

HEMATOLOGY

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Cancer Updates, Research & Education[®]

It Takes a *Village*

Caregivers may face financial toxicity and stress — with little time to care for themselves.

HEMATOLOGY

SPECIAL ISSUE · 10.21

ACUTE MYELOID LEUKEMIA

A batch of clinical trials offers patients hope for a brighter future.

NK CELL THERAPY

The new therapy may lead to a more direct way to kill cancer cells, according to one expert.

CHRONIC MYELOID LEUKEMIA

As the approval of Gleevec turns 20, *CURE*[®] speaks to the longest-living survivor treated with the drug.

ACUTE LYMPHOBLASTIC LEUKEMIA

A three-time survivor gives back as a bone marrow transplant nurse.

CHRONIC LYMPHOCYTIC LEUKEMIA

A novel treatment combo may improve survival outcomes and reduce time in the hospital.



UP ALL
NIGHT
CONCERNED



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MAT-HEM-02320 08/21

A person is lying in a hospital bed, seen from behind. They are wearing a dark-colored t-shirt. The back of the t-shirt has the text "YOUR COUNTS ARE UP TOO?" printed in large, white, bold, sans-serif capital letters. The person's face is partially visible in profile, and they appear to be sleeping. The room is dimly lit with a blueish-green tint.

**YOUR
COUNTS
ARE UP TOO?**

For people with polycythemia vera (PV), fluctuating blood counts can keep you tossing and turning. Before another night passes, visit **KEEPINGCOUNTS.COM**

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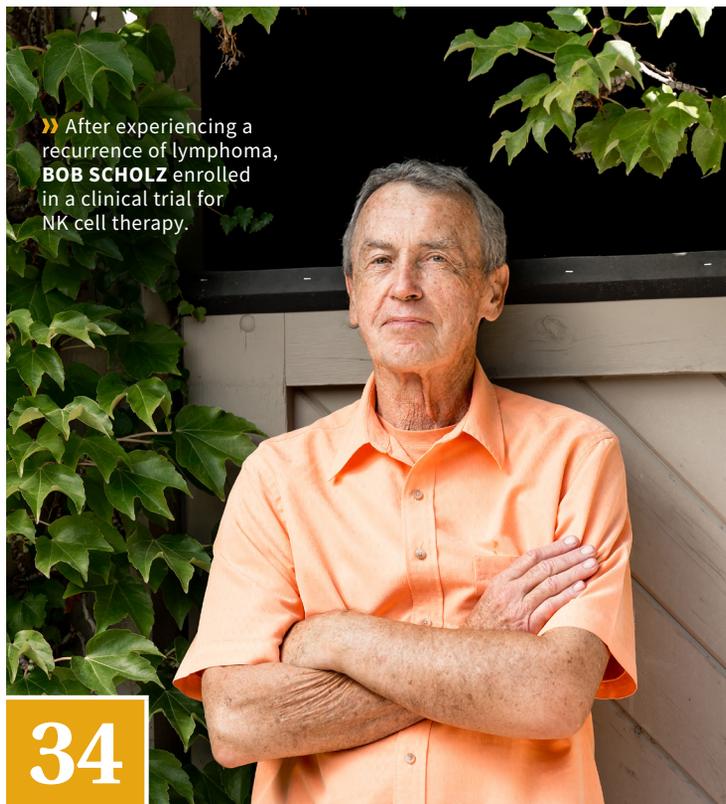
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New Treatments and Tips for Dealing With Blood Cancer

DID YOU KNOW THAT every three minutes someone receives a diagnosis of a blood cancer? According to the National Foundation for Cancer Research, blood cancers account for nearly 10% of new cancer diagnoses in the United States annually. That means that approximately 178,520 people will receive a diagnosis this year — most commonly with leukemia, lymphoma or myeloma. And although survival rates have increased dramatically over the past 20 years, there's still a long way to go when it comes to this patient population.

“According to the National Foundation for Cancer Research, blood cancers account for nearly 10% of new cancer diagnoses in the United States annually.”

Dive into the issue for two patient stories, one about a three-time acute lymphoblastic leukemia survivor who now works as a nurse on the bone marrow transplant floor at Barnes-Jewish Hospital in St. Louis. This year also marks the 20th anniversary of the Food and Drug Administration's approval of Gleevec (imatinib mesylate), the tyrosine kinase inhibitor that saved Mel Mann. Who is Mel Mann? He is the longest-living survivor who was treated with the drug as a part of a clinical trial for chronic myeloid leukemia.

And because cancer is not a disease one should have to face alone, our cover story looks at the responsibilities and experiences of caregivers to patients with blood cancer. Not only will you read about what they've gone through, but you'll also find extra resources and tips for navigating the patient-caregiver relationship.

As always, thank you for reading. 

In this special issue of *CURE*®, you'll read about some of the research going on in blood cancer right now, including new treatment options for acute myeloid leukemia and a novel therapy using BK virus-specific T cells to treat BK virus-associated hemorrhagic cystitis (a painful side effect of stem cell transplants).

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Future Looks Bright With Engineered Cells

THE 1966 MOVIE “FANTASTIC VOYAGE” envisioned a nanotechnologic approach to fighting disease using miniaturized tools. In 2017, the Food and Drug Administration approved the United States’ first chimeric antigen receptor (CAR)-T cell therapy, which employs an immune cell that has been adapted to recognize tumor-specific antigens and destroy the cells that bear them. Since then, the field of engineering cells has matured as researchers begin to dive into the potential use of natural killer (NK) cells through the same technology used for CAR-T cells, but, hopefully, with less of the collateral damage that can result from excessive immune activation and inflammation. Although we are still learning about NK cells, we do know that they function similarly to CAR-T cells as effector lymphocytes of the immune system and work to control several types of tumors and microbial infections.

Currently, there is much sophisticated research behind the new therapy, and it is hoped that it may also have fewer

side effects than CAR-T cell therapy. In this special issue of *CURE*®, read more about the therapy and how it’s being used in different types of blood cancers. One patient tells his story of receiving NK cell therapy through clinical trials after receiving a diagnosis of metastatic lymphoma in the throat, lung and liver. His disease went back into remission in early 2021, and he is thankful for the novel therapy. Another patient, who received a diagnosis of multiple myeloma in 2016, participated in a clinical trial in which she received a dose of allogeneic NK cells. She experienced no side effects except fatigue. Both patient outcomes show promising results of the new therapy for hematologic cancers. Engineered cell technology is an example of ingenuity that brings together cutting-edge laboratory science and clinical trials to address aggressive cancers in a “Star Wars”-style strategy that is already paying off yet continues to evolve as a potential option for more common types of cancers. ■



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chronic myeloid leukemia



«
MEL MANN AND HIS WIFE, CECELIA, at the 2015 Atlanta Peachtree 10K Road Race.

The ‘Miracle Drug’

Gleevec was approved by the FDA in 2001. The groundbreaking oral drug has since been a lifesaver for many patients with chronic myeloid leukemia. *By ANTONIA DEPACE*

IN 1995, MEL MANN visited his primary doctor in Michigan for back pain and slight fatigue. Results from an MRI showed irregularities in his bone marrow. “They ended up taking a simple blood test and they saw that my white (blood cell) count was

elevated to 132,000 where it should have been below 10,000,” Mann explained in an interview with *CURE*®. Soon after, he received a diagnosis of chronic myeloid leukemia (CML) and was given three years to live. He was 37 years old.

After being told that a bone marrow transplant was his best chance at a longer life, Mann visited several donor drives to tell his story and, hopefully, find a match. Another patient with leukemia told him about The University of Texas MD Anderson Cancer Center in Houston. A quick phone call got Mann an appointment, which led to an increased dose of the standard of care at that time — interferon therapy, in which proteins that mimic those naturally made by the immune system are given to reduce the growth and division of leukemia cells — and, eventually, enrollment in the phase 1 clinical trial for Gleevec (imatinib mesylate).

“I was really curious ... How could this pill do what (a bone marrow) operation did?” he remembered. “They (were) telling me that it was a targeted drug, and it was only going to go for the bad cells and ... leave the good cells alone, and that that in itself was a miraculous thing.”

Nearly **27 years later**, Mann is known as the **longest-living survivor** treated with Gleevec.

In 2001, three years after the clinical trial, Gleevec was approved by the Food and Drug Administration (FDA). This year marks its 20th anniversary.

“It (was) really a lifesaver,” Mann said. “It’s a miracle drug.”

Here, *CURE*® looks back with a timeline of the groundbreaking drug, along with Mann’s journey.

1960

Dr. Peter Nowell, a researcher at the University of Pennsylvania, and Dr. David Hungerford, a graduate student at the Fox Chase Cancer Center in Philadelphia, notice that one of the 46 chromosomes in a patient with CML was short. The short chromosome was later named the Philadelphia chromosome. Researchers found that 95% of patients with CML had this genetic abnormality.



^ MANN with his wife and their daughter, who is now a doctor.

1981
TO
1984

Dr. Nora Heisterkamp, then a visiting fellow at the carcinogenesis mechanisms and control section, laboratory of viral carcinogenesis at the National Cancer Institute in Maryland, identifies two genes, BCR and ABL, which become fused as a result of chromosomal translocation (when two chromosomes break and the pieces swap places). This discovery allows researchers to understand the molecular basis of CML as well as Philadelphia-chromosome-positive acute lymphoblastic leukemia. Dr. Owen Witte and colleagues at UCLA later prove that the protein encoded by the genetic hybrid causes CML when it forms in the blood.

1995

Mel Mann, 37, receives a diagnosis of CML. Mann is in the Army and has a 5-year-old daughter.

1998

Dr. Brian Druker of Oregon Health & Science University in Portland tests Gleevec in a phase 1 trial with 83 patients across three sites, one of whom is Mann. Mann stays in Houston for the first 90 days of the trial; he is the second patient at MD Anderson to receive Gleevec.

2001

The FDA approves Gleevec to treat patients with CML who have the Philadelphia chromosome. According to the final data, complete hematologic responses (disappearance of the cancer) were observed in 53 of the 54 patients and cytogenetic (chromosomal) responses occurred in 29 patients, seven of whom had complete cytogenetic remissions.

1999

Mann runs a marathon and completes the 111-mile El Tour de Tucson bike ride in Arizona for the Leukemia & Lymphoma Society's Team in Training.

2003

Of patients from the phase 1 Gleevec trial who received the drug, 98% are still in remission.

2021

Gleevec celebrates the 20th anniversary since its FDA approval. Mann, now 64, continues to take Gleevec and is considered the longest-living patient treated with the drug.



Brukinsa Offers Less Toxic Option for Patients With MCL

The use of Brukinsa may induce fewer cardiac issues and other side effects than other treatments, study results show. *By ANTONIA DePACE*

THE NATIONAL CANCER COMPREHENSIVE NETWORK (NCCN) added Brukinsa (zanubrutinib) as a second-line treatment option for mantle cell lymphoma (MCL) to its guidelines earlier this year, making it a potential option with fewer side effects for patients.

In an interview with *CURE*®, Dr. Elizabeth Budde, an associate professor in the Division of Lymphoma, department of hematology and hematopoietic cell transplantation, at City of Hope in Duarte, California, and a

member of the NCCN Clinical Practice Guidelines in Oncology for B-Cell Lymphomas, discussed the benefits of the drug and what the updated guideline means for patients with MCL.

Q: **Can you go into more detail about the data that led to the 2019 approval and recent NCCN update?**

A: This approval (was) based on a recent clinical trial, which looked at the overall response rate in close to 100 patients — 86, to be

exact. They measured the change of the tumors after treatment and also looked at the median duration of response. What this study found out is that the overall response rate is quite high; (approximately) 84% of patients had lymphoma shrinkage, and the median duration of response (was) around 18.5 months. The (side effects) of the study look to be pretty favorable and seem to be safer than the first-generation BTK inhibitor Imbruvica (ibrutinib), which was the first BTK inhibitor approved for mantle cell lymphoma. Therefore,

this drug was approved based on the overall response rate and the duration of response and became the third BTK inhibitor approved for this patient population.

