancer experience, no task is too big or too small. In fact, scar placement and surgical technique are among the ways I can help keep patients feeling whole. Inside my toolbox are “Hidden Scar” techniques, specialized oncoplastic techniques performed with the hope of minimizing scar visibility and saving the natural breast shape when possible.

There are several reasons, however, why removal of the entire breast — or mastectomy surgery — may be recommended for the treatment and eradication of breast cancer disease. Why? Maybe a patient’s tumor is so sizable that the only way to surgically remove it is to remove the breast itself. Maybe a patient’s genetic mutation

places her at such a high risk of getting another breast cancer that we perform mastectomy surgery for preventive reasons. Or maybe a patient decides to remove the majority of breast tissue for peace of mind; they no longer want annual mammograms or MRIs for screening surveillance because they know they will be a giant ball of nerves every time they need to get a screening study, and the thought of having an emotional roller coaster is just too much. Each of these reasons is equally valid and important and each shows why the decision to have mastectomy surgery is personal and possibly very complicated.

What happens once a breast gets surgically removed? Generally, there are two options. Surgeons can close the incision and skin over the chest wall, which is now lovingly referred to as “going flat,” or we can rebuild a new breast for patients, commonly referred to as breast reconstruction. The latter option is often a very personal decision, but a point I emphasize with my patients is choice. The cancer treatment journey is theirs and so are the decisions they make along the way. This is where empowerment begins.

For some patients, having a breast mound is part of how they identify as women. When they choose to rebuild the breast after mastectomy, either by using an implant (a foreign body) or by using their own tissue from various parts of the body, we recreate a breast shape





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and form. Performing breast reconstruction involves an additional surgery following mastectomy surgery, which can easily double time in the operating room. The truth is, breast reconstruction may involve multiple surgeries in a stepwise fashion to obtain the desired result. Depending on the patient, the reconstruction portion of the cancer surgery can introduce prolonged healing and recovery times, an increased risk for surgical complications, and additional procedures or surgeries in the future, especially if chemotherapy or radiation is part of treatment.

Alternatively, some women opt for a path that likely takes on less risk, which can mean fewer post-surgical complications (both early on and in the future) and a potential for shorter recovery time. Sometimes the adage “less is more” holds true. Eliminating breast reconstructive surgery and “going flat” can be a way women minimize risk and complications while getting back to activities they love faster.

Here’s my take-home message for my patients who choose not to have reconstruction: Going flat does not equate to going without. In fact, once healed from surgery, patients can get fitted for a prosthetic insert and bra from a specialized breast cancer store that offers personalized fittings. These garments, often covered by insurance because of medical necessity, allow women a nice and natural breast shape under clothing without anyone knowing the difference.

To the women who rock a flat physique after mastectomy: Yes, you are beautiful, too!

When it comes to breast cancer surgery, there are no wrong decisions — only personal decisions. After surgery, scarring is inevitable as a natural part of rebuilding and healing. Scarring can sometimes take on a negative meaning, but what if scars could be a beautiful thing?

Through my lens, breast cancer surgery underscores a woman’s strength, courage and tenacity to face the odds. So let’s change the narrative together and respect personal choice. ■

*Dr. Carolyn Bhakta is a breast surgical oncologist and oncoplastic breast surgeon at Cancer Treatment Centers of America in Chicago.*



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# SPEAKING OUT TESTICULAR CANCER

## Lasting a *Lifetime*



As part of its *Speaking Out* video series, CURE® spoke with Michael J. Rovito, on behalf of the Testicular Cancer Foundation, about survivorship. By KRISTIE L. KAHL



**WHILE TESTICULAR CANCER IS** considered one of the most treatable and survivable cancers, survivorship and awareness of long-term effects from the disease and its treatments last a lifetime after diagnosis. Therefore, advocating for oneself and being aware of the risks are essential for patients.

As part of its *Speaking Out* video series, on behalf of the Testicular Cancer Foundation, CURE® spoke with Michael J. Rovito, associate professor in the department of health sciences at the University of Central Florida in Orlando, about survivorship and the key areas patients should be aware of so they can be vigilant and their own best advocates.

**Q:** After treatment has ended and patients have to transition back to their primary care provider, what kind of long-term follow-up is required for a survivor of testicular cancer?

**A:** It depends on the stage at which you're diagnosed and then also the type (of diagnosis you receive). If you have early stage, stage 1 or maybe early stage 2, some of it can be watchful waiting after you have your orchiectomy. And then it could be watchful waiting or active surveillance; that depends on how early you get diagnosed and treated. With later-stage (disease), the long-term follow-up is a little bit more invasive with chemotherapy (and/or radiation), active surveillance, watching and waiting.

**Q:** Are there any long-term effects that have to be monitored after treatment?

**A:** The typical chemotherapy regimen, it does produce some toxic effects later in life. And there's been studies that show survivors are at an increased risk of opioid toxicity or cardiotoxicity. ... I've read there's a bevy of different issues, not just physical health, but mental health issues as well, anxiety and depression, suicide tendencies. There's a whole laundry list of things in survivorship. So testicular cancer is not just about survivorship, which is the ultimate goal, but there's other things as well (like) long-term, health-related quality of life. There's going to be a lifetime of possibilities that may pop up. And so we have to be very diligent with educating survivors on ... continuing follow-up through the decades. There has been a lot of research out there, enlightening research that shows that the survivors are at risk for a lot of things that we didn't think about a few years ago.

**Q:** Are we or should we be utilizing survivorship care plans? If so, what should that look like?

**A:** I've talked to some urologists who have done survivorship care plans with testicular cancer. There has been some published stuff online that you could find for prostate cancer, and they're good. There's treatment plans or survivorship care plans, and they're good for helping organize the



whole team — the survivor, the oncologist or the neurologist, or family, whoever's involved. It's good, in my opinion, to have everyone on the same page. Everyone's clear, everyone's focused, everyone knows what the end goal is. I think they're helpful. But it really all depends on the person, on the type of survivor, on how they best operate in terms of how they're organized and how they think it's probably best talking about them first. But they are helpful for many, many people.

#### How can groups like the Testicular Cancer

**Q:** Foundation help men transition into survivorship and throughout their lifetime?

**A:** I think it's best for organizations like (the Testicular Cancer Foundation) to really be the voice for people. One thing that I've discovered talking and working with survivors is that they realize that they have a voice

and they can ask questions, that they could find information out just by using that internal voice of theirs, (which) is to be inquisitive, and ask your doctors or rely upon organizations like (the Testicular Cancer Foundation) or other survivors themselves, just to get the information that you need. So I would suggest to continue being that voice for people who have not found their voice yet, because there are a lot of men out there and families and caregivers who are suffering silently because they don't know about their risks, about treatments, about advocacy, about other resources out there to help them. So continue to be that voice that you already are.

**What would you say is your biggest piece of advice for those men who are just finishing treatment and they're about to enter survivorship following their testicular cancer diagnosis?**

**Q:**

**A:** The first half of the battle was won, but now there's the rest of your life to live. You've got through surviving, but now there's other issues that (may come) up. It could be weeks or months, even years afterward, even decades afterward, that you have a unique risk for and it could be very different things, but that you can do this, that most men do this, most males that are in this situation do this. And you can do this, too. You have to be educated, aware and be an advocate for yourself so that you could live your life to the fullest, that your quality of life is at the highest amount. **Q**

*Transcription edited for clarity and conciseness.*



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