FOR PATIENTS, SURVIVORS & THEIR CAREGIVERS

LUNG CANCER

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Cancer Updates, Research & Education®

STAYING ON PATH

Targeted therapies offer new hope in HER2-mutated non-small cell lung cancers.

LUNG CANCER
SPECIAL ISSUE · 11.21

ALSO IN THIS ISSUE

MOLECULAR SUBTYPES
Early findings in nonsmoking patients spark hope for earlier diagnosis and better treatments.

STAYING ACTIVE
A patient's garden helped her to cope during diagnosis, through treatment and into remission.

SIDE EFFECTS
A common side effect — dysphagia — may make eating difficult for patients.

BRAIN METASTASES
A PD-L1 inhibitor with chemotherapy may improve brain metastasis responses in a lung cancer subtype.

BOOKSHELF
A retired firefighter reflects on the weeks after 9/11 and his lung cancer diagnosis six years later.

curetoday.com

KEYTRUDA IS A BREAKTHROUGH IMMUNOTHERAPY.

FOR TODAY

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

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

FOR THE FUTURE

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

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

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

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

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

IMPORTANT SAFETY INFORMATION

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

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

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

Important Safety Information is continued on the next page.

keytruda.com/lung

IMPORTANT SAFETY INFORMATION *(continued)*

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

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

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

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

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

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

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

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

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

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

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

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

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

Having trouble paying for your Merck medicine?

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

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

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

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

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

Lung problems

- cough
- shortness of breath
- chest pain

Intestinal problems

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

Liver problems

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

Hormone gland problems

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

Kidney problems

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

Skin problems

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

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

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

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

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

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

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

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

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

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

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

  Females who are able to become pregnant:

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

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

How will I receive KEYTRUDA?

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

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

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

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

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

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

These are not all the possible side effects of KEYTRUDA.

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

General information about the safe and effective use of KEYTRUDA

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

Based on Medication Guide usmg-mk3475-iv-2107r043 as revised July 2021.

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cure® Contents

LUNG CANCER SPECIAL ISSUE · 11.21

» **KRIS MUNDAY** smoked nearly three packs a day before she was diagnosed, which led her to a methodical approach to quitting the habit.

» **CHARLIE THURLOW** quit smoking on his own after receiving a diagnosis of stage 3B lung cancer.

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KILEY AKERS compares his journey with targeted therapy with running a long race.

28

FEATURES

ALSO IN THIS ISSUE

chairman's letter

STUDY RESULTS SHOW THAT smoking tobacco products may lead to an increased risk of lung cancer (in addition to bladder and other cancers), but what happens when a patient quits smoking after receiving a diagnosis of the disease?

While studies show that cigarette smoking accounts for about 80% to 90% of lung cancer deaths in the United States, one recently published study found that in those patients who quit smoking after receiving a diagnosis, higher three- and five-year survival rates were observed. In this special issue of *CURE*®, two patients tell their stories of how they went from going through multiple packs of cigarettes a day to none. Experts also give their take on the importance of quitting, even after a cancer diagnosis, and resources that can help. Readers will also learn about genetic subtypes that may lead to an increased risk of lung cancer in nonsmokers and how they could be used for early detection and more targeted therapies in that patient population.

Also in this issue is a story on Floridian Patti Morelli, who not only underwent treatment after a diagnosis of lung cancer during the COVID-19 pandemic, but also had to let go of her caregiving responsibilities to her husband, who had experienced a severe stroke years prior. *CURE*® catches up with another patient, Jerry Sanford, who helped navigate the chaos of 9/11 weeks after the attacks. Recently, he published a memoir about this time, what led him to New York a few days before and how he faced a diagnosis of lung cancer due to the debris cloud from that day.

As always, I hope you gain insight from the stories we've curated throughout this special issue.

MIKE HENNESSY SR.
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Targeting Lung Cancer From a New Direction

TARGETED THERAPIES HAVE MADE a huge impact on the treatment of cancer over the past couple of decades. Making a breakthrough in the 1980s, they work to identify and attack specific types of cancer cells by interfering with specific proteins that drive the growth of cancer cells. Doctors can test for these molecules, also known as molecular targets, by taking cells through tissue or liquid biopsies. The first Food and Drug Administration (FDA)-approved targeted therapy for lung cancer, specifically, came in 2004 with Avastin (bevacizumab), which inhibits a protein that leads to tumor-associated blood vessels and is currently used to treat advanced colorectal, kidney and lung cancers. Additionally, there has been an explosion of knowledge from sequencing the DNA of many different cancer types to discover the many genes that are mutated, and the proteins encoded by these genes can drive tumor growth.

In this issue of *CURE*®, we explore targeted therapies further as they pertain to the human epidermal growth factor receptor 2 (HER2) protein in non-small cell lung cancer (NSCLC), which can be mutated or amplified in several tumor types and promotes cancer cell growth. This mutation affects about 2% to 4% of patients with NSCLC.

Of note, there is only one FDA-approved targeted therapy for the patient subset. Called Enhertu (trastuzumab deruxtecan), the drug treats patients with metastatic NSCLC that has progressed on chemotherapy. One expert featured in our issue hopes more targeted therapies for HER2 will be approved to give patients more personalized options. With this said, there are more targeted therapy drugs in clinical trials that could help this patient population. One such drug is a tyrosine kinase inhibitor called poziotinib, which targets the HER2 exon 20 insertion mutation. In our feature, we speak to a patient who enrolled in a phase 2 trial of the drug and has been participating since April 2021. While she has experienced some moderate side effects from the therapy, she is optimistic, as other treatment options led to either severe side effects or disease progression.

> "It is my hope that this field continues to grow the novel therapy for not only patients with lung cancer, but well beyond."

Highlighting the importance of participation in clinical trials, it is my hope that this field continues to grow the novel therapy for not only patients with lung cancer, but well beyond. It is critical that the public be aware of how research and clinical trials are catalysts to better the outcomes of patients with cancer. C

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

TOUGH To Swallow

A common side effect from lung cancer or treatment for the disease may make eating difficult for patients.

By ANTONIA DEPACE

DYSPHAGIA, OR DIFFICULTY swallowing, is a common symptom for patients with lung cancer and a side effect from treatment, and it can lead to more long-term effects if not managed quickly, experts said.

Dr. Nagashree Seetharamu, an associate professor of medicine at the Zucker School of Medicine at Hofstra/Northwell and a thoracic oncologist at the Northwell Health Cancer Institute, both on Long Island, New York, refers to the side effect as an umbrella term for anything wrong or not working well within the passage. For patients with lung cancer, this tends to be within the esophagus.

"Dysphagia is a sensation that the patients feel is interfering with their normal passage of swallowed food. Patients with dysphagia often complain that they have some food stuck or it will not go down. They're just unable to push it through. And there are multiple reasons for dysphagia. It can be something that they were born with or something that happened over a period of time. And in this particular case, it could be related to the underlying diagnosis or treatment itself," Seetharamu explained in an interview with *CURE*®, noting that there could be tumors pressing on the esophagus, leading to the side effect.

Other disease-related factors include the recurrent laryngeal nerve, which is often affected in patients with lung cancer and can lead to the sensation, as well as general muscle weakness associated with disease and treatment. Radiation and chemotherapy can also play roles.

There are also preexisting conditions that can lead to an increased risk of developing the side effect, including acid reflux, bariatric procedures (gastric bypass or weight loss surgery), achalasia (a rare disorder that results from damage to nerves and leads to difficulty swallowing food and liquids) or other esophageal conditions.

Levels of Dysphagia

Depending on when symptoms are reported and whether the side effect is managed, there are different levels of dysphagia. In what Seetharamu calls level 1, the patient can eat but needs a bit more moisture in their food to swallow more easily. Level 2 means that the side effect has mechanically altered the way the patient eats (i.e., they are unable to chew), which often necessitates a pureed diet. If the side effect progresses from there, a nutrition team works with the patient to create a special diet, depending on what they can tolerate.

"If (patients) do not report to us, it can go to very significant proportions, to the extent that they are unable to eat or drink anything. We do not want that to happen," she explained. "The last thing we want to do with these patients is to (put) a feeding tube or a G tube or a J tube."

Timra Walsh, a faculty practice nurse in thoracic and head and neck oncology at the Northwell Health Cancer Institute who works with Seetharamu, emphasizes the importance of communication whenever a patient starts to notice any symptoms of dysphagia, no matter how small. "It's a lot of encouraging them that the sooner they let us know the symptoms they're having, even if they don't think it's something serious or important, that they tell us. Because the earlier we can intervene, the better," she said.

If symptoms are ignored or go unnoticed, however, dysphagia could lead to long-term effects, like malnutrition. Walsh explained, "It affects (patients) eating. I think a lot of them get worried about that feeling of things getting stuck, so they are more hesitant to eat, especially solid things."

Side Effect of Treatment

Of note, dysphagia can present during treatment and even after the

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completion of treatment, according to Walsh. The peak of dysphagia diagnoses, though, tends to be two to three weeks into radiation.

Symptoms of the side effect include difficulty swallowing, coughing every time a patient eats, having the feeling of food coming back up through the esophagus and feeling like something is still left in the throat after swallowing. Depending on the patient, this could occur with solids, liquids or pureed foods.

Management of the side effect can vary depending on the level of severity, but can include swallowing exercises, massaging techniques and muscle manipulation. For more severe cases, a gastroenterologist may need to stretch or dilate a tight area of the throat or esophagus to allow food to pass more easily.

In severe circumstances, when symptoms continue without treatment, patients may end up with feeding tubes, which can lead to increased risk for infection. Seetharamu added, "A lot of times, that can be prevented if you're proactively treating the symptoms as they occur."

> If (patients) do not report to us, it can go to very significant proportions, to the extent that they are unable to eat or drink anything. — DR. NAGASHREE SEETHARAMU

Because of this, she said it is of the utmost importance to include other health care teams in patient care, such as nutritionists, swallow and speech therapists, gastroenterologists and thoracic surgeons, so health requirements can be assessed and addressed.

"I would summarize it by saying that (dysphagia) is unpredictable. It can happen anytime. A baseline assessment is extremely important, looking at factors that could predispose patients, but also looking at what their nutritional status is in the beginning and multidisciplinary input on management is important — proactively managing symptoms as they occur," Seetharamu concluded. "Educating patients about dysphagia and the importance of timely reporting of symptoms (is also important). And maybe, support groups for patients who have lingering side effects post chemotherapy and radiation is something that's helpful because they can bounce ideas off each other. I found that extremely helpful when I talk to patients."

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LOOKING FOR ANSWERS

Early findings on molecular subtypes in nonsmoking patients spark hope for earlier diagnosis and better treatments.