Q: What does this mean for patients?

A: I think this is a great option for patients, especially when we think about (patients with) mantle cell lymphoma. These patients tend to be in their late 60s, close to 70s, and some of them might have underlying disease such as an atrial fibrillation (irregular, rapid heart rate) and ... (gastrointestinal) problems such as peptic ulcer or gastritis. ... This drug really distinguishes itself from the first-generation BTK inhibitors in that it doesn't really seem to increase the risk of atrial fibrillation or other cardiac events. It appears to be safe for patients with underlying cardiac conditions. More importantly, the drug doesn't really require the patient to be off any antacid, so there's no interaction whether the patient is on antacid or not. ... It really broadens the patient population that can benefit from BTK inhibitors.

The first-generation BTK inhibitors — as we know, there are more and more studies coming out — clearly show there is an association with the increased risk of cardiac events, but the second-generation (BTK inhibitors) such as Calquence (acalabrutinib) and (Brukinsa) seem to be pretty safe in patients with no previous conditions with cardiac problems. ... For different BTK inhibitors, if you are on an antacid that is required, you have to space it out because it affects the

This drug really distinguishes itself from the first-generation BTK inhibitor in that it doesn't really seem to increase the risk of atrial fibrillation or other cardiac events.

— DR. ELIZABETH BUDDÉ

absorption, but for Brukinsa this is not a problem. Another added benefit is that patients on this particular inhibitor don't seem to have as (many) headaches. ... Also, compared (with) the first generations, the second-generation (BTK inhibitors) seem to have a better safety profile with regard to bleeding.

Q: How does Brukinsa compare with other second-line treatment options for MCL?

A: I think the lack of interaction with antacids is a huge advantage. That's the main safety profile that really distinguishes Brukinsa from other second-generation BTK inhibitors, but with regards to efficacies, all BTK inhibitors are pretty similar.

Q: Why do the second-generation BTK inhibitors seem to be more favorable for patients?

A: (With) the first-generation (BTK inhibitors), the goal is really to target the BTK, which is a kinase in the mantle cell lymphoma signal pathway, and so the first generation has what we call on-target effect but also (has) off-target effect, meaning it is not specific enough. Mainly it

targets BTK, but it also targets other kinase activity, which translates into some of the unwanted side effects. The second-generation BTK inhibitors are more specific, so they still have on-target effect, but the off-target effect is much less; hence, a more favorable safety profile.

Q: What are some of the side effects that patients may have with Brukinsa?

A: Low blood (cell) counts are one of the common side effects, and minor bleeding could also be potential side effect, (along with) rash, diarrhea and cough. Most of these, though, are probably pretty well managed. In most patients, if they develop these side effects ... this will get much better over time.

Q: What should patients consider before choosing a second-line treatment?

A: A good discussion with their (treating) hematologist or oncologist is very important because every patient is different. And based on the underlying conditions, the oncologist might recommend a particular BTK inhibitor. ■

This interview has been edited for clarity and conciseness.

The Power of the Immune System

A new T-cell therapy can be highly effective in treating BKV-associated hemorrhagic cystitis while minimizing side effects. *By ANTONIA DEPACE*



USING BK VIRUS (BKV)-specific T cells from healthy donors to treat BKV-associated hemorrhagic cystitis, a painful side effect associated with immunosuppression from stem cell transplants, may relieve the complication faster in patients with lymphoma or leukemia, according to trial results.

“What was very important was that within a week of giving the cells, the majority of patients’ symptoms improved,” Dr. Katy Rezvani, professor of stem cell transplantation and cellular therapy at The University of Texas MD Anderson Cancer Center in Houston and lead study author, said in an interview with *CURE*®. “The effect of the cells is relatively rapid.”

BKV-associated hemorrhagic cystitis occurs more frequently in patients with leukemia or lymphoma who received a treatment of allogeneic stem cell transplantation. As a result, it can lead to patients having blood in their urine and passing clots, which can cause urinary retention (difficulty urinating or completely emptying the bladder) and, in more severe cases, kidney disease.

In patients who receive stem cell transplants, those who have a half match (when patients only have some genetic similarities with the donor’s immune system) are at an increased risk for BKV-associated hemorrhagic cystitis because they are more immunosuppressed. Approximately 40% of patients

who have a half match develop this complication.

In the phase 2 trial, BKV-specific T cells, which recognize and attack BKV, from healthy donors were given once intravenously, with the option to receive additional doses every two weeks if needed. Of the 59 patients enrolled in the trial, 67.7% had complete (all symptoms resolved) or partial (almost all symptoms resolved) responses within 14 days. This increased to 81.6% after 28 days.

Some intolerance was observed in patients who were previously treated with steroids, which can kill T cells. There were no side effects, and there were no reports of new liver or gastrointestinal graft-versus-host disease (GVHD, occurs when the donor’s cells attack the patient’s cells) associated with the antiviral T cells, aside from a few cases of skin GVHD that quickly resolved with corticosteroids.

This treatment has the potential to stop the vicious cycle that comes with the current standard of care, which consists of hospitalization with continuous bladder irrigation (using a catheter to wash out the bladder) and morphine infusion to help patients tolerate the pain, according to Rezvani.

“This outpatient treatment is preventing patients from having to be admitted (to the hospital), which

is wonderful because patients come into hospital with one thing, they stay in the hospital for a few weeks, then they develop other complications,” Rezvani explained. “They start getting other infections, they get pneumonia, they become malnourished, etc.”

According to Rezvani, one donor can produce up to 50 doses of T cells, which are frozen until needed. “Every time the patient comes (into the hospital), within 24 hours we can treat them,” she said.

Of note, the therapy is only available at MD Anderson, so patients with the complication would need to travel to the health center to receive it — an option that may not be possible because of physical condition or finances. “I’m hoping that we will get to a situation where we’ll be able to start a multicenter study at some point,” Rezvani said, which would make the care more accessible to patients. “In the meantime, I think the greatest limitation really is that patients will have to come to MD Anderson to receive the treatment, and for many patients with the terrible BKV hemorrhagic cystitis, this is not obviously possible.”

Until then, Rezvani is focusing on the next generation of the treatment: genetically modifying BKV-specific T cells that are more resistant to steroids, thus broadening the patient spectrum that the treatment could help.

“It’s important to realize that the use of immunotherapy against viruses and cancers (has) opened up a very exciting new era of treatment for our patients,” she concluded. “We are learning a lot more from the immune system (and are harnessing) the power of the immune system to fight infections and cancers. ... I think the field is going to continue to grow, and many more such treatments to target both viruses and cancers (are) going to become available.” ■

For the treatment of mantle cell lymphoma

Discover a complete treatment in BRUKINSA

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

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

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

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

IMPORTANT SAFETY INFORMATION

What should I tell my healthcare provider before taking BRUKINSA?

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

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

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

What are the possible side effects of BRUKINSA?

BRUKINSA may cause serious side effects, including:

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

- **Heart rhythm problems (atrial fibrillation and atrial flutter).**

Tell your healthcare provider if you have any of the following signs or symptoms:

- your heartbeat is fast or irregular
- feel lightheaded or dizzy
- pass out (faint)
- shortness of breath
- chest discomfort

The most common side effects of BRUKINSA include:

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

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

What is BRUKINSA?

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

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

Please see full Prescribing Information at BRUKINSA.com.

LEARN MORE AT BRUKINSA.COM

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COVER STORY caregiving

It Takes a *Village*



Caregivers may face financial toxicity and stress — with little time to take care of themselves.

By DARA CHADWICK

For Danna Wessels of Austin, Texas, it all began with two itchy patches of skin on her abdomen. In 2007, Wessels, now 63, received a diagnosis of stage 1a mycosis fungoides, a form of cutaneous T-cell lymphoma.

At the time, her then-partner and now wife of nine years, Nancy Noble, made one request: “I asked her not to look at the (internet) when she got the diagnosis,” Noble says. “Because I did.”

Their lives changed quickly as Wessels faced constant itchiness that made

normalcy a challenge. “Danna couldn’t really go out,” Noble says. “I felt pretty helpless.” Still, Wessels, who also has type 1 diabetes and Addison’s disease (an autoimmune disease in which the body attacks the adrenal glands and destroys them), was no stranger to managing chronic medical conditions. She used steroid cream to help control the itching and relied on her wife to help with heated wet wrap treatments.

But Noble knew from her research that things could get worse — and they did. »



NANCY NOBLE (left) took three weeks off work, along with picking up other caregiving responsibilities, after her wife, **DANNA WESSELS** received a diagnosis of a rare type of lymphoma.



The disease moved from Wessels' skin to her blood, and in June 2011, she required a stem cell transplant. To prepare, Wessels had 40 treatments of total skin electron beam therapy, a type of radiation that treats the skin on the entire body, over 10 weeks. After her stem cell transplant, she remained in the hospital for 28 days.

Noble worked from her wife's hospital room and then took three weeks off from her high-pressure job at a medical device company to care for her. "She was amazing," Wessels says. "She was my rock. She did it all."

"All" included learning how to flush the port in her wife's chest with sterile fluid to keep it clean. It also included nonstop housecleaning to help prevent infection and preparing food to help Wessels build her strength. When she had to return to work, Noble hired outside help to care for her wife during the day and drive her to appointments.

A blood cancer diagnosis a loved one is frightening, Noble says. "I knew there was only so much I could personally do," she notes. Instead, she focused on the practical details and relied on her faith that things would work out. "It's one of those experiences where I say, 'How did we do that?'" Noble says. "I just remember doing what we had to do."

Noble knew taking care of herself was critical. "I lost about 30 pounds in preparation for Danna's transplant because the last thing you need is to get sick yourself," she says, adding that as the provider of the family's insurance, she worried about job security. "I told management, 'This is what's going on, and it's a big deal.' Fortunately, they were sympathetic."

REALITY OF CAREGIVING

Wessels says Noble took on another important caregiving role: keeper of information. She spoke with doctors and »



“She was amazing. She was my rock. She did it all.”

—DANNA WESSELS

managed details so Wessels didn't have to. But for some caregivers, managing those details and participating in the decision-making process can feel overwhelming.

Having a good understanding of disease prognosis can prove critical. Yet sometimes caregivers may not be clear on what they're being told or may have trouble accepting it. A study presented at the 2021 annual meeting of the American Society of Clinical Oncology found that some caregivers don't acknowledge that their loved one is terminally ill.

Study author Dr. Elizabeth O'Donnell, director of lifestyle medicine and a medical oncologist in the Multiple Myeloma Disease Center at Massachusetts General Cancer Center in Boston, and her colleagues studied 127 caregivers of patients with multiple myeloma in various treatment stages. They found that although more than 80% of caregivers understood the oncologist's message that multiple myeloma is an incurable cancer, only 53% said their loved one was incurable.

Although physicians do a good job of telling patients and caregivers about prognoses, caregivers often leave "space for hope," O'Donnell says. Still, understanding prognosis plays an important role in how caregivers cope. In O'Donnell's study, more than 88% said it was extremely helpful for coping.

"Within our blood cancer population, particularly with multiple myeloma, where you have an incurable but long-term illness, levels of stress and distress can be quite high for most patient caregivers," she says, adding that that's why having support is critical for caregivers.

Sarah Miretti Cassidy, director of external affairs for the Chester, New Jersey-based Cancer Hope Network, knows exactly how important support is. The organization trains cancer survivors and caregivers as support volunteers and matches them with clients currently undergoing treatment or caring for a loved one with the disease. Cassidy, herself, was matched with a caregiver volunteer when she was caring for her mother-in-law.

"Connecting with a volunteer helps you know that you're not alone," she says. "That's probably the biggest benefit that Cancer Hope Network offers to caregivers. It may be the first time you're caring for a loved one, but you're not the first person who is caring for a loved one."