By ANTONIA DEPACE

RESEARCHERS IDENTIFIED THREE molecular subtypes of lung cancer in patients who never smoked, showing the potential of better prevention and more precise treatment options for the patient subset.

Of note, about 10% to 20% of lung cancer cases are in people who never smoked or smoked fewer than 100 cigarettes in their lifetime, according to the Centers for Disease Control and Prevention. Previously, these cases were attributed mainly to lifestyle factors like exposure to carcinogens, pollution and diet.

"We wanted to study these tumors and … characterize them, also from the point of view of the genomic architecture because the idea was that maybe by studying the genomic features, we could trace back the processes that lead to the formation of the tumor," Dr. Maria Teresa Landi, of the Integrative Tumor Epidemiology Branch in the National Cancer Institute's Division of Cancer Epidemiology and Genetics, explained in an interview with *CURE®*.

According to Landi, this is of utmost importance, as many novel treatments in lung cancer don't work as well in this patient subset. "Nonsmokers tend to have a lower number of mutations in general, and this unfortunately means that they may not benefit from immunotherapy, which is now one of the major hopes for lung cancer in smokers because they have a lot of mutations," said Landi, who was also the lead author on the study. Therefore, finding these subtypes could give this patient subset a better set of treatment options within immunotherapy with increased efficacy.

THREE COMMON MOLECULAR SUBTYPES OF LUNG CANCER

1. **piano** had the fewest mutations and was associated with the activation of progenitor cells, which are involved in the process of creating new cells, as well as slow tumor growth;
2. **mezzo-forte** had specific chromosomal changes and mutations in the growth factor receptor gene EGFR, a common genetic alteration in lung cancer, and showed faster tumor growth; and
3. **forte** exhibited whole-genome doubling, which is often seen in lung cancers diagnosed in smokers and grows quickly.

Through the study, which examined tumor tissues from 232 never-smokers, researchers identified three common molecular subtypes of lung cancer.

Each subtype allows for different advances for patients with lung cancer who never smoked. For example, "some (subtypes) are very, very slow — I'm talking about years. And so they could provide potentially a time window for early detection, while others tend to … grow very rapidly. And these could potentially provide information for targeted treatment," she said.

If the subtypes were adopted into practices, they could be identified in cases like this. This may allow patients to be eligible for screening and to obtain an earlier diagnosis rather than late stage, which is often the case for lung cancer in patients who never smoked. According to Landi, if this patient population became eligible for screening based on these subtypes, there could be a 20% decrease in the risk of mortality.

She said that while there isn't much information on this topic, next steps for her team include extending the analysis to a larger dataset that includes more ethnic groups and different geographical areas. It is her hope that this will allow researchers to study the inherited germline variants to see if there are some genes that predispose people to a higher risk of lung cancer, even if they don't smoke, as well other medical conditions that could increase risk. "And then we are also trying to identify some markers that are in tumors that could be found also in the blood," she added.

Landi concluded: "The hope for the future is to potentially identify precise, sensitive and specific markers for screening to identify the subject at risk so that they can be monitored very closely, so that the tumor can be detected immediately. And then by continuing studying these tumors, we can understand better the biology of the tumor and the evolutionary objectives so that we could have potential information for treatment that is precisely directed to the different types of tumors with different characteristics."

The First of Many to Come

Two new FDA approvals for patients with lung cancer and EGFR exon 20 insertion mutations have given the subset its first targeted therapies.

By ANTONIA DEPACE

RECENT DRUG APPROVALS by the Food and Drug Administration (FDA) are giving patients with non-small cell lung cancer (NSCLC) and EGFR exon 20 insertion mutations the first two treatments that specifically target those mutations.

"EGFR is one of the classic driver mutations," Dr. Catherine Ann Shu, clinical director of the thoracic medical oncology service at Columbia University Irving Medical Center in New York, explained in an interview with *CURE®*. "When patients hear about having an EGFR mutation, it's typically associated with drugs like osimertinib (Tagrisso) or lorlatinib (Lorbrena) … and those patients tend to do very well on those treatments with a very high response rate. … But unfortunately, there is another type of EGFR mutation. Most people aren't really aware of it, but it's called exon 20 insertion. And patients with those EGFR exon 20 insertions generally do not respond to the classic drugs."

EGFR mutations exist within 85% of lung cancer cases. Of those, about 10% are exon 20 insertions. "Because it's more rare, it hasn't been something that's been explored as much," Shu said. "And it is more heterogeneous than the other EGFR mutations. The other EGFR mutations tend to be exon 19 deletions and L858R, which is a pretty standard thing. And exon 20 insertions can be a whole variety of insertions or duplications, so they don't all look exactly the same. Sometimes it's a little bit harder for patients and providers to know exactly what's going on."

Dr. Pasi A. Jänne, a translational thoracic medical oncologist at Dana-Farber Cancer Institute in Boston and a professor of medicine at Harvard Medical School, noted that it's easiest to think of exon 20 as a collection of mutations that occur within a particular part of the exon 20 part of the gene. He also said there are data that suggest the mutation is more common in those of Asian descent, likely due to a genetic contribution that hasn't been thoroughly researched.

A Big Approval

For patients with lung cancer and an EGFR exon 20 mutation, the standard of care has been chemotherapy, according to Jänne. "Until recently, all of the therapies that have been approved for the more common types of EGFR mutations have not been effective in this subset of lung cancer; hence, there's been a great interest in trying to develop specific therapies that would be effective in the EGFR exon 20 subset of lung cancer," he added.

The emphasis being on "until recently," Jänne noted that the FDA approved Rybrevant (amivantamab-vmjw) as the first targeted therapy for the patient subset in May 2021.

In the study that led to the approval, 81 patients with NSCLC and an EGFR exon 20 insertion mutation whose disease had progressed after platinum-based chemotherapy participated. After treatment with Rybrevant, patients had an overall response rate (patients who had a complete or partial response to the therapy) of 40%. There was also a median duration of response (the time that a tumor responds to treatment without growth or spread) of 11.1 months in all patients, while 63% of the patients experienced a response to the therapy for at least six months.

"The response is higher than probably just chemotherapy would be, but remember that these response rates are in patients who have had chemotherapy," explained Shu, who was the lead author on the study that led to the drug's approval. "This is post-platinum chemotherapy. Generally, we see a decrease in response rate with every line of therapy. If you think about it, this 40% is already after they've progressed on chemo, so it's really quite good."

Common side effects from the drug included rash, skin infections around the fingernails or toenails, nausea, fatigue, sores in the mouth, cough, constipation and vomiting. Shu added that there's also an infusion-related reaction that typically presents on the first dose as shortness of breath, flushing or nausea. It can be managed by lowering the dose and prescribing pre-medications.

One factor to be aware of, according to Shu, is the scheduling around the drug, which is an IV infusion. "The schedule is a little bit more of a pain than being on a pill," she said. "You have to go in for infusion, (and) the first infusion is split up over two days. You have to go on day one and on day two because we try to do it slowly to prevent that infusion-related reaction, then you have to come in again on day eight, which is the following week. You have to come in again on day 15. »

It's weekly for the first few weeks, and then it goes out to every other week. It is a little bit more time intensive than even some chemotherapies, but if you can see past that … the pros definitely outweigh the cons."

Make It Two

After the FDA's first targeted therapy approval for this patient subset, the dominoes quickly fell into a second one. In September 2021, Exkivity (mobocertinib) was approved for the treatment of locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations with disease progression after receiving platinum-based chemotherapy.

Within this study, researchers observed an overall response rate of 28% and a median duration of response of 17.5 months. The median overall survival (the time from treatment that a patient with cancer is still alive) was 24 months, while the progression-free survival (amount of time during and after treatment that a patient lives with cancer without it progressing) was 7.3 months.

"For (Exkivity), the side effect profile is a little bit different (compared with Rybrevant). It's more gastrointestinal (GI) side effects. There's more of a diarrhea type of side effect, there is some skin rash, but it's not as predominant as the GI side effect can be. They're sort of two different classes: skin side effects and GI side effects. And both, with appropriate management and dose reductions, can be manageable," explained Jänne, who was the lead author on the study that led to the drug's approval.

More specifically, common side effects included diarrhea, rash, nausea, stomatitis (inflamed and sore mouth), vomiting, decreased appetite, paronychia (infection surrounding the fingernail), fatigue, dry skin and musculoskeletal pain.

According to Jänne, next steps for further investigating therapies for this patient subset include looking at the newly approved drugs as monotherapies or combination therapies. "There are clinical trials to see whether — in combination with chemotherapy — (Rybrevant) would be better than chemotherapy as initial therapy. And as a single agent, whether (Exkivity) would be better than chemotherapy as initial therapy for this subset of individuals," he said. "The paradigm is typically that you get an approval in a following treatment with prior standard of care. And then the next question is: Is this an agent to replace or add to the standard of care? But it's exciting to have these options for individuals. We didn't have these several months ago, and we hope that (these two approvals are the first of) many to come."

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Medical World News®

NSCLC

Study Outcomes in Advanced Cancer May Not Match Real-World Data

Findings from this study may equip patients with the knowledge needed to make informed treatment decisions.

By JAMIE CESANEK AND ANTONIA DEPACE

ALTHOUGH IMMUNOTHERAPY has been adopted quickly to treat advanced non-small cell lung cancer (NSCLC), real-world outcomes need to be assessed against clinical trial data to provide the most realistic expectations of the treatment, study results demonstrated.

Findings from the study published in *JAMA Network Open* may help patients decide which treatment option is most suitable for them.

"This study is probably most useful for helping patients and their clinicians have a conversation about what they can expect from treatment. In other words, I don't think we've necessarily uncovered a problem in access that needs addressing at least to these treatments. Rather, we're seeing that these treatments were rapidly adopted into standards of care," Dr. Kenneth L. Kehl, a medical oncologist in the thoracic oncology program at Dana-Farber Cancer Institute in Boston and an assistant professor of medicine at Harvard Medical School, said in an interview with *CURE*®. "If anything, it's an indication of the need to repeatedly reassess real-world outcomes, given the rapid pace of innovation and cancer treatment in general and lung cancer treatment in particular."

Researchers in this retrospective study assessed Medicare data of 19,529 patients aged 66 years to 89 years with advanced NSCLC who received a first-line systemic therapy regimen. The regimens included Keytruda (pembrolizumab), platinum/pemetrexed chemotherapy, platinum/taxane chemotherapy or platinum/pemetrexed/Keytruda chemoimmunotherapy.

The objective was to further understand the treatment patterns associated with this patient subset. Knowledge of immunotherapy uptake and effectiveness is lacking outside clinical trials, according to the published study.

The uptake of the regimens that included immunotherapy was rapid within the Medicare population. First-line treatment with immunotherapy increased from 0.7% in 2016 to 42.4% in 2018. Older patients (age 70 years and above) had higher risk stratification scores, meaning a higher burden of comorbid illnesses, and were more likely to receive immunotherapy than chemotherapy.

Survival among patients receiving Keytruda was about 15 months shorter than data reported in the KEYNOTE-024 trial. Among patients receiving the platinum/pemetrexed/Keytruda chemoimmunotherapy, survival was about 10 months shorter than data reported in the KEYNOTE-189 clinical trial.

Kehl, who was the lead author on the study, added: "This doesn't mean that immunotherapy doesn't work. Rather, we're seeing it used in patients who may not have had any other treatment options. Even if patients have outcomes that are not as good as what we've seen in clinical trials, one thing our study doesn't do is ask: How are those outcomes compared to not getting any treatment? It's important to keep that in mind."

Because the study was limited to data pulled from the databases, Kehl stated that ideal next steps would be to replicate the trial question and look into more detailed patient information like molecular details and clinical characteristics of patients when they start treatment, as well as expand access to clinical trials.

"It's important to try to expand access to clinical trials in general and parts so that our results are more representative of what we might see in the population," Kehl concluded. "But there may always be a need to take a step back and do these observational studies to understand what's happening outside of trials."

JERRY SANFORD reunited at the Prospect Avenue firehouse in the Bronx, which is home of Ladder 42/Engine 73, where the helmet is displayed.

'Together as One Neighborhood'

Twenty years after 9/11, a retired firefighter reflects on the weeks following the attacks, as well as his own diagnosis of lung cancer six years later, in a newly published book. *By* ANTONIA DEPACE

PHOTOS COURTESY OF SANFORD

JERRY SANFORD RETIRED to Naples, Florida, after a 29-year career as a New York City firefighter, but the city managed to call him back to help his brothers right before one of the most critical times in the history of the United States: 9/11. Although Sanford later developed cancer potentially associated with the fumes and toxins surrounding Ground Zero, he felt it was important to recount his experiences from the weeks leading up to and following 9/11 in his book, "It Started With a Helmet: A Retired Firefighter's Return to New York City the Day Before 9/11."

Within the pages of the book, which was published soon before the 20th anniversary of the attacks, readers will also find stories about Sanford's time as a New York City police officer before starting with the city's fire department, as well as his own diagnosis of adenocarcinoma, a type of lung cancer found in the glandular cells in the organ's tissues, which likely developed from his exposure to the toxic air.

"It's an appropriate title because it all started in Naples, Florida. How did a helmet from New York City get from the Bronx to Naples, and from Naples back to the Bronx? The book is all about that," Sanford said in an interview with *CURE*®. "It's a very slim novel, but it categorizes a little bit of my life when I was a police officer, my story about 9/11 and then what happened, what (I did) after 9/11."

NOT LEAVING ANYONE BEHIND

After what he describes as "driving his wife crazy" for five months, Sanford found himself at the North Naples Fire District station for an interview with the chief for a public information officer position.

About a month into the job, Sanford was presented with an old New York City firefighter helmet that had been dropped off at the station in Florida. "(The chief) said to me, 'We have an old New York City fire helmet here that a man brought in. It was his father's, and he didn't want it anymore,'" Sanford explained. He called Ladder 42, the company the helmet came from. The station was undergoing a renovation, so it was decided that Sanford would return it when the work was done in 2001.

SANFORD shared a copy of his book with the firefighters of Ladder 131 in Red Hook, Brooklyn in August 2021.

On September 11, 2001, Sanford was flying from New York City back home to Naples with his wife, Maria. A few days before, he had come to return the old helmet to Ladder 42, and participated in a rededication ceremony for it. But two hours before he flew out of LaGuardia Airport, the world changed. The two planes had crashed into the World Trade Center, releasing about 24,000 gallonsof jet fuel, at least 100,000 tons of organic debris and 230,000 gallons of transformer, heating and diesel oils. It wasn't until he was changing planes in Pittsburgh that he learned what was happening.

"And at first, I didn't comprehend. I thought it was a sightseeing plane or something. But then we got thrown off the plane and it was pandemonium »

JERRY SANFORD kept some of his credentials from working at the press office after 9/11. He also previously reunited with his first firehouse in Harlem.

in the airport. We then quickly tried to get a car and get out of Pittsburgh. And then we found out by listening to the radio that, in fact, the second plane had hit the second tower, (then) Shanksville and the Pentagon. So it (was) a very heavy day," Sanford remembered.

Two weeks later, Sanford returned to Brooklyn to help. "And the job was just torn apart. We had lost so many men from so many different ranks," he said.

Sanford was assigned to the press office, where he would handle the media and attend funerals of those rescue workers who had died in the chaos. He recalled: "I could go into the firehouse and cry and grieve, which I did with my brother firefighters, but the media … you had to kind of keep them at bay because they were from all over the world. This was a worldwide story. It wasn't just a New York City story."

Sanford said he knew about half of the rescue workers who lost their lives that day.

"I thought, wait a minute, this can't be New York City, this can't be where I served for 30 years," Sanford recalled. "And it was just a horrible experience seeing that, but you know what, you have to do it, you got to pull up your pants, you got to get out there and you have to do it. Because you know what? They would have done it for me. And that's why I was there. Because the brothers, we don't leave anybody behind. We get in there and as the thousands of people are exiting the World Trade Towers — we're going in. I'm very proud of the role, my small role. Everybody played a role that day. Everybody has a story. But I'm very proud that I was able to come back to New York and help."

THE AFTERMATH

After the towers fell, a giant, toxic cloud loomed over Ground Zero. For hours, days and weeks after, rescue workers — including Sanford — inhaled the fumes. Twenty years later, the impact of those fumes is still being felt. According to Cancer Treatment Centers of America, an estimated 2,000 responders and Ground Zero workers have died from diseases including prostate cancer, leukemia, thyroid cancer and lung cancer, possibly attributed to the fumes they inhaled on the site.

In addition, rescue workers who helped during the aftermath of 9/11 may have a 9% increased risk of receiving a cancer diagnosis.

In December 2007, Sanford was diagnosed with adenocarcinoma in his upper right lung. His oncologist at the H. Lee Moffitt Cancer Center & Research Institute in Tampa, Florida, recommended a surgical approach. A recurrence in February 2008 of the same cancer in the lower left lung led to another successful surgery. "I went every year after that to my oncologist, and I had my CAT scan every year and everything was fine," he explained.

But in 2012, the cancer returned. This time, his oncologist recommended extensive chemotherapy and radiation. "But God is good. I never got sick," Sanford said.

Sanford has been cancer free since that year.

Twenty years ago, "we all came together as one neighborhood. Everybody was a New Yorker 20 years ago, helping everybody," Sanford said. "But on the sad side, we keep losing firefighters and police officers every day from something that happened 20 years ago — from that cloud, that terrible cloud that we ingested, including myself. It took six years for (doctors) to detect it in me."

SCAN THE QR CODE to learn more about how Sanford helped rescue efforts after 9/11.

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Lung Cancer Support Community message boards provide patients and caregivers with peer-to-peer support and information.

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About LUNGevity Foundation

LUNGevity Foundation is firmly committed to making an immediate impact on increasing quality of life and survivorship of people with lung cancer by accelerating research into early detection and more effective treatments, as well as by providing community, support, and education for all those affected by the disease. For more information, please visit www.LUNGevity.org. Call the toll-free Lung Cancer HELPLine at 844-360-5864.

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KRIS MUNDAY quit smoking after receiving a diagnosis of lung cancer. Before her diagnosis, her smoking habit had increased after she retired at 35 and became a dog rescuer and breeder full time.

PHOTO PROVIDED BY MUNDAY

GOING SMOKE-FREE AFTER A LUNG CANCER DIAGNOSIS

Studies show that quitting smoking after a lung cancer diagnosis has a huge payoff for patients.

By AMY PATUREL, M.S., M.P.H.

Kris Munday was 10 years old when she smoked her first cigarette. Her friend's mom had packs stashed in her purse and the girls smuggled them. By age 12, Munday was smoking regularly, and in her 20s, she was up to a pack and a half a day. When she moved to Sutherlin, Oregon, with her fiance and retired at age 35, her daily cigarette count doubled to fill the time.

"I no longer had to work in an office environment, which meant I had more time to smoke," says Munday, a dog rescuer and breeder. "It had gotten so bad that I was waking up in the middle of the night to smoke." To curb midnight cravings, Munday started wearing a nicotine patch overnight. But in 2014, when she was 45, she developed a horrific cough. Despite multiple rounds of antibiotics and half a dozen X-rays, doctors couldn't get to the bottom of her coughing fits.

Within months, Munday developed debilitating fatigue and her cough became so aggressive her lungs partially collapsed. Doctors ordered two bronchoscopies at separate facilities to determine the cause of her symptoms, which showed that Munday had a pea-sized spot on her lungs. "I was hospitalized for unrelated gallbladder surgery and the pulmonologist came to my room and said, 'Kristine, you have lung cancer,'" she remembers. »

Lung cancer will affect an estimated 236,000 Americans this year, and cigarette smoking is the No. 1 risk factor for the disease, according to the Centers for Disease Control and Prevention. In the United States alone, smoking accounts for 80% to 90% of lung cancer deaths, with smokers up to 30 times more likely to die from lung cancer than those who are smoke free. The more years a person smokes and the more cigarettes they puff daily, the higher the odds of negative effects. But cigarettes aren't the only culprit. Tobacco products, including e-cigarettes and cigars, also increase a person's risk of lung cancer.

"Tobacco harms every organ and system in the body," says Judith (Jodi) Prochaska, an addiction specialist with the Stanford Prevention Research Center in California. "It can affect wound healing, post-surgical outcomes and the metabolism of medications, including chemotherapy." In fact, there's evidence to suggest that nicotine spurs the growth of new blood vessels that feed cancerous tumors. So patients with lung cancer who continue to smoke after receiving a diagnosis are not only more vulnerable to a second lung cancer, but they're also at higher risk of developing other cancers, such as head and neck, bladder, cervical, stomach and pancreatic.

To make matters more complex, nicotine is highly addictive. "Even patients who have quit smoking for years may crack under the pressure of a lung cancer diagnosis and return to cigarettes," Prochaska says. To address these challenges, the National Cancer Institute (NCI) developed the Cancer Center Cessation Initiative in 2017 as part of then-Vice President Joe Biden's Cancer Moonshot initiative. Since then, more than 50 NCI-designated cancer centers have implemented smoking cessation treatment programs.

Major cancer organizations, including the American Society of Clinical Oncology, the American Association of Cancer Research and the Association for the Study of Lung Cancer, say smoking cessation should be standard of care for patients with cancer — and for good reason. The benefit of quitting on survival rates is on par with emerging therapeutics for lung cancer. Unlike smoking cessation, these therapies could cost thousands of dollars and may not be accessible for the lion's share of patients. But quitting smoking is possible for every smoker, and many smoking cessation resources are completely free for patients.