Her volunteer helped with practical information such as what to expect when chemotherapy started and a helpful method for moving her mother-in-law without hurting her, Cassidy says.

"Volunteers don't tell you what you should do," she says. "They share their experience and offer suggestions. They say, 'Here's what worked.'"

Patricia Hlafter of Princeton, New Jersey, volunteers with the organization to help support other caregivers. She cared for her husband, who has been treated for what she calls a "very treatable" hairy cell leukemia. "He did pretty well," Hlafter says, noting that he had a busy job at the time, so in

her role as a caregiver, she had to make sure he ate and took care of himself.

But Hlafter also cared for her mother, who had stage 4 non-Hodgkin lymphoma and died in 2000. That experience was very different from caring for her husband, she says, adding that she shared caregiving responsibilities with her two sisters.

Hlafter scaled back her work so she could drive her mother to chemotherapy appointments, and the two would chat during her treatments. "One of the benefits was the opportunity to have all that time with her," she says.

When cancer ultimately returned, Hlafter's mother decided to forgo a third round of chemotherapy. "That made me sad," she says. "But I knew there was no choice except to respect her decision."

Now, Hlafter helps caregivers strategize about how to care for their loved one and themselves. "I think that when someone is a caregiver for the first time, you don't know what the rules are," she says. "You have to know that you will make mistakes, and you have to follow your instincts."

COMMUNICATION IS KEY

Listening is critical, Hlafter says. She encourages caregivers to talk with their loved one about how they're feeling. When caregivers pay attention to those everyday conversations, they can learn a lot, she says. "Be alert for the clues your patient gives you," Hlafter adds. "It helps you to help them."

It's also important for caregivers to know as much as possible about the patient's illness. "The more you know, the more you'll understand some of the things that might happen during the course of treatment," she emphasizes. "It helps you know what's normal for someone who is undergoing cancer treatment and what is alarming and needs to be brought to the attention of the doctor immediately."

Getting needed information can be challenging for some caregivers, according to Carma Bylund, a professor in the department of health outcomes and biomedical informatics in the College of Medicine at the University of Florida in Gainesville. Bylund and her colleague Carla Fisher, have partnered with the Leukemia & Lymphoma Society to study caregivers of people with blood cancer. Their most recent study, which was published in the May 2021 issue of *Translational Behavioral Medicine*, examined the effects of COVID-19 on adult caregivers of parents with blood cancer. But some of the themes that emerged are applicable to all caregivers — particularly those around communication, Bylund says.

"We're seeing more attention being paid to what's called the triad in the clinical encounter and some of the challenges that come with that," she says. "You have a caregiver, a patient and a clinician."



PATRICIA HLAFTER had experience caregiving prior to her husband's diagnosis of hairy cell leukemia.

Older patients may have grown up with a paternalistic model, where whatever the doctor says is what must be done, Bylund adds.

Bylund and her colleagues developed models to help caregivers communicate more effectively with doctors. One, called PACES, encourages caregivers and patients to present information, ask questions, check understanding, express concerns and state preferences. Caregivers may need to use some additional communication skills — for example, introducing themselves to the doctor, asking permission from the patient to share information and checking with their patient to make sure what they're saying is accurate. These conversations help build trust between caregivers and their loved ones and between doctors and caregivers.

TAKE CARE OF YOURSELF

Managing clinical conversations and constantly sharing information about a loved one's condition with friends and family can take a toll on caregivers. Also exhausting: feeling as though they never get a break. Yet many caregivers struggle with the balance of finding the resources they need to make sure their loved one is cared for and feeling guilty when they need a pause.

"Taking care of yourself is one of the most important things that should be on every caregiver's list, as hard and impossible as it may seem," Hlafter says, "even if it's just arranging for someone to have a cup of tea with your loved one while you run out to do something for yourself."

Cassidy agrees, adding that in addition to offering peer support and mentorship, organizations such as Cancer Hope »



“Taking care of yourself is one of the most important things that should be on every caregiver’s list, as hard and impossible as it may seem.”

—PATRICIA HLAFTER

Network can connect caregivers with other resources to ward off burnout. Some of these resources can help with finding respite care or financial assistance. “Financial toxicity is a massive challenge people face,” she says. “All of a sudden you’ve got these additional burdens at home while you’re trying to keep the job that may be providing the insurance that’s getting your loved one treatment.”

Cassidy encourages caregivers to talk with their treatment center’s navigator or social worker. “They know a lot of resources available in your community,” she says. “It’s a great place to start.”

Talking with others who’ve been in the caregiving role can provide reassurance that feeling overwhelmed, exhausted and afraid is normal. Another critical task in avoiding burnout? Try to find personal meaning in the caregiver role.

“Caregiving is one of life’s great honors,” Cassidy says. “You’re fighting alongside somebody you love. It’s also frustrating. Those two feelings aren’t mutually exclusive.”

RESOURCES FOR CAREGIVERS

For information and resources to help manage the stress of caring for a loved one with cancer, visit:

Bag It
www.bagitcancer.org

Cancer Hope Network
www.cancerhopenetwork.org

Family Caregiver Alliance
www.caregiver.org

Rosalynn Carter Institute for Caregivers
www.rosalynncarter.org/



EXPECT PROGRESS

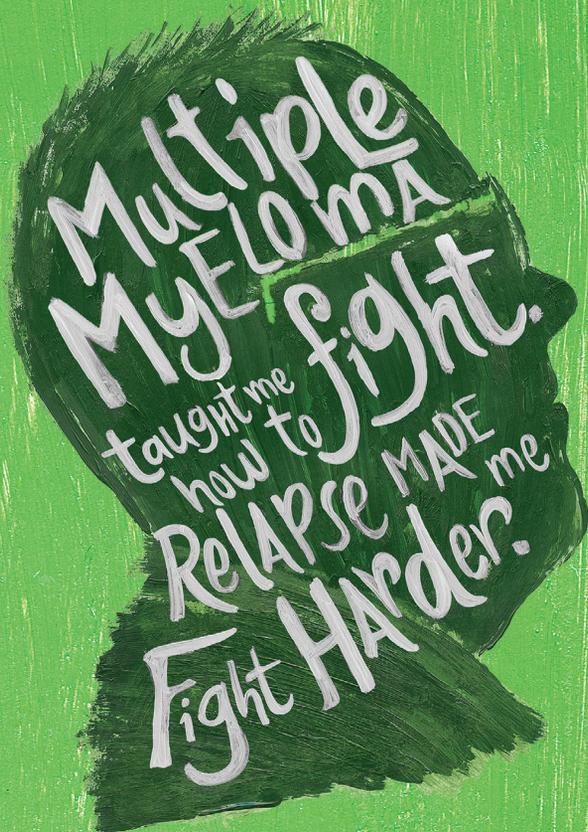
The MMRF's Events platform supports our ongoing critical research efforts and unites our dynamic community.

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MMRF Events: Crucial to a Cure.

Visit [TheMMRF.org/Events](https://www.themmr.org/events) to learn more and register today.





IMPORTANT FACTS ABOUT BLENREP

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

What is BLENREP?

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

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

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

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

BLENREP can cause serious side effects, including:

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

- Your healthcare provider will send you to an eye specialist to check your eyes before you start treatment with BLENREP,

prior to each dose of BLENREP, and for worsening symptoms of eye problems.

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

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

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

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

If you don't have prescription coverage or need help paying for your medicines, call us at 1-844-4GSK-ONC (1-844-447-5662).



IN RELAPSED OR REFRACTORY
MULTIPLE MYELOMA...

RESOLVE BROUGHT
YOU THIS FAR

TALK TO YOUR DOCTOR TO SEE WHERE
BLENREP
MAY TAKE YOU

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

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

What is BLENREP?

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

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

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

How will I receive BLENREP?

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

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

- have a history of vision or eye problems.
- have bleeding problems or a history of bleeding problems.
- are pregnant or plan to become pregnant. BLENREP can harm your unborn baby. **Females who are able to become pregnant:** Your healthcare provider may do a pregnancy test before you start treatment with BLENREP. You should use effective birth control during treatment with BLENREP and for 4 months after the last dose. Talk to your healthcare provider about birth control methods you can use during this time. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with BLENREP. **Males with female partners who are able to become pregnant** should use effective birth control during treatment with BLENREP and for 6 months after the last dose.

- are breastfeeding or plan to breastfeed. It is not known if BLENREP passes into your breast milk. Do not breastfeed during treatment with BLENREP and for 3 months after the last dose.
- BLENREP may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.

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

These are not all the possible side effects of BLENREP.

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

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


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FEATURE acute myeloid leukemia



ACUTE MYELOID LEUKEMIA / STOCKADO BECOM

Better Days Ahead for Patients With AML

An abundance of clinical trials is giving patients hope for a better future.

By MEERI KIM

As an almost 30-year veteran of the Secret Service, Jim Helminski took pride in maintaining his physical health — both for his own sake and to be better fit to protect others. His demanding career placed the safety of Presidents Bill Clinton and George W. Bush and then-Vice President Joe Biden in his hands.

In late 2015, he retired as deputy assistant director to live a more tranquil life on Orcas Island, Washington, with his wife, Teresa Patrick, a former Department of Justice attorney. Not one to sit still, Helminski started a security consulting business on the side while running, weightlifting and practicing karate. He even earned his private pilot's license and began flying a vintage Cessna. »



During a routine yearly checkup in 2019, his primary care doctor remarked that Helminski was in better shape at 61 than most 30-year-olds who came into the office. But later, that changed.

"I went for a jog one day that week after my exam, and my cell phone rings. It was my doctor, and he said, 'Jim, there's something wrong with your blood. Your white blood cell count is dangerously low,'" Helminski, now 63, recalls. "I had no symptoms. I felt nothing."

The direness of the situation hit him when he arrived at a Seattle-based health facility for a consultation with a hematologist that ended with a bone marrow biopsy. A few days later, he received a diagnosis of myelodysplastic syndrome (MDS), a type of cancer in which immature blood cells in the bone marrow do not mature or become healthy blood cells. MDS can be a precursor to different types of leukemia. His myelodysplastic syndrome progressed rapidly to acute myeloid leukemia (AML).

AML, which starts in the bone marrow, usually moves

quickly into the blood. From there it can spread to other parts of the body, including the lymph nodes, liver, spleen, brain and spinal cord. Typically, AML develops from the malignant transformation of cells that would turn into white blood cells, but it also may start in very immature forms of red blood cells or cells that make platelets. Approximately 19,940 new cases of AML were diagnosed last year in the U.S., with most occurring in adults.

"It was a huge shock," Helminski says. "I scheduled an appointment at the (regional) cancer center to see one of their top leukemia doctors, and it became the lowest point in my life."

The reviewing oncologist advised him that standard treatment gave him only a 10% to 20% chance of remission and provided little guidance about which therapy to pursue. Instead, he simply recommended that, rather than attempting standard chemotherapy, Helminski and his wife look online to find a list of clinical trials for AML and pick one. »



JIM HELMINSKI

received a diagnosis of myelodysplastic syndrome, which quickly progressed into AML, after he retired following almost 30 years with the Secret Service.



FEATURE

acute myeloid leukemia

Understandably, they left the appointment dissatisfied and began looking elsewhere for guidance. Meanwhile, Helminski broke the bad news to family and friends, including his flight instructor, whose daughter happened to be an oncologist at the University of California, San Diego. She shared his patient profile with a colleague at Johns Hopkins Medicine in Baltimore, who in turn recommended that Helminski consider a clinical trial helmed by her friend, Dr. Courtney DiNardo, an associate professor of leukemia in the division of cancer medicine at The University of Texas MD Anderson Cancer Center in Houston.

Less than two weeks later, Helminski had an appointment and jumped on a plane to Houston to meet DiNardo in person. The study was planning to test a novel three-drug therapy: Tibsovo (ivosidenib tablets), a targeted therapy for patients with the IDH1 gene mutation; Venclexta (venetoclax), an oral medication approved for adults 75 years and older or adults who cannot tolerate chemotherapy; and azacitidine. After an extensive new-patient visit, he was accepted into the clinical trial as one of 48 participants.

Similarly, Irma Smith saw her doctor for isolated pain in her toe and received a diagnosis of AML in 2016. The 75-year-old lived in Fort Wayne, Indiana, with no major health problems and had worked as a real estate agent for the past 29 years.

"I didn't have a clue. I felt great. I went into shock when I heard the diagnosis because I thought, 'How can somebody feel so good and then get hit with AML?'" Smith, now 80, says. "The doctor gave me two weeks to two months to live."

Smith and her daughter decided to seek a second opinion from Dr. Hamid Sayar, a professor of clinical medicine at Indiana University School of Medicine in Indianapolis. Instead of painting a bleak picture, he went straight to work by putting Smith on induction chemotherapy followed by consolidation chemotherapy. After successfully achieving remission in early 2017, Smith was entered into a clinical trial for oral azacitidine as maintenance therapy to prevent relapse.

In September 2020, oral azacitidine was approved by the Food and Drug Administration (FDA) for patients aged 55 years and older with AML who achieve remission after

chemotherapy and are not able to complete intensive curative therapy with a stem cell transplant.

PAVING THE WAY

After decades of stagnation, progress in AML treatments has experienced a resurgence in recent years due to rapid advances in genetics, understanding of molecular mechanisms and development of novel therapeutics. Since 2017, nine new drug approvals by the FDA have significantly changed the treatment landscape of the disease. As a next step, clinical trials such as DiNardo's aim to find which combinations of therapies will offer patients the best outcomes.

"AML is still, unfortunately, a very life-threatening cancer. Cancer is clever — it's going to figure out a resistance mechanism to evade a single agent," DiNardo says. "Putting agents together, if you don't have overlapping toxicity, is just a smarter way of giving cancer therapy. So we're trying to move these drug combinations into the frontline setting where they have the best chance of eradicating all disease and preventing relapses."

Other studies focus on improving treatment for elderly individuals with AML, given that the average age at receiving a diagnosis is 68. Researchers are also testing new targeted therapies, immunotherapies and different ways of delivering drugs that are more convenient for patients.

"AML is more a disease of older populations. Historically, one challenge in the treatment of older adults has been exposing them to intense therapies, which we can do for the younger patients," Sayar explains. "But treatment of AML at any age, at any phase of the disease, is a challenge. There is an unmet need at every aspect of treatment."

REFINING AND PERSONALIZING THERAPY

The approval of more therapies has certainly helped many patients, and researchers such as DiNardo are looking to optimize their administration even more by finding the most effective combinations and timings. The clinical trial that Helminski participated in brought together three approved agents for the first time in the frontline setting for patients who have AML with an IDH1 mutation.

“AML is still, unfortunately, a very life-threatening cancer. Cancer is clever — it’s going to figure out a resistance mechanism to evade a single agent.”

— DR. COURTNEY DINARDO



IRMA SMITH was treated with induction chemotherapy followed by consolidation chemotherapy.



Helminski underwent a 28-day isolation in his hospital room at MD Anderson while receiving the three medications due to his immunocompromised state from the leukemia and the treatment. It kept him as infection-free as possible until his immune system recovered. He remained as active as he could — using an exercise bike daily, strength training with resistance bands and meditating with the help of a smartphone app — but did experience some setbacks, such as pneumonia and minor liver inflammation attributed to an antifungal drug.

On the 28th day, the results of Helminski's follow-up bone marrow biopsy showed that he went from 40% leukemic myeloblasts — immature blood cells that serve as a marker of AML progression — to just 1%.

"He's a great example of someone who went into a really deep remission. He's been leukemia-free and doing great for over a year now," DiNardo says. "We have all of these new approvals now, and they were approved in the single-agent setting. But that's probably not the best way to actually use them in the real world."

LOOKING AHEAD

Two years after going into remission, Smith's disease returned in 2019 while she was still participating in the clinical trial for oral azacytidine. When the randomized trial was unblinded, it was revealed that she was administered a placebo as part of the control group instead of the maintenance therapy. She is currently being treated indefinitely with Venclexta (venetoclax) and decitabine, a chemotherapy drug, every six weeks — which temporarily takes a toll on her body.

"I don't want to go out or see anybody. I'm pretty miserable, but I know it's not going to last," Smith says. She still enjoys maintaining her house, going on long walks with her dog and spending quality time with family: "The side effects stop in a week and a half, and the rest of the time, I'm just fine. I have a lot of energy."

Other studies aim to help patients like Smith who relapse after undergoing therapy. Sometimes another round of chemotherapy can put the leukemia into remission again, but it is not likely to be long-lasting. A stem »



«
After going into remission in 2017, **SMITH** enrolled in a clinical trial for oral azacitidine as maintenance therapy to prevent disease recurrence.

cell transplant or newer targeted therapy for a specific genetic mutation could be better options, but with much more toxicities, and patients must be eligible for these therapies.

“Unfortunately, AML still is a disease where the leukemia does recur or come back, so a lot of research is focused on treating patients who have relapsed after upfront therapy,” Dr. Sangmin Lee, an assistant professor of medicine at Weill Cornell Medicine in New York City, says. “Several ongoing clinical trials are geared toward relapsed and refractory settings, such as those investigating cell-based therapies, targeted therapies and drugs that overcome resistance.”

For example, a number of clinical trials are exploring the use of chimeric antigen receptor (CAR)-T cell therapy, a novel treatment that involves engineering a patient’s own immune cells, for AML. CAR-T cell therapy has shown promise in other blood cancers. Research is still in the early stages for AML, with initial studies looking at the safety and feasibility of the therapy in adults and children.

Overall, experts agree that several avenues are being explored by researchers to help patients with AML, who are recommended to look into clinical trials as soon as they

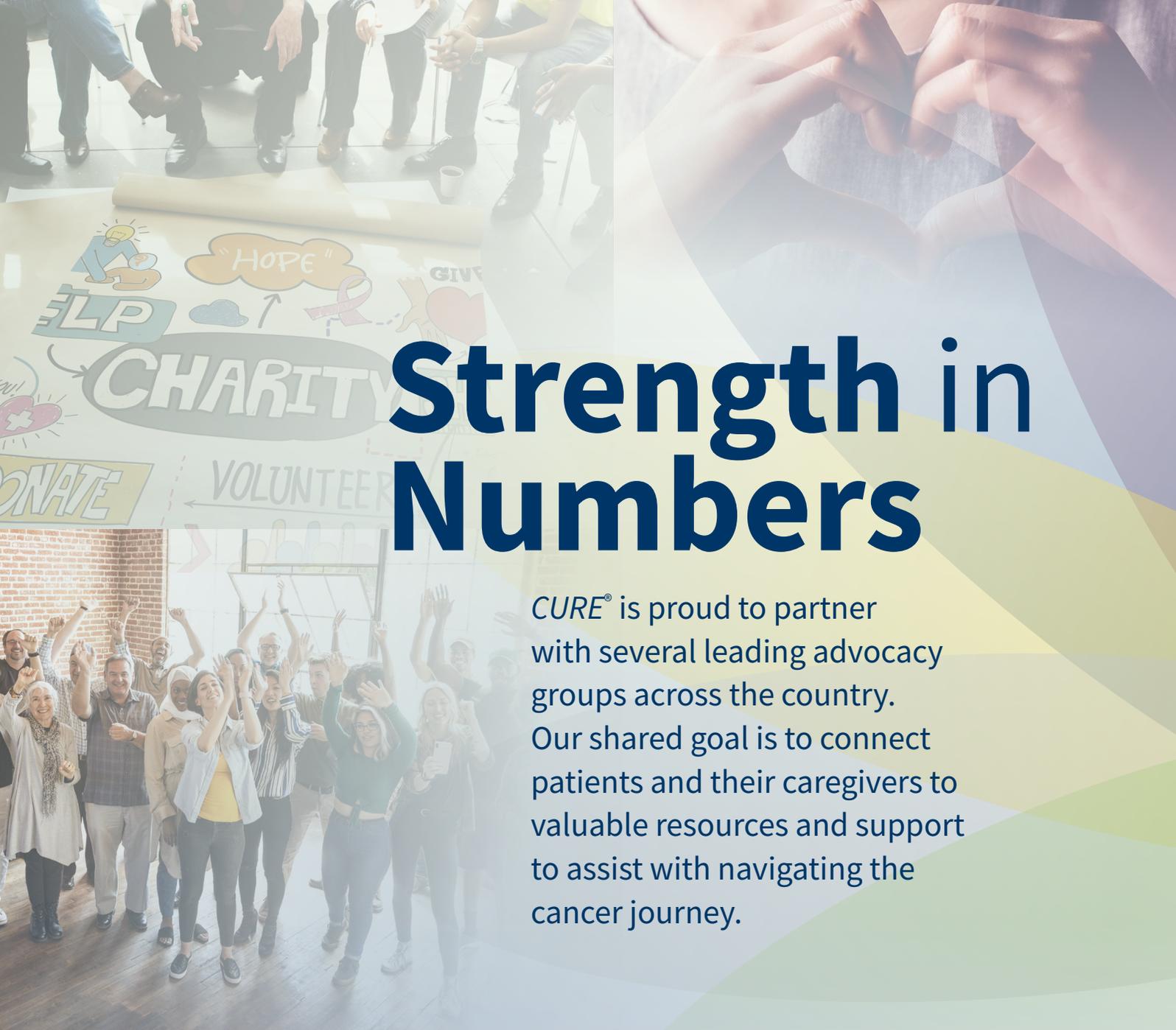
receive their diagnosis. Helminski, for example, emphasized that he would not have been eligible for DiNardo’s study if he had undergone standard therapy first.

“There is a lot of research trying to see if novel therapies provide benefit, so patients should be on the lookout for clinical trials — both in an upfront setting and also in the relapsed or refractory setting — when they (receive a diagnosis of) leukemia,” Lee says.

Since the trio of medications Helminski received worked well enough to induce a deep remission, he was able to undergo a curative stem cell transplant in February 2020 from an unrelated donor.

After the stem cell transplant, he gradually regained his strength over the course of 100 days. Today, at more than 500 days post-transplant, Helminski shows no signs of measurable residual disease. He is back to having a full life on Orcas Island with his wife, exercising regularly, flying his airplane and building furniture.

“I initially believed that I was terminally ill, and there was no hope for me. And there’s always the monster of a possibility of a recurrence,” Helminski says. “But I take life one day at a time, and I’m very appreciative of every day that I have.” ■



Strength in Numbers

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



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



IMPORTANT SAFETY INFORMATION

What is XPOVIO?

XPOVIO® (selinexor) is a prescription medicine used:

- in combination with bortezomib and dexamethasone to treat adult patients with multiple myeloma who have received at least one prior therapy.

It is not known if XPOVIO is safe and effective in children less than 18 years of age.

Your healthcare provider will do blood tests before you start taking XPOVIO, and often during the first 3 months of treatment, and then as needed during treatment.

XPOVIO can cause serious side effects, including:

- **Low platelet counts.** Low platelet counts are common with XPOVIO and can lead to bleeding, which can be severe and can sometimes cause death. Your healthcare provider may prescribe platelet transfusions or other treatments for your low platelet counts.

Tell your healthcare provider right away if you have any bleeding or easy bruising during treatment with XPOVIO.

- **Low white blood cell counts.** Low white blood cell counts are common with XPOVIO and can sometimes be severe. You may have an increased risk of getting bacterial infections during treatment with XPOVIO. If needed, your healthcare provider may prescribe antibiotics if you have signs or symptoms of infection.