THE BENEFITS OF QUITTING

Charlie Thurlow was 57 when doctors told him he had stage 3B lung cancer. After months of coughing, weight loss, night sweats and eventually the collapse of his right lung, Thurlow's doctor ordered a CT scan. "There was an 11-centimeter tumor across the top of my right lung," says Thurlow, now 70 years old and retired from a publishing career in New York City. "And there was pain there, too. At times, I'd tried to wrap my chest with a knee bandage so I wouldn't cough so deeply."

HELLION PHOTOGRAPHY

Thurlow had been smoking at least a pack of cigarettes a day for 40 years (more during his college and graduate school years). By the time the pulmonologist said, "It's cancer, and I think it's curable," he was struggling to light up. What had once brought him immeasurable pleasure was now producing excruciating pain. "For the last several weeks before the diagnosis, I was stretching one to two cigarettes over the course of a day because that's all I could stand," Thurlow remembers. "I'd light up, suck in a drag or two then snuff the thing out. I'd repeat the process with the same

cigarette a few hours later. I could extract half a dozen such episodes from one cigarette."

Fortunately, ditching cigarettes has an immediate impact on the immune system, producing a dramatic drop in the body's natural inflammatory response after someone stops smoking. "Getting rid of that inflammatory load before surgery has a profound impact on treatment outcomes," says Dr. Matthew Triplette, medical director of the Lung Cancer Early Detection and Prevention Clinic at Seattle Cancer Care Alliance in Washington state.

Plus, there's strong evidence that people who quit smoking after a lung cancer diagnosis do better than those who don't. "They live longer and they're less likely to have a recurrence of the cancer after treatment," says Dr. Nancy Rigotti, director of the Tobacco Research and Treatment Center at Massachusetts General Hospital in Boston. "They're also more likely to tolerate the treatment and have fewer adverse events than those who continue smoking." They also lower their risk for getting a second cancer associated with smoking such as head and neck or bladder cancer.

According to a 2021 study published in the *Annals of Internal Medicine*, of 517 patients with non-small cell lung cancer, patients who stopped smoking lived almost two years longer without disease recurrence compared with patients who continued smoking (6.6 years versus 4.8 years). Smokers who quit also had higher three- and five-year survival rates than those who kept at it. Other research, including a review of 10 studies consisting of nearly 11,000 patients for the 2020 Surgeon General's Report, suggests that smoking cessation improves treatment outcomes and increases survival among patients with cancer. The longer a person goes without smoking, the lower their year-to-year risk of getting lung cancer becomes.

For the 40% to 50% of patients who are current smokers when they receive a lung cancer diagnosis, these findings may provide much-needed motivation to quit. "When smokers get a lung cancer diagnosis, they sometimes think that the worst has already happened, so why quit," Triplette explains.

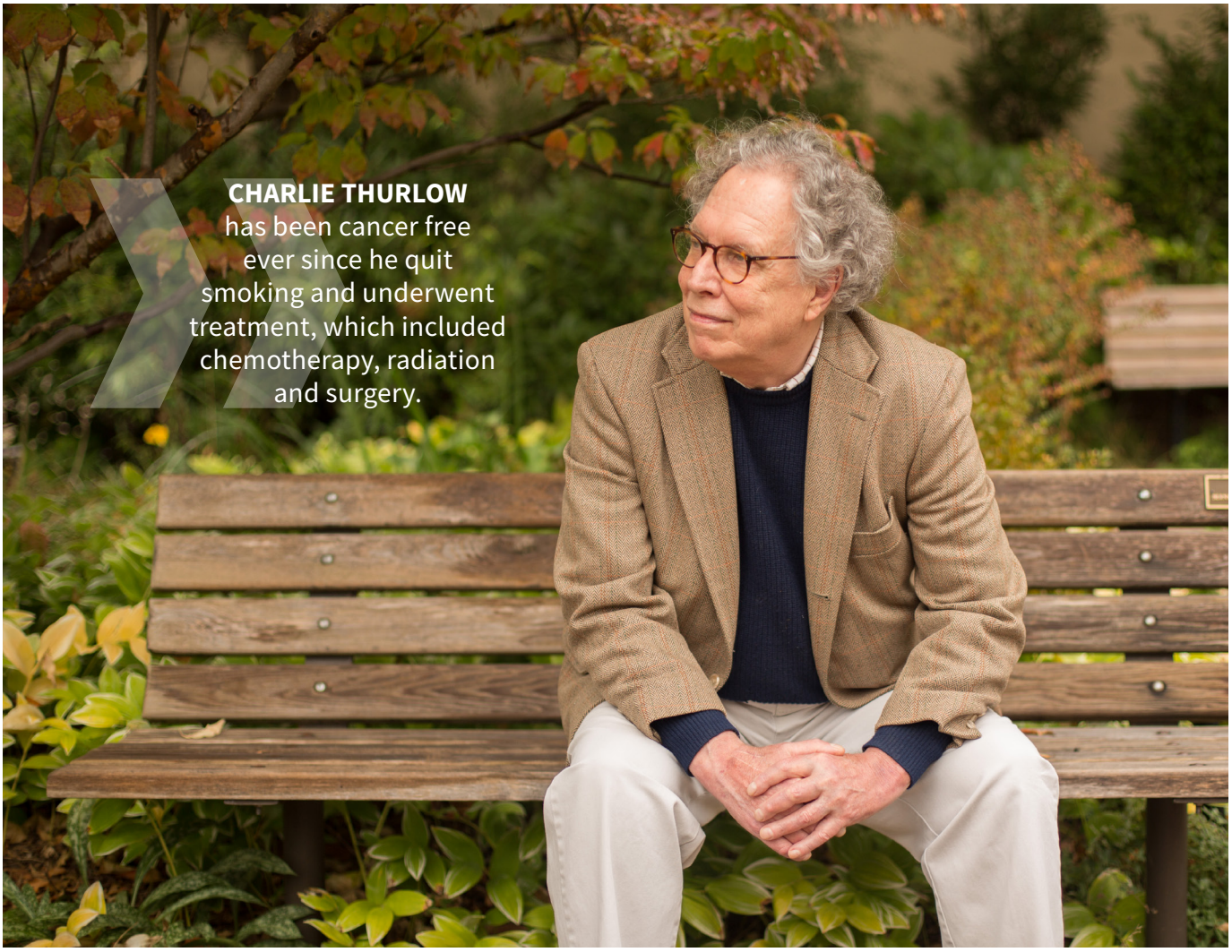
That was certainly the case for Thurlow, who quit smoking as soon as he found out he had cancer. Unfortunately, doctors weren't sure they could operate because his tumor was attached to the chest wall, but after eight weeks of low-dose chemotherapy coupled with 15 rounds of radiation, the tumor had shrunk. Thurlow became a candidate for surgery to remove the remaining cancer. He went on a high-powered chemotherapy regimen following surgery to ensure the cancerous cells were gone, and he has been cancer free ever since.

THE SCIENCE OF ADDICTION

While the perks of quitting are undeniable, walking away from nicotine isn't easy. Like most addictions, smoking is entangled in a complex web of physiological and psychological factors. Studies show that about 70% of smokers want to quit, and in any given year, 55% of smokers try to do so.

"With each puff of a cigarette, the feel-good hormone dopamine floods your system, and that keeps you coming back for more," Prochaska explains. "Plus, if you're used to smoking when you're drinking coffee or chatting on the phone, smoking becomes almost Pavlovian. You hear the bell; where's the drug?"

Despite the massive tumor lodged in Thurlow's chest »



CHARLIE THURLOW has been cancer free ever since he quit smoking and underwent treatment, which included chemotherapy, radiation and surgery.

and permanent pulmonary damage, he still reached for a nonexistent pack in response to a variety of triggers, such as a ringing telephone. "I had a nagging sense of a hole that I couldn't fill, an itch that I couldn't scratch," he explains. Today, Thurlow is 12 years out and he still hasn't entirely freed himself of these vague yearnings, and he still loves the smell of cigarette smoke when a waft comes his way.

"Preoccupation with my disease and mortality provided a distraction from withdrawal," says Thurlow. "Psychologically, a belligerent attitude is an undervalued ally in the great battle, and defying my addiction went hand-in-hand with defying my disease. I had to satisfy myself (with the fact) that I was doing everything within my power to get well, and smoking would have violated that commitment. Smoking would also have betrayed the trust of everyone embracing the cause of my recovery — particularly my wife, but also my children and other family; my oncologist, radiologist, and surgeon; an army of nurses and social workers; and countless friends. Had I smoked, I'd have felt guilty. Not smoking, I could enjoy a clear conscience."

Munday took a more methodical approach. A respiratory nurse at the hospital where she had gallbladder surgery coached her on how to quit. "She told me that a nicotine craving lasts only three minutes and that you can tolerate anything for three minutes," she says. "She also explained that it takes three days for your body to adjust to a new level of nicotine. So if you gradually cut back each week, you can be done with cigarettes inside of a month."

Armed with that information, Munday set out to be smoke free before her first chemotherapy treatment. Every five days, she took half a pack of cigarettes and set it aside, starting by dropping from three packs a day to two-and-a-half packs, and then from two-and-a-half packs to two. She also began chewing ice to fill the void of smoking cigarettes. "It took me three to four weeks to stop smoking completely," Munday says.

HELLION PHOTOGRAPHY

Munday had tried to quit before. She even paid $900 for hypnosis sessions, but her attempt to quit lasted less than a month, in part because her fiance was also a smoker. This time, however, they kept a smoke-free zone on one side of their home, and she used a nicotine pen to take the edge off. "I used the pen part-way through chemotherapy and radiation and then just titrated down my use the same way I had with the cigarettes," she says.

According to Triplette, a week or even a day without cigarettes before smoking again isn't a sign of failure. Instead, it shows that they can break the biochemical addiction and be able to do it again. The threat of a cancer diagnosis may even make the idea of quitting more palatable. "Cancer is a teachable moment. Something profound that happens in your life that you can directly tie to a behavior," says Triplette. "When you make that link for the patient, it can improve the success of their quit attempt."

> (My nurse) told me that a nicotine craving lasts only three minutes and that you can tolerate anything for three minutes.
>
> —KRIS MUNDAY

TOOLS TO QUIT

After receiving a lung cancer diagnosis, some people can quit more easily than they imagined because smoking becomes physically difficult. But many others struggle to quit. Navigating cancer is stressful, and many turn to cigarettes when they're stressed. Yet according to the 2020 Surgeon General's Report, less than one-third of people who try to quit smoking use evidence-based smoking cessation treatments.