- **Serious infections.** Infections are common with XPOVIO and can be serious and can sometimes cause death. This includes upper or lower respiratory tract infections, such as pneumonia, and an infection throughout your body (sepsis). **Tell your healthcare provider right away if you have any signs or symptoms of an infection such as cough, chills, or fever during treatment with XPOVIO.**

- **Neurologic side effects.** XPOVIO can cause dizziness, fainting, decreased alertness, and changes in your mental status, including problems with thinking, seeing or hearing things that are not really there (hallucinations). These problems can sometimes be severe and life-threatening. **Tell your healthcare provider right away if you get any of these symptoms. Do not drive or operate heavy or dangerous machinery until you know how XPOVIO affects you. Take precautions to prevent a fall.**

- **Nausea, vomiting and/or diarrhea.** Nausea, vomiting and/or diarrhea can occur when you take XPOVIO and can sometimes be severe. You may be at risk for becoming dehydrated. Your healthcare provider may prescribe anti-nausea or anti-diarrhea medicines.

- **Loss of appetite and weight loss.** Loss of appetite and weight loss are common with XPOVIO. Tell your healthcare provider if you have a decrease or loss of appetite and if you are losing weight.

- **Decreased sodium levels in your blood.** Decreased sodium levels in your blood are common with XPOVIO. Your healthcare provider may talk with you about your diet and prescribe IV fluids or salt tablets.

- **New or worsening cataract, cloudiness, or loss of transparency of the lens in the eye.** New or worsening cataract are common with XPOVIO. If a cataract forms, your vision may decrease, and you may need eye surgery to remove the cataract and restore your vision. **Tell your healthcare provider right away if you have symptoms of a cataract such as double vision, blurred vision, or sensitivity to light or glare.**

Common side effects of XPOVIO include:

- tiredness
- weakness
- low red blood cell count (anemia). Symptoms may include tiredness and shortness of breath
- constipation
- shortness of breath
- increased blood sugar
- changes in body salt and mineral levels in your blood
- changes in kidney and liver function blood tests

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

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

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

- have or have had a recent or active infection
- have or have had bleeding problems
- are pregnant or plan to become pregnant. XPOVIO can harm your unborn baby
- are taking prescription and over-the-counter medicines, vitamins, and herbal supplements

Ability to have children: XPOVIO may affect the ability of both women and men to have children. Talk to your healthcare provider if you have concerns about fertility.

Females who are able to become pregnant: Your healthcare provider will check to see if you are pregnant before you start taking XPOVIO. You should use effective birth control (contraception) during treatment with XPOVIO and for 1 week after your last dose, as XPOVIO can harm an unborn baby. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with XPOVIO. Do not breastfeed during treatment with XPOVIO and for 1 week after your last dose of XPOVIO. It is not known if XPOVIO passes into your breast milk.

Males with female partners who are able to become pregnant should use effective birth control during treatment with XPOVIO and for 1 week after your last dose.

Please see the Medication Guide and the full Prescribing Information for XPOVIO.

To report SUSPECTED ADVERSE REACTIONS, contact Karyopharm Therapeutics Inc. at 1-888-209-9326 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



XPOVIO[®]
(selinexor)

NEW INDICATION FOR PATIENTS WITH MULTIPLE MYELOMA

Your doctor may prescribe XPOVIO, the only FDA-approved medication of its kind, as early as 1st relapse in multiple myeloma.

XPOVIO[®] (selinexor) is **now approved** in combination with other treatments (bortezomib and dexamethasone) to treat adult patients with multiple myeloma who have received at least one prior therapy.

[LEARN MORE ABOUT TREATMENT AT XPOVIO.COM](https://www.xpovio.com)

PATIENT INFORMATION

XPOVIO® (x-PO-Vee-O)
(selinexor)
Tablets



What is XPOVIO?

XPOVIO is a prescription medicine used in combination with the medicines VELCADE® (bortezomib) and dexamethasone to treat adults with multiple myeloma (MM) who have received at least one prior treatment for their disease.

It is not known if XPOVIO is safe and effective in children less than 18 years of age.

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

XPOVIO can cause serious side effects, including:

- **Low platelet counts.** Low platelet counts are common with XPOVIO and can lead to bleeding which can be severe and can sometimes cause death. Your healthcare provider may prescribe platelet transfusions or other treatments for your low platelet counts.

Tell your healthcare provider right away if you have any bleeding or easy bruising during treatment with XPOVIO.

- **Low white blood cell counts.** Low white blood cell counts are common with XPOVIO and can sometimes be severe. You may have an increased risk of getting bacterial infections during treatment with XPOVIO. Your healthcare provider may prescribe antibiotics if you have signs or symptoms of infection, or certain medicines to help increase your white blood cell count, if needed.

Your healthcare provider will do blood tests before you start taking XPOVIO, and often during the first 3 months of treatment, and then as needed during treatment to monitor you for side effects.

Your healthcare provider may change your dose of XPOVIO, stop your treatment for a period of time, or completely stop your treatment if you have certain side effects during treatment with XPOVIO.

See “What are the possible side effects of XPOVIO?” for more information about side effects.

What should I tell my healthcare provider before taking XPOVIO?

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

- have or have had a recent or active infection.
- have or have had bleeding problems.
- are pregnant or plan to become pregnant. XPOVIO can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will check to see if you are pregnant before you start taking XPOVIO.
- You should use effective birth control (contraception) during treatment with XPOVIO and for 1 week after your last dose.
- Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with XPOVIO.

Males with female partners who are able to become pregnant:

- You should use effective birth control during treatment with XPOVIO and for 1 week after your last dose.
- are breastfeeding or plan to breastfeed. It is not known if XPOVIO passes into your breast milk.
- Do not breastfeed during treatment with XPOVIO and for 1 week after your last dose of XPOVIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Talk with your healthcare provider before taking any new medicines.

How should I take XPOVIO?

- Take XPOVIO exactly as prescribed by your healthcare provider.
- Your healthcare provider will prescribe dexamethasone with your XPOVIO treatment. Take dexamethasone exactly as prescribed.
- Your healthcare provider will tell you how much XPOVIO to take and when to take it. Do not change your dose or stop taking XPOVIO without talking to your healthcare provider first.
- Swallow XPOVIO tablets whole with water. **Do not break, chew, crush, or divide the tablets.**
- Be sure to take any medicines prescribed by your healthcare provider before and during treatment with XPOVIO to help prevent nausea and vomiting. Tell your healthcare provider if the prescribed medicine does not control your nausea and vomiting.
- It is important for you to drink enough fluids to help prevent dehydration and to eat enough calories to help prevent weight loss during treatment with XPOVIO. Talk to your healthcare provider if this is a problem for you. **See “What are the possible side effects of XPOVIO?”**
- If you miss a dose of XPOVIO, take your next dose at your next regularly scheduled day and time.
- If you vomit after taking a dose of XPOVIO, do not take an extra dose. Take your next dose at your next regularly scheduled day and time.
- If you take too much XPOVIO, call your healthcare provider right away.

What should I avoid while taking XPOVIO?

XPOVIO can cause neurologic side effects.

- **See “What are the possible side effects of XPOVIO?” below.**
- If you have any neurologic side effects with XPOVIO, **do not drive or operate heavy or dangerous machinery until your neurologic side effects go away.**
- **Avoid falling.** Use care as needed to avoid falling due to neurologic side effects.

What are the possible side effects of XPOVIO?

XPOVIO can cause serious side effects, including:

- **See “What is the most important information I should know about XPOVIO?”**
- **Nausea and vomiting.** Nausea and vomiting are common with XPOVIO and can sometimes be severe. Nausea and vomiting may affect your ability to eat and drink well. You can lose too much body fluid and body salts (electrolytes) and may be at risk for becoming dehydrated. You may need to receive intravenous (IV) fluids or other treatments to

help prevent dehydration. Your healthcare provider will prescribe anti-nausea medicines for you to take before you start and during treatment with XPOVIO. **See “How should I take XPOVIO?”**

- **Diarrhea.** Diarrhea is common with XPOVIO and can sometimes be severe. You can lose too much body fluid and body salts (electrolytes) and may be at risk for becoming dehydrated. You may need to receive IV fluids or other treatments to help prevent dehydration. Your healthcare provider will prescribe anti-diarrhea medicine for you as needed.
- **Loss of appetite and weight loss.** Loss of appetite and weight loss are common with XPOVIO and can sometimes be severe. Tell your healthcare provider if you have a decrease or loss of appetite and if you notice that you are losing weight at any time during treatment. Your healthcare provider may prescribe medicines that can help increase your appetite or prescribe other kinds of nutritional support. Your healthcare provider will monitor your appetite and weight before you start XPOVIO and often during the first 3 months, then as needed during treatment.
- **Decreased sodium levels in your blood.** Decreased sodium levels in your blood is common with XPOVIO but can also sometimes be severe. Low sodium levels in your blood can happen if you have nausea, vomiting, or diarrhea, you become dehydrated, or if you have loss of appetite with XPOVIO. You may not have any symptoms of a low sodium level. Your healthcare provider may talk with you about your diet and prescribe IV fluids for you based on the sodium levels in your blood. Your healthcare provider will do blood tests before you start taking XPOVIO, and often during the first 2 months of treatment, and then as needed during treatment to monitor the sodium levels in your blood.
- **Serious infections.** Infections are common with XPOVIO and can be serious and can sometimes cause death. XPOVIO can cause infections including upper or lower respiratory tract infections, such as pneumonia, and an infection throughout your body (sepsis). **Tell your healthcare provider right away if you have any signs or symptoms of an infection such as cough, chills or fever, during treatment with XPOVIO.**
- **Neurologic side effects.** XPOVIO can cause neurologic side effects that can sometimes be severe and life-threatening.
 - XPOVIO can cause dizziness, fainting, decreased alertness, and changes in your mental status including confusion and decreased awareness of things around you (delirium).
 - In some people, XPOVIO may also cause problems with thinking (cognitive problems), seeing or hearing things that are not really there (hallucinations), and they may become very sleepy or drowsy.
 - Taking other medicines that can cause dizziness or mental status changes during treatment with XPOVIO may increase your risk of neurologic side effects.

Tell your healthcare provider right away if you get any of these signs or symptoms.

- **New or worsening cataract, a cloudy or loss of transparency of the lens in the eye.** New or worsening cataract are common with XPOVIO. If a cataract forms, your vision may decrease, and you may need eye surgery to remove the cataract and restore your vision. **Tell your**

healthcare provider right away if you have symptoms of a cataract such as double vision, blurred vision, sensitivity to light or glare.

Your healthcare provider may change your dose of XPOVIO, stop your treatment for a period of time, or completely stop your treatment if you have certain side effects during treatment with XPOVIO.

Common side effects of XPOVIO include:

- tiredness
- low red blood cell count (anemia). Symptoms may include tiredness and shortness of breath.
- increased blood sugar
- changes in body salt and mineral levels in your blood
- changes in kidney and liver function blood tests

XPOVIO may cause fertility problems in males and females, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility. These are not all the possible side effects of XPOVIO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XPOVIO?

- Store XPOVIO at or below 86°F (30°C).
- XPOVIO comes in a child-resistant blister pack.

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

General information about the safe and effective use of XPOVIO.

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

What are the ingredients in XPOVIO?

Active ingredient: selinexor

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, Opadry 200 clear, Opadry II blue, povidone K30, and sodium lauryl sulfate.

Manufactured for and marketed by: Karyopharm Therapeutics Inc., 85 Wells Avenue, Newton, MA, 02459
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For more information, call 1-888-209-9326 or go to www.XPOVIO.com.
Based on Medication Guide approved by the U.S. Food and Drug Administration, as revised in December 2020.

FEATURE NK cell therapy

BOB SCHOLZ received a diagnosis of diffuse large B-cell lymphoma in 2018.



A NEW LINE *of* Defense in Blood Cancer

Natural killer cell therapy is making strides in blood cancer research, but there's still much more to learn.

By DEBORAH ABRAMS KAPLAN

Bob Scholz knew something was wrong when he had a hard time walking up the hill while golfing in December 2018. At 73, he still walked the 18 holes at the Albuquerque, New Mexico, golf course every week. After a chest X-ray, his doctor sent him to the hospital immediately. Two liters of fluid were removed from Scholz's lungs several times during his four-day hospital stay. Extensive testing revealed malignant pleural effusion, or excess fluid and cancer cells between the tissues separating the lungs from the chest cavity.

Scholz sought a second opinion at The University of Texas MD Anderson Cancer Center, in Houston, a 13-hour drive away. There, he received a diagnosis of diffuse large B-cell lymphoma. He and his wife, Cindy, quickly packed up and moved to Houston for six months of R-CHOP chemotherapy, a combination of five drugs infused to kill cancer cells. »

FEATURE NK cell therapy



➤ **SCHOLZ** and his wife, **CINDY**, moved to Houston so he could receive treatment at The University of Texas MD Anderson Cancer Center.

After chemotherapy, Scholz thought he was cancer-free, but in late 2020 he lost his voice completely, which sent him back to his oncologist at MD Anderson. A positron emission tomography scan revealed a recurrence of lymphoma in his throat, lung and liver. This time his doctor offered him treatment through a clinical trial for natural killer (NK) cell therapy, a type of infusion therapy that uses the body's natural killer immune cells or donor NK cells, which are grown into larger quantities and sometimes genetically engineered with additional targeting abilities.

NK cells are a type of white blood cell in the immune system that can kill cancer and virally infected cells. "They

have the innate ability to recognize and attack cells infected with viruses or cancer cells," says Dr. Sarah Holstein, a multiple myeloma researcher and an associate professor of internal medicine at the University of Nebraska Medical Center in Omaha. However, cancer cells can sometimes evade NK cells' ability to interact with and kill cancer cells. "The idea behind NK cell therapy is to augment the body's natural NK cell response and increase it and, hopefully, lead to a more direct cell-killing effect against the cancer cell," she explains.

Over the past two decades, researchers have studied various ways to do this; for example, by collecting the

continued on page 38 »

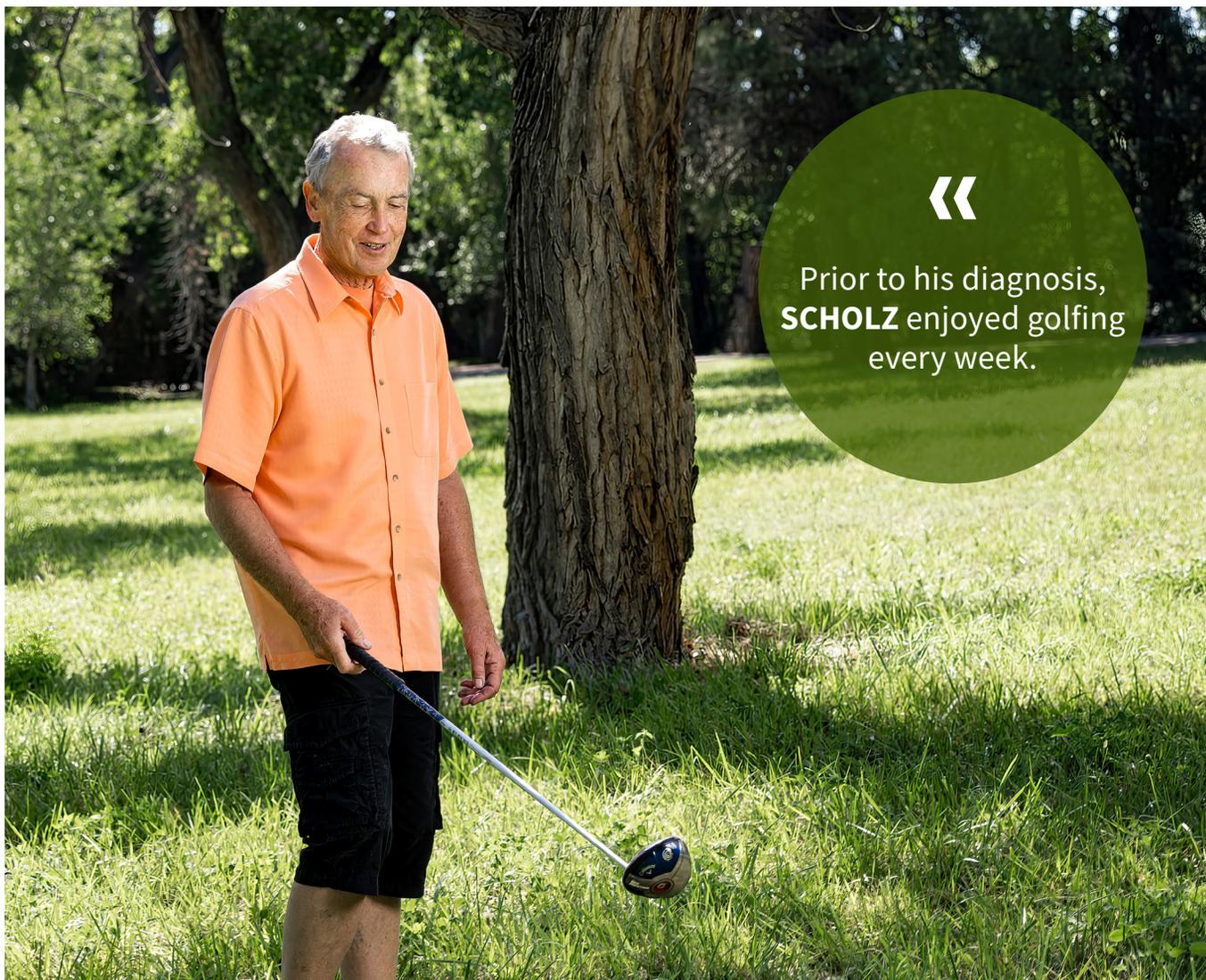
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MORE THAN
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«
Prior to his diagnosis,
SCHOLZ enjoyed golfing
every week.

« continued from page 36

patient's NK cells, growing them and then reinfusing them. When using the patient's cells, it's called an autologous adoptive transfer. Doctors also are growing cells from donors, called allogeneic adoptive transfer. These cells come from sources such as cell lines, peripheral blood or pluripotent stem cells, which can be found in neonatal foreskin or the umbilical cord, for example. Pluripotent stem cells have the ability to differentiate into many types of mature cells and can develop into NK cells or other needed cell types. "One cell in the lab can produce millions of NK cells," says Dr. Paolo Strati, an assistant professor in the department of lymphoma and myeloma and the department of translational molecular pathology at MD Anderson Cancer Center. More recently the field has evolved to study genetically engineered NK cells, such as chimeric antigen receptor (CAR)-NK cells, that have the ability to recognize a specific target on the cancer cell.

Following three days of chemotherapy to prepare his immune system, the doctors gave Scholz three infusions of

modified NK cells. He finished his treatment in early 2021 and is in remission. "I'm thankful every day about how fortunate I was to go there. I'm thankful to have that kind of a place with treatments with that chance of success," he says.

A GROWING RESEARCH FIELD

Dr. Jeffrey Miller, a professor of medicine in the division of hematology, oncology and transplantation at the University of Minnesota in Minneapolis, has been researching NK cell treatments for more than 25 years. He published a paper in 2005 about administering haploidentical allogeneic NK cells, which were taken from a related donor, to patients. The research showed that the cells can persist and expand in the body and may have a treatment role. His 2014 update, which was published in *Blood*, included 57 patients with relapsed/refractory acute myeloid leukemia (AML). Researchers used the immunotoxin interleukin (IL)-2 diphtheria toxin fusion to deplete T regulatory cells and thereby



NANCY GESSMANN

received a diagnosis of multiple myeloma after seeing her primary care doctor for back pain and a fever.



help improve NK cell growth rates. In the study, successful NK cell expansion correlated with remission. Patients were given NK cells, cytokines and lymphodepleting therapy.

“There was excitement in the field when we started to see (complete) response rates between 25% and 40% with those updates,” Miller says. “These were patients who progressed after standard therapy and had no other options.” The response allowed some patients to become eligible for allogeneic bone marrow transplants, even when they were not previously eligible.

Today, researchers are trying different trial designs, including an NK multidose strategy from allogeneic cells. “We couldn’t do it when we had to collect cells from individual donors. That only gave us one cell dose,” Miller explains. Allogeneic cells can be expanded much faster, allowing for multiple doses and freezer storage until needed. Some trials are now giving up to six weekly doses of these off-the-shelf cell products, and doctors can infuse the cells in an

outpatient clinic instead of during a hospital stay. “The cells are thawed at the bedside and given, and the patients are watched for a few hours for allergic reactions,” Miller says.

The idea behind multidosing is that NK cells don’t persist in the body for as long as T cells, which are used in CAR-T cell therapy. “Think of it as a living drug,” Holstein says. “Once you put them in, those engineered cells persist and continue to fight against the tumor, should there be any remaining tumor cells that flare up again.” Researchers don’t think the NK cells can live as long as T cells, “but we don’t know if they need to live that long. Perhaps they’re super effective early on and we don’t need them to persist,” Holstein says.

In her multiple myeloma research, Holstein led a study that explored the use of off-the-shelf NK cell therapy given shortly after the time of a stem cell transplant. “There are data showing that early recovery of the patient’s own NK cells after a stem cell transplant is associated with improved outcomes. It is hypothesized that this early recovery of NK cells is »

contributing to the killing off of residual myeloma cells,” she says. By giving multiple doses of off-the-shelf NK cells — or allogeneic cells — researchers are hoping to boost the effect, ensuring that there’s enough time for NK cells to attack any errant myeloma cells during the critical bone marrow recovery time. “At this time, we’re not sure yet if this approach is effective,” Holstein explains.

Although more recent trials are studying multiple dosing, earlier trials such as Holstein’s used one dose. That’s partly because it was difficult to grow enough cells for multiple doses per patient, even using donor cells. Nancy Gessmann was 59 years old when she enrolled in Holstein’s earlier trial in 2017.

She hadn’t heard of multiple myeloma before back problems and a fever sent her to her primary care doctor in Harlan, Iowa, in 2016. After receiving her diagnosis, Gessmann sought treatment an hour away at the University of Nebraska Medical Center, where she received chemotherapy followed by a stem cell transplant in May 2017.

During her 18 days in the hospital for the transplant, she received a single dose of allogeneic NK cells as part of Holstein’s phase 1 study, along with a series of seven cytokine shots (they help stimulate the NK cells) to help the cells expand. “It gave me hope that if there was anything out there that could help me, it was worth trying,” she explains. Aside from feeling tired after the transplant and growth factor shots — which are given to aid the therapy — Gessmann does not think she experienced any side effects from the NK cell infusion.

With the clinical trial, “I had the opportunity to possibly help myself, my family and others. I benefited from clinical research done by others before me with stem cell transplants and chemotherapies. Others helped my treatment plan and made it easier for me. I’m paying it forward,” Gessmann says.

CAR T VERSUS NK CELL THERAPY

NK cell therapy may have advantages over T cells. Infused CAR-T cells will recognize a cancer cell and attack it. One attack method involves releasing toxins called cytokines, which can lead to a hyperinflammatory state known as cytokine release syndrome (CRS). CRS is caused when a large number of cytokines, proteins made by some immune cells, are quickly released into the blood from immune cells. They can lead to CRS symptoms such as fever, but patients can also experience low blood pressure, low blood oxygen and neurotoxicities such as difficulty finding words, and severe issues

such as a seizure or coma. About 10% of patients receiving CAR-T cell therapy for lymphoma experience severe CRS, and 40% experience severe neurotoxicity. “It’s a real problem; hence, we need to look into different treatments,” Strati says.

NK cells potentially can be less toxic than, and as effective as, T-cell therapy. “Treatment for me was extremely easy, and the results were great,” Scholz says. “It wasn’t like serious chemotherapies. I didn’t feel real good for a couple of days, but it was minor. There were no repercussions from treatment.”