With smoking, there is a very addictive, habit-forming behavior in addition to a substance — nicotine — that is physiologically addictive. To address both parts of the equation, a growing number of comprehensive cancer centers are offering patients a full buffet of options, including evidence-based counseling approaches, medications to help reduce withdrawal symptoms and curb cravings, and nicotine replacement therapy. Cessation programs that combine counseling with pharmacotherapies show cessation rates up to 57% in the first six months after starting the program, according to some studies. "Each of these approaches can work alone but they work better when they're combined," Rigotti says.

To give patients who smoke the best shot, many cancer centers incorporate tobacco treatment into standard patient care unless a patient opts out. At Seattle Cancer Care Alliance, for example, patients who indicate they are current or former smokers are automatically connected with the smoking cessation team. They don't have to worry about getting a referral for treatments like counseling and medication for tobacco dependence.

"Patients may be hesitant to share that they're smoking or even that they're former smokers, so we've worked hard to overcome barriers around stigma," Triplette says. Social workers can also help connect smokers and former smokers with support groups specific to patients with cancer who are trying to quit. Prochaska's team even uses breath sample analysis to show former smokers how their CO levels have dropped to zero. "That can be motivating both for the patient and for those who are in the group," she says.

Other avenues of support include the federal government-sponsored quit line (1-800-QUIT-NOW), where a tobacco counselor guides individuals through a quit process through telephone appointments. "Many free resources, including the quit line, also provide nicotine replacement therapies, such as patches, lozenges and gum, to help people quit smoking," Rigotti says.

For many smokers, that support is critical, and it's one reason Thurlow became a volunteer with the Cancer Hope Network, a nonprofit organization that matches patients to survivors by diagnosis and treatment. Although he was able to quit cold turkey, he recognizes that it is often harder for most and always suggests hospital-based cessation programs first. "But the best thing I can tell a match is that despite a dreary prognosis, I've been cancer free for 12 years, in no small part because I have had a team of supporters in my corner, including my wife and children."

While Munday's loved ones, friends and medical team applauded her efforts to quit smoking and reveled in her success, she didn't have that same support at home. After four total weeks of chemotherapy and 37 rounds of radiation, Munday realized she couldn't stay with her fiance. "He refused to stop smoking in our home and our cars," she explains. "There were other reasons, too, but that was a huge one." She ended the 18-year relationship and moved into her own place a few months after completing cancer treatment.

"When I went back to the oncologist two months shy of my five-year mark, he said, 'You're 100% cancer free,'" she says. That was a welcome turn of events for Munday, who was once told that her odds of surviving the disease were 20% to 30%. Could ditching cigarettes be the reason she survived? No one knows for sure. But there's no doubt that going smoke free has given Munday a second lease on life.

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

Living longer could start with LIBTAYO.

LIBTAYO will not work for everyone.

Patient portrayal.

What is LIBTAYO?

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

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

Important Safety Information

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

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

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

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

In a study,

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

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Median overall survival (OS)*

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

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

More patients were alive with LIBTAYO compared with chemotherapy

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

Individual results may vary.

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

Important Safety Information (continued)

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

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

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

  Females who are able to become pregnant:

  – Your healthcare provider will give you a pregnancy test before you start treatment

  – You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of LIBTAYO. Talk with your healthcare provider about birth control methods that you can use during this time

  – Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO
- are breastfeeding or plan to breastfeed. It is not known if LIBTAYO passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO

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

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

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

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

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Explore what could be possible with LIBTAYO

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

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

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

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

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- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness

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

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

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

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

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with LIBTAYO. Call or see your healthcare provider right away for any new or worsening signs or symptoms which may include:
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- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising

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

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

Continued on following page

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

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

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

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

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

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

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

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

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

REGENERON | SANOFI GENZYME

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

STAYING ON PATH

Targeted therapies offer new hope in HER2-mutated non-small cell lung cancers.

By DARA CHADWICK

Kiley Akers of La Canada, California, is in the best shape of his life. Before the sun came up on a recent morning, he ran 7 miles. The day before, he ran 6.

But Akers, 48, who serves as a running coach for The Leukemia & Lymphoma Society's Team in Training program, isn't your typical runner. He also has mucinous adenocarcinoma, a type of non-small cell lung cancer (NSCLC). More specifically, genetic testing of his tumor revealed that Akers has a mutation in the human epidermal growth factor receptor 2 (HER2) gene, which creates an opportunity for cancer cells to grow and spread.

While that might sound like bad news, Akers doesn't see it that way. Knowing he has this specific mutation has meant his medical oncologist — Dr. Ravi Salgia with City of Hope, a comprehensive cancer center in Duarte, California — could create a medication regimen tailored to his specific genetic mutation. This regimen, known as targeted therapy, attacks the mutation to slow cancer's growth. »

KIM SIAY & MARYNAMOVA / STOCK.ADOBE.COM

» **KILEY AKERS'** treatment with a targeted therapy regimen for NSCLC allows him to continue running.

ALYSSA STEFEK

> I'm able to continue with one of my passions. I'm fortunate and grateful.
>
> —*KILEY AKERS*

AKERS holds the six pills of Nerlynx that he takes daily.

ALYSSA STEFEK

In fact, Akers says his targeted therapy regimen — six daily pills of Nerlynx (neratinib) combined with an infusion of Herceptin (trastuzumab) every three weeks — allows him to keep running while undergoing treatment. "Because of City of Hope and Dr. Salgia, and the research they do, I'm able to continue with one of my passions," he says. "I'm fortunate and grateful."

TARGETING THE ENEMY

About 80% to 85% of all lung cancers are NSCLC, on authority of the American Cancer Society. Today, targeted therapies offer new hope to people with HER2-mutated NSCLC. But just how do these therapies work?

According to the National Cancer Institute, targeted therapies block the growth and spread of cancer by interfering with specific molecules, most commonly proteins, that help cancer grow. Researchers have discovered these proteins, known as molecular targets, by taking cells through tissue biopsies or blood tests (liquid biopsies) and comparing the number of certain proteins in cancer cells with the number of those proteins in healthy cells. If cancer cells contain the protein (but healthy cells don't) or if the cancer cells contain much more of the protein than the healthy cells, the protein may be a substance doctors can "target" with these drugs. Additional experiments in the laboratory can confirm that specific genetic changes generate these cancer-driving proteins, and this allows for new drugs to be created that can block their activity, resulting in cancer responses.

The HER2 protein is one such target. According to Dr. Kwok-Kin Wong, a medical oncologist at NYU Langone's Health Perlmutter Cancer Center in New York City, HER2 is one of the most studied proteins in cancer, particularly its role in HER2-positive breast cancer, where cells often make hundreds, if not thousands, of copies of themselves (known as amplification). Studies of HER2's role in NSCLC have shown that while HER2 can be overexpressed (present in higher amounts than normal cells), it's not amplified as much as it is in breast cancer, Wong says.

"What we have noted in the last 10 years is that HER2 can be mutated," he says. "About 2% to 4% of lung adenocarcinomas have HER2 mutations that cause the gene to be oncogenic."

Oncogenes are gene mutations that cause cancer cells to grow. "Overexpression might be a consequence that might »

help cancer grow faster, but it's not the driver," Wong explains. "These specific mutations in the HER2 gene are drivers."

Dr. Jennifer Carlisle, a medical oncologist at Winship Cancer Institute of Emory University in Atlanta, explains how targeted therapy works by comparing a cancer cell to a manufacturing plant whose products are the building blocks that help cancer grow and spread. Picture multiple "receiving bays" where the cancer cells receive materials (in this case, growth signals) to help cancer grow, she says. In lung cancers with HER2 mutations — like that of Akers — the lock on the HER2 receiving bay is broken.

"The door stays open, leading to constant growth signals that cause tumors to progress," Carlisle says. "Targeted therapies work like master keys that can fit in the broken lock and close the door." Closing the door stops the growth signaling.

> Targeted therapies work like master keys that can fit in the broken lock and close the door.
>
> —DR. JENNIFER CARLISLE

THE 'ULTIMATE PRECISION MEDICINE'

Targeted therapy is a form of precision medicine, a way of saying that doctors use drugs designed to address what's happening in a person's unique cells. Oncologists learn about an individual's cells by studying them and understanding how they differ from healthy cells.

"This is a very complicated field," Wong adds. "Even though we say HER2 mutated, the type of mutation in HER2 makes a difference. It's the ultimate precision medicine. The type of mutation of that gene dictates how well it would respond to certain drugs."

That's why biomarker testing is so important. "We highly, highly recommend biomarker testing for our lung cancer patients," Salgia says. "For sure with non-small cell lung cancer and for sure with later-stage disease, it's a moving needle at this moment in time, but we strongly believe it should be done for early-stage disease as well."

Targeted therapy isn't yet the standard of care for people with NSCLC. Carlisle explains that biomarkers currently have limited standard use in early-stage NSCLC, which is best treated by surgery, she says, adding that clinical trials are testing multiple approaches to reduce the risk of recurrence. Immunotherapy and targeted therapy for epidermal growth factor receptor (EGFR) mutations are approved postoperatively for resected stage 2 and 3 NSCLC, and ongoing studies are looking into treating other driver mutations perioperatively (around the time of surgery).

For people with stage 3 disease whose tumors can't be removed completely with surgery, chemotherapy and radiation followed by immunotherapy is recommended, Carlisle says. In those who have stage 4 HER2-mutated NSCLC, chemotherapy, immunotherapy or a combination of both — depending on the patient's health and tumor factors — is the typical frontline treatment, she adds.

An approved HER2 targeted therapy for NSCLC would give patients a more personalized treatment option, Carlisle says. "We have found with other driver mutations, such as EGFR and ALK (anaplastic lymphoma kinase), that going after the driver first and saving chemotherapy and/or immunotherapy for later helps patients live longer," she explains.

In May 2020, the Food and Drug Administration granted a breakthrough therapy designation to Enhertu (trastuzumab deruxtecan) in treating people with metastatic NSCLC that has progressed on chemotherapy. This drug is an antibody-drug conjugate that links the HER2-binding antibody trastuzumab to a very potent chemotherapy drug called deruxtecan, which inhibits cell division. When this drug binds to the cell, it is drawn inside, where deruxtecan is released, killing the cancer cells more specifically with less injury to normal cells. Carlisle mentions that additional trials of Enhertu are being conducted for people with stage 4 HER2-mutated NSCLC that continues to grow after standard therapy options.

Salgia says the floodgates have really opened for people with lung cancer thanks to genetic testing, known as next-generation sequencing.