The good thing about NK cells compared with T cells, Miller says, is that NK cells don’t induce graft-versus-host disease, which is when infused allogeneic T cells attack the patient’s healthy cells. NK cells are missing the mechanism in T cells that cause it. For NK therapy, “as far as we know, no known neurotoxicity or CRS has been reported in any consistent way today,” Miller says.

The CAR technology also is being used for some NK cell treatments. With CAR, “we engineer NK cells in the lab,” Strati says. “We make them able to recognize specific proteins on top of lymphoma.” Using donor cells, both CAR-T and CAR NK cells can be available to patients more quickly than the patient’s cells.

The first in-human trial in the United States with CAR NK cells was

for relapsed/refractory CD19-positive B lymphoid malignancies. The trial encoded NK cells to recognize CD19 and express cytokine IL-15 to improve persistence. Results were published in a 2020 *New England Journal of Medicine* study, and it continues to receive a lot of attention, Holstein says. The phase 1 and 2 study showed proof of concept that CAR-NK therapy is possible and effective. Of the 11 patients, 8 had a response and 7 had a complete remission.

THE FUTURE OF NK CELL THERAPY

Researchers developed data for NK cells having a similar cancer-killing strategy but different recognition pattern as T cells, leading to “a crazy interest in NK cells,” Miller says. “Until the past decade, people mostly ignored NK cells.” It’s not just academic labs pursuing them but also cell companies with their own constructs and expansion strategies. The field opened up considerably with the ability to grow billions of cells for off-the-shelf usage in the past 10 years.

Given the multibillion dollar market for anticancer antibody therapy and the ability of cell therapy companies to genetically manipulate cells with CARs, “I would expect we’re going to see somebody close to clinical approval in the next three to five years,” Miller says. ■

“It gave me hope that if there was anything out there that could help me, it was worth trying.”

—NANCY GESSMANN

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Bouncing BACK



LEUKEMIA &
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A three-time acute lymphoblastic leukemia survivor became a bone marrow transplant nurse and now helps other patients with the same diagnosis. *By ANTONIA DePACE*

JOEY RENICK WAS 3 YEARS OLD when he first received a diagnosis of acute lymphoblastic leukemia (ALL). The Missouri native went through three years of treatment before going into remission at age 6.

“I was in remission for almost 12 years,” he said. “So it was a really long time. It was a pretty normal 12 years for me. I was active. I was always in sports, just regular school stuff.”

Renick spent most days of his childhood playing soccer and baseball, going on hikes and fishing. Every summer, he would attend HIS KIDS Cancer Support, a weeklong camp near St. Louis for children with cancer and their siblings. There he met his future wife, Caylee, whose sister had cancer.

In 2011, Renick was in high school when he started to become more fatigued, quickly getting out of breath when exercising. After a follow-up appointment with his oncology team, it was confirmed: Renick’s disease had relapsed.

ALL accounts for 1% of all cancers in the United States, according to the American Cancer Society. The risk for ALL is increased in children younger than 5 and then decreases every year until a patient is in their mid-20s. Four in 10 patients with ALL are adults. At the time of his disease relapse, Renick was 18.

“(The doctors) weren’t even sure it was going to be the same exact leukemia because it’s really rare that the same exact one comes back after 12 years of being in remission,” he explained.

His health care team immediately placed him on what he described as a higher-intensity chemotherapy regimen. He was still in high school and distinctly remembers feeling that he was missing out as he scrolled through social media from his hospital bed.



Some of **RENICK’S** support team, including his mother, pastor and wife.

“That was the hardest, just being a young adult and knowing what I should have been doing,” he said. He does remember having some happy moments, including when grade-school friends would visit, which he describes as a “window of time where I felt like I had some normality,”



I just felt like I was in a nightmare that I was going to wake up from and everything was going to go back to normal.

- JOEY RENICK

and a luau-themed spring break party that the nurses threw to surprise him.

"I just felt like I was in a nightmare that I was going to wake up from, and everything was going to go back to normal," Renick explained. "When you're in high school and even (at a) young college age, you feel like you have all these plans set for you, and then, obviously, the rug's kind of taken up from underneath you. You can't really plan anything in life."

At 20, he went into remission again, then experienced a third relapse at 22 after noticing a swollen supraclavicular lymph node in his clavicle. At the time, he had just started classes at Goldfarb School of Nursing at Barnes-Jewish College in St. Louis.

"That's when they decided to go ahead and do a bone marrow transplant," he said. Caylee, who had watched her sister die from cancer, served as a caregiver during this period. At the time, the couple was newly engaged. "She was able to empathize with the situation and really offer me a shoulder to lean on and an ear to listen," Renick remembered. That was in 2016.

Soon after completing treatment for his third relapse,

Renick decided to participate in the 100-mile bike ride with The Leukemia & Lymphoma Society Team In Training.

"It was pretty emotional at the end because I felt like I really hit a huge milestone that I never thought I would have," he said of the experience.

In 2017, Renick went back to nursing school, completing his degree in 2018.

Today, Renick, 27, is a three-time ALL survivor who also doubles as a nurse on the bone marrow transplant unit at Barnes-Jewish Hospital.

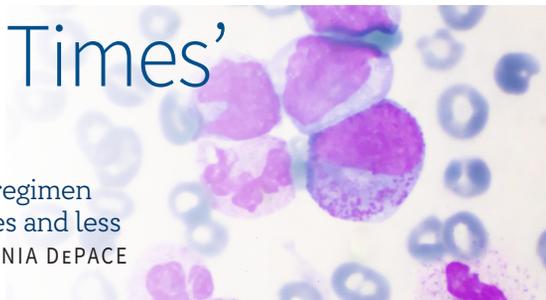
"Coming out of school, I always said I wasn't going to work with cancer patients. I kind of thought it would maybe hit too close to home," he said. "But then I just started to realize that my identity really has formed around my cancer diagnosis, and instead of trying to run away from it, I thought I would embrace it."

As a nurse and cancer survivor, Renick finds that he brings a unique perspective to the table.

"When I tell (a patient that) I'm actually a transplant patient, they almost don't even believe me. They're like, 'You don't even look like you've had cancer three times,'" he said. "I'm like, 'I know, that's just the point. You can bounce back.'" ■

‘Promising Times’ in CLL

A fixed-duration treatment regimen may result in better outcomes and less time in the hospital. *By ANTONIA DEPACE*



A FIXED-DURATION TREATMENT

regimen of Imbruvica (ibrutinib) and Venclexta (venetoclax) may lead to better progression-free survival, as well as less time spent in the hospital, for patients with chronic lymphocytic leukemia (CLL).

Results from this study were presented at the European Hematology Association 2021 Virtual Congress.

“These are promising times for patients with CLL. Unfortunately, we still (can’t) say that we have cured the disease, but, for sure, we have prolonged progression-free survival,” lead study author Dr. Arnon P. Kater, a professor at Amsterdam University Medical Centers, locatie AMC, in the Netherlands, told *CURE*. “These new agents also improved quality of life, not only when (a) patient is in remission, but specifically also when a patient is under treatment.”

Of note, the standard of care is indefinite treatment with anti-CD20 therapy in combination with chemotherapy or Venclexta, or Imbruvica alone.

In the study, the combined treatment of Imbruvica and Venclexta, compared with the standard of care of Leukeran (chlorambucil) and Gazyva (obinutuzumab), reduced the risk of disease progression or death by 78% after a median follow-up of 28 months. The treatment regimen was 12 weeks.

The drug combination works well because the cancer cell behavior of CLL in the lymph nodes creates a microenvironmental protective niche, Kater said. This niche uses protective signals from other cells in the body

and allows the cancerous cells to proliferate rapidly. Imbruvica inhibits this, prevents new cells from migrating to the lymph nodes and causes them to exit the lymph nodes. Venclexta, on the other hand, is an inhibitor of the protein BCL-2, which is known to be increased in patients with CLL and is responsible for the survival of cancerous cells in the blood. The cancerous cells die when this protein is inhibited.

“That’s why, theoretically, there might be very much of a synergy between the two drugs because one drug is very good (at) killing cells in the blood (Venclexta), and the other drug is very good in getting the cells out of these protective niches in the lymph nodes and maybe other organs as well,” Kater said.

After reviewing the data, Dr. Akiva Diamond, an assistant professor of medicine in hematology and oncology at Baylor College of Medicine in Houston, wondered what oncologists would be able to do next if the combination did not work for the patient. “These are our two best drugs, and we’re starting with them together. What do we do next?” he said. “That’s going to be a very important question for us as investigators and for patients. Are we able to reuse this again later? If, let’s say, they get a good few years of benefit, can we try it again? ... Or is there going to be a resistance to these two agents and then we need to move to the next line of therapy? So there (are) still a lot of questions to be

answered, but certainly (the treatment has) promising efficacy.”

Outside of the projected efficacy of the two drugs, other benefits include that the regimen is fixed duration and that it is administered mainly in an outpatient setting. “I think that a fixed-rate treatment is the preferred option (for three reasons),” Kater said. These reasons include the fact that patients have a shorter time frame for experiencing side effects, the possibility of reducing financial burden by shortening the duration of treatments and the increased possibility of using the same agents for years versus treating a patient until cells become resistant.

Diamond also emphasized the importance of outpatient treatment options such as this combination compared with others like Leukeran and Gazyva, as well as Venclexta and Gazyva. “Currently, (taking Venclexta and Gazyva) ... does require quite a bit of hospitalization. So during the (COVID-19) era, we’ve been using a lot less of it and using that less frequently because patients (are) really looking to avoid hospitalizations,” he explained. “I’m hopeful that with this therapy, we might have the option to first start with (Imbruvica), decrease the disease burden and then be able to do the rest of the treatment maybe as an outpatient. I think that would be a benefit.”

Kater added that there is the possibility of differentiating data due to regional differences for older and frail patients from the study. Of note, there were no new side effects outside of those already common to the drugs when used as single agents. Common side effects of Venclexta and Imbruvica include arrhythmia (irregular heart rhythm) and hypertension. “I think it’s a very promising combination,” Kater explained. “But I think this is really something that both the doctor and the patient should be aware of.”



Keep inspiring

Because CLL/SLL shouldn't define you



Ask your doctor about CALQUENCE for CLL/SLL

Learn more at [CALQUENCE.com](https://www.calquence.com)

CLL=chronic lymphocytic leukemia; SLL=small lymphocytic lymphoma.

Select Safety Information

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

If you cannot afford your medication, AstraZeneca may be able to help. Visit [AstraZeneca-us.com](https://www.astrazeneca-us.com) to find out how.

Please see Brief Summary of Prescribing Information on adjacent pages.

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CALQUENCE[®]
(acalabrutinib) 100 mg capsules

PATIENT INFORMATION

CALQUENCE® (KAL-kwens) (acalabrutinib) capsules


CALQUENCE®
(acalabrutinib) 100 mg capsules

What is CALQUENCE?

CALQUENCE is a prescription medicine used to treat adults with:

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

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

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

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

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

How should I take CALQUENCE?

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

(continued)

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

What are the possible side effects of CALQUENCE?

CALQUENCE may cause serious side effects, including:

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

(continued)

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

The most common side effects of CALQUENCE include:

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

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

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

How should I store CALQUENCE?

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

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

General information about the safe and effective use of CALQUENCE.

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

What are the ingredients in CALQUENCE?