"Next-generation sequencing identifies a set of molecular abnormalities," he says, adding that researchers can look at the gene's amplification as well as its translocation — meaning whether it moved from one chromosome to another chromosome. "This is how the code is being broken for lung cancer. Lung cancer is no longer lung cancer. It's a cancer that arises in the lung that has certain characteristics under the microscope, at the protein level and at the gene level."

MICHELLE BAUER

MARY MODICA credits the targeted therapy she's been taking since April 2021 for picking up her spirits.

TANEL LEIGHER

OPTIMISM ABOUNDS

Mary Modica, 76, of Queens, New York, has been participating in a phase 2 study of a targeted therapy drug called poziotinib (a tyrosine kinase inhibitor) since April 2021. The drug targets HER2 exon 20 insertion mutations — a specific type of HER2 mutation known to be an oncogenic driver in NSCLC.

"I wasn't feeling well and they thought maybe I had pneumonia," says Modica, a never-smoker. "That's when I went for a chest X-ray and my primary care doctor told me I had lung cancer."

Her doctor referred her to a thoracic surgeon who delivered the awful news: Modica had a stage 4 inoperable lung tumor. Biopsies soon showed that the cancer had spread to her tailbone and clavicle.

She was first treated with immunotherapy and radiation, but she developed a terrible rash that led doctors to stop the therapy. She then received chemotherapy followed by chemo maintenance, but the cancer continued to grow and spread.

Her oncologist referred her to another doctor for potential access to a targeted therapy clinical trial. Modica says she sought several opinions before deciding on the Perlmutter Cancer Center at NYU Langone Health. There, her medical oncologist, Dr. Joshua Sabari, recommended that she join a clinical trial of poziotinib based on the results of her tumor biomarker testing.

Modica admits she doesn't know much about the molecular profile of her tumor — or about how targeted therapy works. What she does know is that she has complete faith in Sabari, who mapped out several different treatment options for her to consider.

She learned that poziotinib would be administered as a pill, not infused through an IV. "That was better for me because my veins were kind of shot," she says. Today, she takes 12 milligrams of the drug each day.

"Once I went on it, it really picked up my spirits," Modica says, adding that being in the trial involves many follow-up visits. "They monitor you extremely closely."

Modica says she sees her care team once a month for blood draws, consultations with her doctor and sometimes, a nutritionist. Every other month, she has CT scans of her abdomen, lungs and pelvis; she also has an MRI of her brain every six months.

While she feels optimistic, Modica says targeted therapy has some side effects she's had to manage. These have included extremely dry skin, hair loss and diarrhea. But they haven't deterred her from the drug. "You have to learn »

Targeted therapy has also allowed **MODICA** to volunteer, which sometimes requires her to be busy all day.

> You have to learn how to make it work for you. I'm not going to be cured, but this is my life.
> —*MARY MODICA*

how to make it work for you," she says. "I'm not going to be cured, but this is my life. So I'm going to live it to the fullest. I'm out every day. Yesterday, I volunteered at a golf outing and I was outside all day."

Many people on targeted therapies experience side effects like diarrhea, liver problems, skin issues and high blood pressure. Akers says diarrhea has been the most challenging side effect of his targeted therapy regimen because he works and is active, he says.

He uses some over-the-counter medications to manage it, but also uses other strategies. "It's about learning the right foods to eat and what I can tolerate," he explains. "I also think stress can add to it. I really try to stay on top of hydration, too."

Ultimately, Akers says, something his doctor told him has helped him understand the value of targeted therapy. After his scans showed that he was having a good response to treatment, his doctor told him, "This is like managing high blood pressure."

"That blew my mind," Akers says. "I was like, 'What? This is cancer.' I liken it to running one of my long races where they mark the courses with trail ribbon. I tell myself to just follow the ribbon. I feel like I'm going to overcome this and it'll be something in the rearview mirror. With this therapy, I get the benefits of the cancer-killing property of chemotherapy, but without it destroying all the healthy cells. I ran before treatment yesterday."

That kind of optimism is what keeps doctors and researchers going in the quest to identify novel targeted therapies to treat NSCLC. Salgia encourages people with HER2-mutated NSCLC and their families to seek out expertise in treating the disease and to consider clinical trials.

"Every time a new drug gets approved, it's an incredible win for patients," Salgia says. "These novel therapies can actually impact survival and quality of life. We're definitely not done until we cure lung cancer. That's why I'm here. That's why our team is here. We need to support lung cancer research."

TANEL LEIGHER

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patient
SPOTLIGHT

The Garden of Life

One patient's garden helped her to cope and stay active during diagnosis, through treatment and into remission. *By* ANTONIA DEPACE

AUDREY HEPBURN ONCE SAID, "To plant a garden is to believe in tomorrow." This is especially true for Patti Morelli, who used her garden as a healing therapy throughout a diagnosis and treatment of metastatic stage 4 lung cancer.

"I would go out there and just (putter) around, even if I didn't feel well," Morelli said in an interview with *CURE*®. "I'd just go out in the garden. … I could always come in the house and go to sleep, but at least I made myself do something and (watched) the flowers bloom."

To date, she has planted over 40 types of flora and fauna in what she calls her "healing garden," as well as trellises robust with tropical mandevilla — all of which attract a plethora of butterflies.

PLANTING THE SEED

Leading up to her diagnosis of lung cancer, Morelli kept busy. She owned a medical billing company and was a caregiver to her husband who had a massive stroke in 2008, which left him with impaired speech and partially paralyzed on the right side of his body. In 2010, they decided to move to Oxford, Florida, for the sunny weather and lower cost of living. In 2017, they moved to Stuart, Florida, to be closer to the ocean.

Two years later, Morelli came down with the flu, which led her to find a new primary care doctor at Cleveland Clinic Martin North Hospital in Stuart (she had been meaning to do this for a while, but caretaking responsibilities for her husband took precedence). "I told (the doctor) I was a past smoker and I had something in my thyroid in the past, so she automatically ordered four tests, which were CT of my lung, ultrasound of my throat, bone density and mammography," Morelli said. "And I went for those tests on Thursday night at 5:00. And at 11:30 a.m., their office called me and said that my bone density came back bad, and would I want to go on medicine? Or would I want to come in to see the doctor? I said no, I'll just go on the medicine, no problem. An hour later, they called me back and they said we need you to come into the office."

Immediately, a PET scan was ordered for that Monday and an appointment at Stuart Oncology Associates was scheduled for Tuesday. There, she received a diagnosis of lung cancer with a prognosis of one year to 18 months to live. Morelli was 62 years old.

Immediately, the oncologist set up a biomarker test to see if Morelli was a candidate for immunotherapy. "When I went to my doctor, he knew I wasn't crazy about chemotherapy. … I've seen so many of my friends pass away and deteriorate away and I said, 'If I'm going to die, I don't want to deteriorate,'" she said.

The oncologist and Morelli decided on treatment with Keytruda (pembrolizumab), given intravenously through a port. Her first year consisted of treatments every three weeks, while the second year was every six weeks. Morelli did not undergo any surgery, radiation or chemotherapy.

Within three weeks, her lymph nodes had shrunk and within three months, the cancer had stopped growing altogether.

OTHER ELEMENTS AT PLAY

While a diagnosis of lung cancer is overwhelming enough, Morelli also had to think about her husband. "That was my hardest part of trying to understand (my diagnosis). The dying part, I wasn't that upset. I think I was more upset over him because it was (the question

NUTHAWUT / STOCK.ADOBE.COM; PHOTOS COURTESY OF RENICK

During and after cancer treatment, **PATTI MORELLI** used gardening as a motivator to keep her going every day, along with her dog, **BRONSON**.

of) who was going to take care of him," she explained. "If I go, I had a great life, I've had a very big, crazy life, but I really lived my life. You know, it wasn't that I did nothing. I had three children. I have two grandchildren. If God is going to take me, I believe in God, and if that's his calling for me, then that's his calling for me. … Everybody has a time clock in this world. We don't know when it's going to end. And when you get up, you are alive and you need to live."

Between her diagnosis and the demands of treatment, Morelli ended up having to place her husband in independent living, but she came by frequently to visit and take care of small chores.

In 2020, it all changed. "When COVID-19 hit, I couldn't go any longer, and then I had to pay somebody. I just don't know how I survived that year; it was a horrible year," Morelli said of not being able to see her husband while he was in independent living. "Last time my family and I saw him was at the hospital after suffering from a massive heart attack."

STARTING TO LIVE AGAIN

On September 2, 2021, Morelli was declared cancer free. "I feel like I'm taking baby steps to live again," she explained, noting that some of those steps include helping with a local fundraiser. This is the first time in over 12 years that she has been able to live completely for herself and not as a caregiver or patient.

Morelli said gardening "keeps me going every day," continuing to keep her in a positive mindset and moving her forward in life. She also hopes to start bird-watching. Morelli added, "I believe nature heals you, I really do — just going out getting yourself out of the house, (even) if it's just taking a walk."

It's moments like those that keep her happy. "I remember years ago, I had a therapist who said, 'Don't look for a happy day, just look for a happy moment in the day. And if you go to sleep at night, don't have all your worries upon you and think about how bad your day was. Think of that one happy moment of the one thing that made you smile today,' she said. "And it's really funny because it really does work."

cancer HORIZONS cure

SCAN THE QR CODE

Listen to *CURE*®'s podcast with Patti Morelli, where she talks about losing her spouse during cancer treatment.

2021 World Conference on Lung Cancer

September 8-14

Facing Disparities

Looking deeper into mortality rates highlights the importance of eliminating disparities and expanding screening eligibility for at-risk populations. *By* ANTONIA DEPACE

DESPITE A DECREASE IN lung cancer rates across the country, significant differences in disease rates and outcomes remain at the state level because of a variety of disparities, according to study results presented at the annual meeting.

In the presentation, Dr. Raymond U. Osarogiagbon, a medical oncologist at the Baptist Cancer Center in Memphis, Tennessee, discussed the geographic disparities in lung cancer mortality rates across the United States.

"We know that (lung cancer) is the oncologic challenge of our age. If one takes the perspective of the sheer cost in terms of human life, (it is) the No. 1 killer of men and women in the United States and in a lot of countries around the world. … In the United States, the good news is it has been going down sequentially over time," Osarogiagbon explained in an interview with *CURE*®. "The bad news, though, is in the United States, if you dug in a little bit deeper, you will find a very different picture. At the state level, if we disaggregated lung cancer as a cause of death, you will find a huge difference between the states … with the cluster of highest per capita death risk in the Southern and Midwestern United States."

States with the worst lung cancer mortality rates include Kentucky, Mississippi, Arkansas, Tennessee, West Virginia, Alabama, North and South Carolina and Louisiana, according to Osarogiagbon.

"At the county level, the difference is even worse," he said, noting that there are some that have rising numbers of death due to lung cancer such as the Appalachian Regional Authority and Delta Regional Authority, while others have plateaued with no decrease.

Disparities that come into play include women and racial minorities being at a higher risk for lung cancer despite lower levels of tobacco exposure.

Dr. Kim Lori Sandler, an associate professor of radiology and radiological sciences and co-director of the Vanderbilt Lung Screening Program at Vanderbilt University School of Medicine in Nashville, Tennessee, emphasized that there are exposures other than smoking that can

DEEPAGOPI2011 / STOCK.ADOBE.COM

contribute to disparities. "We know that smoking is the No. 1 cause of lung cancer, but there's also other causes. We know radon exposure and other types of exposures can be a cause of lung cancer. Certain populations are continuing to have those exposures like smoking and other high-risk exposures," she told *CURE*®.

This is where the importance of lung screenings comes in, said Sandler, who was not associated with the study presented at the meeting. "The populations that were highlighted in the presentation, a lot of it looks at this Southeast region where we continue to have very high rates of smoking," she said. "And unfortunately, our rates of lung cancer screening (in that region) have remained lower than other areas of the country, like in the Northeast. If you look at maps of the availability of lung cancer screening programs, you see them very highly localized in these Northeast centers where there are a lot of different programs available, and then when you get to the Southeast, they're more spread out and patients need to travel further in order to be able to enroll in those programs."

The Importance of Lung Screenings

According to Osarogiagbon's presentation, keeping up with yearly lung cancer screenings, which are usually covered by insurance, would reduce the risk of dying from the disease by 20%.

"It is from the point of onset on, whether it is finding (lung cancer) early, whether it is receiving optimal treatment for it, whether it is receiving the proper surveillance for it after diagnosis and treatment … there are highly preventable differences," he said. "It is people who live in parts of the world, or parts of the country that have resources that are organized in a certain way, who do well and not others. It is White people who do well, better than racial minorities. It is oftentimes when we're talking about interventions themselves and access to them, it is men who do better than women. And these are all things that are all necessary — things that significantly inhibit the full benefits of discovered innovations."

The lack of screenings taking place in those states with higher cases of death from the disease may also lead to later-stage diagnoses. In this circumstance, that means that not as many patients with lung cancer will be able to be cured with surgery. For example, 50% of patients with lung cancer in Wyoming can be cured by surgery versus 90% in states like New Jersey, Massachusetts and Utah.

"If you drill further down and go to the county level, it's even uglier than that. There are counties at the low end as low as 12% of patients with early-stage lung cancer that can be cured by surgery," Osarogiagbon added.

Of note, the five-year survival rate of an early-stage lung cancer diagnosis is 90%. But once the disease enters late-stage, the five-year survival rate drops to 10% or lower. "Ideally, when we detect lung cancer, we'd love to find it at its earliest stage where we could cure a patient with a minimally invasive surgery, not requiring chemotherapy or radiation therapy," Sandler explained. "In our screening program, it's unusual to say finding cancer is a win. But if you can find it that early, and truly offer a curative option for the patient, that's an enormous victory for us."

Eliminating Disparities

These disparities must be confronted with a multipronged approach, according to Osarogiagbon.

"We (need to) begin to focus on preventing, narrowing (and) eliminating disparities. We have to understand that the solutions come from multiple levels. The least effective is the level of directly hectoring, nagging (and) blaming the victims of disparities. (Patients) don't go in with the idea that they will do something to hurt themselves. A (patient with) lung cancer who is poor does not stand up in the morning and decide, 'Yippee, I am going to make sure I get the wrong treatment today. I don't care if I die.'" he said. "When we talk about disparities, it is very important for (providers) to get away from the traditional, narrow lens of who are these people or why do they have such terrible outcomes, and recognize that we have seen the enemy. It is us."

Sandler agreed with the outlook, emphasizing the need to banish the stigma around smoking and lung cancer, especially when other factors could be at play.

Because of this, Sandler believes that further investigation on eligibility for screenings and expanding eligibility to at-risk populations would make an impact, along with engaging further with communities to enhance outreach and education.

She noted that there have been some steps forward. "In terms of the disparities, the guidelines were just updated earlier this year, and they did decrease the age to 50 (and the pack-year smoking history) to 20, from 55 and 30, respectively," she said. "And if you look at the recommendations from the (United States Preventive Services Task Force), they specifically say that this is to address disparities in the African American community and for women, because those are the populations that we're really going to see an increase in eligibility. It's not perfect. It's a first step. But I think having that conversation and seeing the readiness of different organizations to accept new guidelines and continue to work on new guidelines is a really, really positive step forward."

‘Miraculous Class of Drugs’

Recent results may lead to more checkpoint inhibitor options and lower treatment prices, giving accessibility to more patients worldwide.

By JACKIE COLLINS AND ANTONIA DEPACE

TISLELIZUMAB PLUS chemotherapy demonstrated clinically meaningful improvements in progression-free survival (the amount of time that a patient lives with cancer without disease worsening after treatment) versus standard of care chemotherapy as a first-line treatment for patients with stage 3B or 4 advanced squamous non-small cell lung cancer (NSCLC).

Of note, tislelizumab is not approved by the Food and Drug Administration, but there are ongoing trials looking into this monoclonal antibody checkpoint inhibitor.

According to Dr. Jorge J. Nieva, a medical oncologist and section head of solid tumors at USC Norris Comprehensive Cancer Center in Los Angeles, while the data presented don’t necessarily show anything new, these results foreshadow innovations like lower drug prices, which will benefit patients with lung cancer worldwide who may not have been able to afford the treatment otherwise.

“The development of these Chinese drugs is going to drive two things. It’s going to drive lower prices and it’s going to drive innovation,” he explained in an interview with *CURE*®. “It’s going to be easier for these Chinese firms to replicate Western clinical trial results with new antibodies. From my standpoint, these antibodies are all more alike than they are different. While many of us prefer to drink Coca-Cola or Pepsi, generic colas taste pretty similar. That’s effectively what we have here. This is going to require the drug manufacturers in the U.S. and Europe to begin to develop more innovation. … These changes are all good for patients.”

In the study, patients received one of the following combinations:

- A treatment regimen of tislelizumab plus paclitaxel (group A).
- Tislelizumab plus Abraxane (nab-paclitaxel) and carboplatin (group B).
- Standard-of-care chemotherapy with paclitaxel plus carboplatin (group C).

Findings showed that progression-free survival was longer in the groups that received tislelizumab. Specifically, for those with stage 3B disease, the median progression-free survival for group A was 9.8 months versus 5.6 months in group C. The median progression-free survival in group B was 11 months.

For patients with stage 4 disease, the median progression-free survival in group A was 7.6 months versus 5.2 months in group C; the median progression-free survival was 7.4 months in group B.

In terms of overall response rate (the number of patients who see a partial or complete response to therapy), patients with stage 3B disease demonstrated an overall response rate of 84.2%, compared with 82.5% in group B and 59.1% in group C. For patients with stage 4 disease, group A showed an overall response rate of 67.1%, compared with 70.9% in group B and 44.2% in group C.

Nieva said the outcomes associated with tislelizumab are similar to those of a common checkpoint inhibitor.

“This is generic Keytruda, and (patients) don’t need to think about it as anything more than that,” he said. “It’s a similar strategy in terms of drug selection (and) effect size. It’s another study of chemotherapy in combination with a PD-1 checkpoint inhibitor. It shows that adding a checkpoint inhibitor to chemotherapy makes it work better, so there’s nothing new to learn here. ... All we learned is that it doesn’t matter who manufactures the antibody; you’ll get a similar effect. And so to that sense, the only thing the study told us is that maybe someday prices will come down.”

The most common side effects across all groups included anemia, hair loss, decreased white blood cell count and low neutrophil count.

“There (are) a lot for patients who have high PD-L1 scores. They can be treated with a checkpoint inhibitor alone, ... with a checkpoint inhibitor plus chemotherapy (or) ... two checkpoint inhibitors and chemotherapy. All of these are options. And they all represent overwhelming advance over how we treated lung cancer patients 10 years ago that no matter which particular strategy is selected by a patient and their doctor, they know that anything that involves these — I could say almost miraculous class of drugs — is going to be giving them an opportunity for cure,” Nieva said.

He also added that he hopes that studies like this will push researchers in the U.S. to discover more innovative treatments, including subcutaneous formulations (drugs given as an injection) instead of intravenous ones (drugs given through the veins). He also said that this could lead to newer

checkpoint inhibitors that may generate similar responses.

"There are a number of exciting new checkpoints that are going to come out and understanding how to use those checkpoints in an additive fashion with the current standards of care is going to be important," Nieva said. "We're going to have additional science around delivering these drugs and new delivery methods. Are these drugs safe enough to administer at home and self-administer? That's going to be something that could potentially become a wave of the future for the checkpoint inhibitors, because I do see the drugs as actually being quite safe. Other innovations are going to come from understanding why some people don't respond and trying to fix that so that they do."

Facing Brain Metastases Head On

The PD-L1 inhibitor Tecentriq plus chemotherapy improved responses on disease spread in non-squamous non-small cell lung cancer.

By ANTONIA DEPACE

A trial looking at a chemoimmunotherapy regimen of Tecentriq (atezolizumab) plus carboplatin and pemetrexed for advanced non-squamous non-small cell lung cancer and untreated brain metastases showed a 40% intracranial response rate.

These findings illustrate the start of research looking further into treatment efficacy in this patient population.

"If you have untreated, asymptomatic deposits in your brain, you have about a 40% chance that if you (get) this regimen, you can probably hold off on radiotherapy. And the real question is, What do you do with something that is a 40% chance? If there's a 40% chance of rain, do you take an umbrella?" Dr. D. Ross Camidge, a professor of medicine/oncology and Joyce Zeff Chair in Lung Cancer Research at the University of Colorado Anschutz Medical Campus in Aurora, said in an interview with *CURE*®.

Camidge emphasized the importance of this study, as it reflects the field growing awareness of the importance of addressing brain metastases. "Brain metastases are very common in lung cancer, and yet patients with those deposits have either been excluded from clinical trials or they're only allowed into clinical trials if the deposits in the brain have previously received radiotherapy, which means that you can never really assess the activity of a drug in that setting because you've already treated them with radiotherapy," he said. "Because this study allows patients with untreated brain metastases to be included in the study, we're able to directly assess the activity of this chemoimmunotherapy regime in brain metastases."

About 40% of patients with lung cancer will develop brain metastases, according to a study in *Nature.*

At a median follow-up of 17.3 months, progression-free survival (time that a patient with cancer lives without disease worsening) was 8.9 months. The median intracranial progression-free survival was 6.9 months.

"The good news is that they did show that the deposits in the brains of the patients in this study did shrink, and that's exciting," Camidge said, noting that he would like to see more studies completed in this setting.