Active ingredient: acalabrutinib

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

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

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

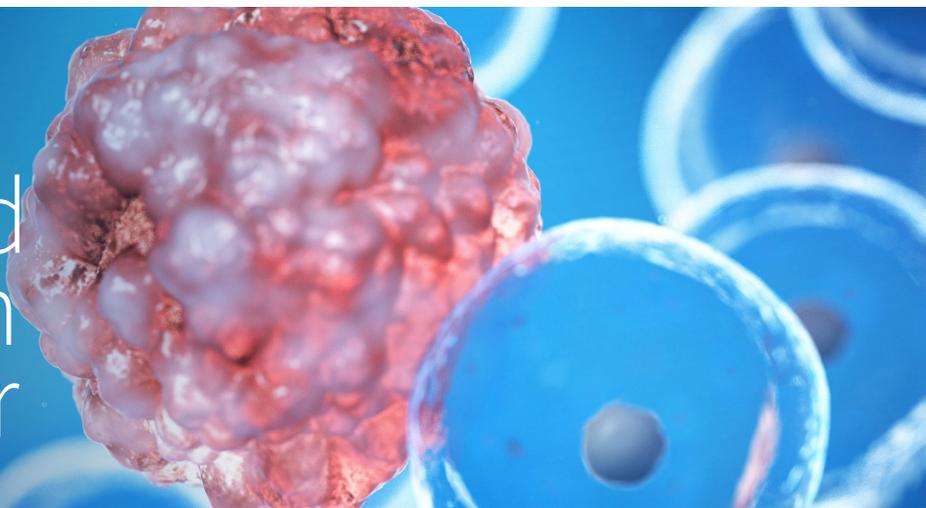
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SPEAKING OUT MYELOPROLIFERATIVE NEOPLASMS

Becoming an Informed Patient With Rare Cancer



Dr. Gabriela Hobbs offers insight into a rare cancer, myeloproliferative neoplasms, to help patients learn more during their treatment journey. *By KRISTIE L. KAHL*

MYELOPROLIFERATIVE NEOPLASMS

(MPNs) can be difficult to understand, but patients should not feel alone. Many patients with this rare type of cancer are collaborating to not only bring the MPN community together but to also advance treatment options for the disease.

As part of its “Speaking Out” video series, on behalf of the MPN Research Foundation, *CURE*[®] spoke with Dr. Gabriela Hobbs, clinical director of leukemia at Massachusetts General Hospital in Boston, about the disease, why patients should be informed, how they can learn more and what they can be hopeful for in the future.



DR. GABRIELA HOBBS

comfortable with their diagnosis and to feel in control. When (patients receive a diagnosis), there’s a sense of loss of control where something happened that was not something that anybody asks for. I think a part of gaining some of that control is information. I really am a big believer in patients being informed patients, understanding what their disease is ... even being educated in terms of knowing what the name of the disease is.

Thankfully, in the MPN world, there are lots of great foundations (such as the MPN Research Foundation) that can help patients get reliable information. And I think that’s one of the things that’s really difficult about this, the world we live in, where there’s so much information out there. It’s hard sometimes to get reliable information. I (would recommend) going to the MPN Research Foundation,

the National Cancer Care Network guidelines, American Cancer Society guidelines — reputable sources (that) are written by reputable people. It is really important to learn about what the (disease is), what trials or treatments exist, what potential complications are, etc. Once you’re an informed patient, you can go to your physician, nurse or whoever is treating you with a set of questions and things that you’ve learned online, and that makes the visit much more productive — even something as simple as saying, “I found the MPN symptom assessment form online, and I have the symptoms; what do you think about that? Am I a candidate for treatment?”

On the flip side of that, I also think that we need to be very careful with what we find online. Some of my patients definitely spend a lot of time on social media. And though I’m somebody who really likes social media (because it) makes us all connected, it can sometimes also have a lot of »

Q: Why is it important for patients to learn more about their treatment options?

A: That’s really important. For a patient with a diagnosis that’s rare, I think it’s really difficult to feel

information that is shared that is anecdotal, meaning it is the experience of only one patient. And although that can certainly bring community to some degree, sometimes the information that's shared in these groups is just one person's experience and doesn't necessarily reflect what a group of large patients may experience. Sometimes I spend a lot of time talking to my patients (telling them that) just because this person had a bad side effect doesn't mean that (will happen to you). I think we have to be really careful with the information that we get, both in social media and just online in general. Make sure that it's from a reputable source.

Q: Why should patients be hopeful looking toward future treatment options?

A: Now is definitely a time to be hopeful. One of the things that I say is that the reason why I was hired to work where I work is because there's so much understanding about MPNs now that they can hire a person who just treats MPNs. Whereas before, that would have been funny, right? (Before), how do you hire somebody to treat diseases that don't have any treatments? That's just one sign of the changing times.

There are lots of clinical trials (evaluating) medications for advanced stages that will, hopefully, get approved in the next couple of years. I feel optimistic about that because I'll be able to offer more treatments to my patients. Another thing to remember is that in the past decade, our understanding of how these diseases start and progress or evolve

over time has really changed exponentially. The amount of people who are doing research on these diseases has increased significantly. And nothing is more proof of that than the fact that there are dozens of clinical trials across the country testing a variety of medications to treat MPNs.

And so, even though when a patient has an MPN they may feel like they're the only one that has it, remember that you're not the only one who has it. A lot of people are really thinking about these diseases and trying to improve treatment and improve quality of life for these patients. 



LEARN MORE ONLINE
SCAN the QR code to watch videos from our "Speaking Out" series.

cure® | mpn
HEROES®

Celebrate our Heroes!

Join us for the ninth annual MPN Heroes® celebration on **Friday, December 10, 2021.**

Register today! Scan the QR code or visit curetoday.com/mpn21.

The CURE® and Incyte communities are coming together for an evening of gratitude for individuals who go above and beyond in their efforts to support patients with MPNs. Help make it an evening to remember for our MPN Heroes!



Support for MPN Heroes® is made possible by Incyte.



Do you have a patient with myelofibrosis?

We are conducting three research studies to evaluate an investigational medication (called navitoclax) in patients with myelofibrosis. The primary objective of this program is to evaluate the effect of navitoclax (in some cases, in combination with ruxolitinib) on reducing spleen volume in patients with myelofibrosis. Patients may continue on study as long as they are receiving benefit. We need help from the local medical community to help us identify qualified study participants.

LOCATIONS WORLDWIDE

If you would like to speak with a Principal Investigator conducting one of the AbbVie myelofibrosis studies in your area, please contact us today.

AbbVieResearchStudies.com

Navitoclax, an investigational medication, is under clinical development and is not approved by regulatory health agencies.

Safety and efficacy have not been established.



MULTIPLE MYELOMA Research Foundation



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KERRY TRACY,
with his daughter, attended
the New York City Marathon on
behalf of the MMRF. He had gone
through three transplants at
this point.

PROVIDED BY KERRY TRACY

Paying It Forward

After receiving a diagnosis of multiple myeloma, this patient relied on the Multiple Myeloma Research Foundation for information and is becoming part of the conversation.

By ANTONIA DEPACE

IN 2010, KERRY TRACY ran a half-marathon for his daughter's best friend's mom. She had just received a diagnosis of multiple myeloma and, knowing he was an avid runner, she asked him to participate.

"You do obviously learn about (the disease) and see what it's all about," he said of the time spent leading up to the event.

Two years later, after going to the doctor for back pain, he, too, received a diagnosis of multiple myeloma.

"As my oncologist said, 'This is not your garden-variety multiple myeloma,'" explained Tracy, who lives in New York City. "I had multiple compression fractures throughout my vertebrae and needed three kyphoplasty surgeries immediately." Kyphoplasty is a minimally invasive surgery used to treat vertebral compression fractures by inflating a balloon to restore bone height. Bone cement is then injected into the vertebrae.

"It was kind of a shock. I was in pretty good shape and never really had any medical issues," said Tracy, who was 52 when he received his diagnosis. The then-CEO of Working Media Group was used to working out six days a week, skiing, coaching and playing golf with his children — two were in high school and one was in elementary school — and wife.

One of the first things Tracy did after receiving his diagnosis was reach out to experts at centers well

MMRF was one of the places that I looked at and kind of relied on. I've been really thankful for what they've done.

— KERRY TRACY

known for treating multiple myeloma, including Memorial Sloan Kettering Cancer Center, NewYork-Presbyterian Hospital, Mount Sinai Health System, The University of Texas MD Anderson Cancer Center and Dana-Farber Cancer Institute. All told him the same thing: If you're going to do your research, do it on legitimate websites.

"MMRF (Multiple Myeloma Research Foundation) was one of the places that I looked at and kind of relied on," he explained, noting that foundation staff members helped connect him with doctors. "I've been really thankful for what they've done."

Tracy said that the MMRF helped him zero in on the most accurate information. "I subscribe to Google alerts on everything and anything about myeloma, and there's a lot of information out there that you see that's credible, and there's some information out there that's not," he said.

This realization, combined with his positive experience with the MMRF, led Tracy to start his company, Digitent, nine years after receiving his diagnosis.

Through his company, he is striving to produce accurate health and wellness multimedia content.

"It goes back to what the doctors told me when I was diagnosed," he explained. "(They) ... gave me three sites to try to stick to because when you first get diagnosed, you're looking up everything. You want to be as well-informed as possible, and sometimes it's pretty scary in terms of the stuff that you read. ... There's no police out there saying what you can (and) can't post."

One of his upcoming series includes a podcast with doctors and patients who have orphan diseases (diseases that affect less than 200,000 people worldwide) such as multiple myeloma, providing a space for those patients and experts to learn and connect.

"Every time I had a (stem cell or bone marrow) transplant, the thing that ... I always wanted to see was who had it done before me, and what was their experience? I think podcasts are a great way to tell your story and hear other people's stories," he concluded. ■

There Are 2 Sides to Every MPN Story

When you're living with a myeloproliferative neoplasm (MPN), a rare, chronic blood cancer, you may say that you're *fine*—even when physical and emotional symptoms are affecting your quality of life. But when you don't discuss how your MPN makes you feel, you miss the opportunity to get the care and support you may need from friends, family and *especially* your MPN Healthcare team.

Fine is not enough for your MPN journey.

MPNs are progressive diseases, which means they can change or get worse over time. That's why it's important to **speak up and spell out** how your MPN affects you. It's an effective way to take an active role in your ongoing care.



Redefine your MPN communication

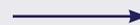
Watch real patient stories, plus explore helpful MPN communication tools and resources at FinelsNotEnough.com/patientstories



Take the *FINE* pledge

Empower your MPN journey by making a commitment to having more informed, meaningful conversations about your MPN.

Louise, real MPN patient



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FEEELING
TIRED EVERY
SINGLE DAY

ITCHING AFTER
HOT SHOWERS

NIGHT SWEATS
KEEP ME UP

EEATING LESS
BECAUSE I'M
FEELING
FULL



We are helping to move mountains for myeloma patients

Moving Mountains for Multiple Myeloma (MM4MM) is an award-winning collaboration between CURE Media Group and the Multiple Myeloma Research Foundation (MMRF), which raises funds and awareness for myeloma research.

Since its inception in 2016, Moving Mountains for Multiple Myeloma teams have climbed Mount Kilimanjaro, hiked the Grand Canyon, summited Mount Fuji, trekked the Inca Trail to Machu Picchu, reached Everest Base Camp and conquered Iceland's many landscapes. Our team members have raised over \$3 million, 100% of which goes directly to the MMRF, which spearheads and funds critical myeloma research. These amazing journeys are captured via blogs, social media posts and video.

After pausing for the global pandemic, we are back with a new schedule of exciting climbs. Patients, caregivers, loved ones with myeloma, and others impacted directly by multiple myeloma will trek through the wilderness of Alaska's Kenai Peninsula, summit Mount Washington and discover the dynamic terrain of Colorado's Backcountry Continental Divide. They will raise funds for multiple myeloma research and demonstrate that the advancements being made in recent years, led by the MMRF, are helping patients live longer with a higher quality of life than ever before.

To learn more and join a MM4MM team visit:
MovingMountainsForMultipleMyeloma.com

To learn more about the MMRF, visit TheMMRF.org

LEARN MORE ABOUT OUR CLIMBS!

2021-2022 TREK SCHEDULE

Alaska Trek

August 16-21, 2021

Mount Kilimanjaro

February 19 - March 1, 2022

Greenland Trek

Summer 2022

Sweden Trek

Summer 2022

Mount Washington

Date to be announced

Colorado Trek

Date to be announced

endurance.themmr.org/MM4MM