Camidge noted that brain scans should be performed earlier than six weeks, which was the time duration performed in the study. "If you're trying a regimen that you don't know is going to work in the brain, and you're including people with untreated brain metastases, I might want to have a brain scan earlier because you don't want people to have symptoms in their brain," he explained. "You don't want them to damage part of their brain."

If the treatment regimen didn't work, Camidge said the patient would be recommended for radiotherapy.

Other limitations from the study, according to Camidge, included the fact that it was a single-arm study, which means that the researchers gave patients only the treatment regimen in question rather than comparing it directly to another. It was also unclear if enrolled patients had other biomarkers or mutations that could have led to an increased efficacy of the regimen.

"The excitement about this study is its design and its inclusion of untreated brain metastases and directly looking at activity in the brain with an intracranial response rate should be the beginning of how we develop drugs in lung cancer in the future," Camidge concluded. "And this has been proposed in national guidelines for a few years. Obviously, it takes a little time from an idea to get to a clinical trial to moving forward. I hope this is some of the first reflections of people picking up on these international guidelines and changing how we address the brain in clinical trials."

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

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

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

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

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

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

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

What are OPDIVO and YERVOY?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

What are the possible side effects of OPDIVO and YERVOY?

OPDIVO and YERVOY can cause serious side effects, including:

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

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

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

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

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

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

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CURE® Honors Oncologists, Patient Advocate for Their Impact on the Community

CURE®'s Lung Cancer Heroes® award program celebrated and thanked the heroes who make a difference in the lives of patients with lung cancer. *By* DARLENE DOBKOWSKI, M.A.

TWO PHYSICIANS AND A cancer survivor-turned-advocate were honored during *CURE*®'s Lung Cancer Heroes® awards program, which honors people who have made contributions in the field of lung cancer.

CURE Media Group recognized Dr. Hossein Borghaei, Heidi L. Nafman-Onda and Dr. Kenneth Rosenzweig, who were nominated by their peers for the second annual Lung Cancer Heroes® award ceremony, which was sponsored by Takeda Oncology. The three awards were presented Oct. 28 during a virtual celebration held in conjunction with the fourth biennial International Association for the Study of Lung Cancer (IASLC) Small Cell Lung Cancer Meeting.

Essays were submitted by colleagues, patients and family members who wrote about Borghaei, Nafman-Onda and Rosenzweig and nearly 30 other Lung Cancer Heroes® nominees, detailing noble acts of patients, physicians, caregivers and others involved in the lung cancer community. Some examples from the essays include a daughter caring for her mother with stage 4 non-small cell lung cancer, researchers conducting studies to expand the knowledge base and patients who used their experience to be powerful advocates for the community.

"There's hope in survivorship,

LUNG CANCER HEROES® HONOREES

FROM LEFT: **DR. HOSSEIN BORGHAEI; HEIDI L. NAFMAN-ONDA; AND DR. KENNETH ROSENZWEIG**

BORGHAEI BY KRISTA PATTON; NAFMAN-ONDA BY LINDSAY AIKMAN; ROSENZWEIG BY CLAUDIO PAPAPIETRO

as science rapidly advances and improves care and treatment," said Kristie L. Kahl, vice president of content at MJH Life Sciences™, parent company of *CURE*®, during the ceremony. "Lung cancer affects a wide range of people. The bottom line is anyone with lungs can get lung cancer. Together as one community we can raise awareness of lung cancer and most importantly, recognize and celebrate the esteemed individuals contributing to improving the lives of lung cancer patients."

'The Urgency Around Awareness'

The keynote speaker for the event was Laura Dern, Academy Award, Emmy and Golden Globe winner, who starred in "Wild," the story of author Cheryl Strayed, whose mother, played by Dern, died from cancer. Dern felt deeply connected to the character she played in "Wild" because it reminded her of her experience with her grandfather's lung cancer journey when Dern was 6 years old.

Dern discussed her personal experience with cancer and how it motivated her to become an advocate, and highlighted how everyone can be a hero in one way or another.

"Everyone is in the wings wanting to make a difference to a loved one, a friend and a stranger," Dern said. "So many of us sit isolated in our own homes wondering how we can make a difference, feeling the impact, watching the news alone, we're all wondering how our voice can matter. And what's incredible about your work and about advocacy in general is it's also guiding the heroes who wait to know how they can make the difference."

The American Dream

One of the three Lung Cancer Heroes® recognized at the awards ceremony was Dr. Hossein (Hoss) Borghaei, chief of the division of thoracic medical oncology, professor in the department of hematology/oncology and co-director of the immune monitoring facility at Fox Chase Cancer Center in Philadelphia. As a teenager, he came to the United States as a political refugee from Iran and supported himself through college then medical school. He has led numerous clinical trials, contributed to his institution, advocated for the lung cancer community and devoted his time to every patient.

> What's incredible about your work and about advocacy in general, is it's also guiding the heroes who wait to know how they can make the difference.
>
> —LAURA DERN

Borghaei was nominated by his colleague, Dr. Martin J. Edelman, chair of the department of hematology/oncology and deputy cancer center director for clinical research at Fox Chase Cancer Center in Philadelphia. Edelman described how Borghaei was a leader in advancing the field of immunotherapy in lung cancer treatment, especially as it made a return to solid tumor oncology.

"Hoss was a leader in that, both understanding the science as well as bringing (it) into the clinic and being a leader in that area," Edelman said during the ceremony. "And while doing all that, (he was) seeing a variety of patients here, overseeing large clinics, playing a very active role in the cancer center on some of the thankless committees … where you do a lot of work on behalf of the institution, not always for personal reward. All during this (he's) always having a great sense of humor."

Borghaei said recognition, such as the Lung Cancer Heroes® award, confirms the work that he has done in the lung cancer community.

"I don't think you get into this business thinking that people are going to recognize you for this and that; you become a physician to help people," Borghaei said. "It's always nice to be able to be recognized as someone who's done something, and Dr. Edelman's comments make me feel that what I have done so far has been noticed and has made a difference. And hopefully, the progress that we've made in the world of lung cancer in the past decade will continue with supportive people like Dr. Edelman."

Facilitating Change

CURE Media Group also recognized Heidi L. Nafman-Onda, a lung cancer survivor and founder of The White Ribbon Project. The organization is a product of Nafman-Onda's frustration with the lack of attention paid to the lung cancer community. It started with her husband making a plywood ribbon that reads, "Lung Cancer Awareness" for their front yard and has grown to a movement of thousands of white ribbons that have been made and shipped throughout the United States, Canada, the Philippines and the European Union.

Nafman-Onda was nominated by Michelle Hills, who was diagnosed with stage 4, ALK-positive lung cancer. She met Nafman-Onda through a LUNGevity Foundation virtual Zoom meetup during the pandemic, where she wanted to meet somebody like her, a competitive athlete with no history of smoking.

"The determination that Heidi had to facilitate that change (to increase lung cancer awareness) was really remarkable," Hills said during the awards ceremony. "Heidi struck me as one of those really talented people. I thought, if there's anyone here who can facilitate this change, she is a one-woman powerhouse that was looking to take down the cancer center. And I thought, "If I had to make a bet, I'm »

going to put my odds on Heidi because I really think that she can impact change.'"

Even with the strong determination to increase awareness, Nafman-Onda is still overwhelmed by how The White Ribbon Project has taken off.

"I was angry and hurt by the lack of planning and by being ignored as not only myself, but you were trying to reach your cancer center," Nafman-Onda said at the ceremony. "And the more people we talked to on the LUNGevity support groups, we were all feeling the same way, getting the same type of treatment and it was just so hurtful. It was a knee-jerk reaction that day to scream to (my husband,) Pierre, 'Please make me a white ribbon,' so I could just scream from our front door that I have lung cancer. I'm not ashamed of having lung cancer. No one should be ashamed of having lung cancer. No one should be ashamed of having any cancer, and why should this cancer then not be embraced?"

Applying Life Lessons to Clinical Work

Another Lung Cancer honoree was Dr. Kenneth Rosenzweig, professor and system chair of radiation oncology at Mount Sinai School of Medicine in New York. Rosenzweig has conducted research in lung cancer and mesothelioma, taught other physicians how to treat lung cancer, improved patient care and volunteers for several lung cancer organizations. Although he does not speak about it often, he also has a personal connection to lung cancer, as his father received a diagnosis and died from metastatic lung cancer when he started specializing in the treatment of lung cancers and other thoracic cancers in his career.

"I think that was an important learning experience for me, as painful and as excruciating as it was at the time to see firsthand what a patient goes through when they're getting chemotherapy and radiation," Rosenzweig said during the ceremony. "I've tried to bring that to my clinical career and clinical practice, the research and just even the way we set up the department. I don't speak about that a lot, but to hear (my nominators) say these kind words makes me feel that I'm honoring my father's legacy and makes it even more poignant for me to have gotten this award."

Rosenzweig was nominated by several of his peers: Dr. Fred R. Hirsch, executive director at the Center for Thoracic Oncology in The Tisch Cancer Institute at Mount Sinai and the Joe Lowe and Louis Price Professor of Medicine at the Icahn School of Medicine at Mount Sinai in New York; Dr. Ramon Parsons, director of The Tisch Cancer Institute; and Dr. Matthew Galsky, professor of medicine and director of genitourinary medical oncology at The Tisch Cancer Institute.

"I would thank you actually for all your support for the building of (the) thoracic oncology team at the Tisch Center Institute at Mount Sinai," said Hirsch, who was one of the 2020 Lung Cancer Heroes® honorees. "You have been a cornerstone in this development and still are a cornerstone in the development to build up a multidisciplinary culture around thoracic oncology, collaborative research and educational aspects."

Another nominator highlighted the efforts Rosenzweig makes to aid in patient care.

"You're really an incredible colleague. (You) always answer the phone to talk about patients (and) really put patients first," Galsky said. "And that's on top of all the things that you do to advance the field. Congratulations on this award, really richly deserved. Thanks for everything that you do for our patients."

Parsons, the third nominator, also recognized the innovative thoughts it took to achieve what Rosenzweig has done throughout his career.

"Since I've been (at Mount Sinai) for eight years, you've been a great colleague," Parsons said. "I got to watch you build and continue to build a really terrific department of radiation oncology. Building out the research and the clinical side of this across a very large health system requires a lot of dedication, patience and also creativity, and I've seen all of that with you."

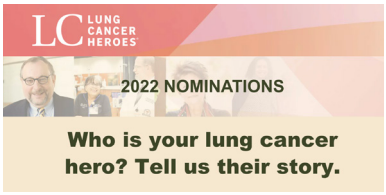
Erik Lohrmann, vice president of CURE Media Group, thanked the heroes honored at this event.

"Whether through research and development, patient advocacy or patient care, you've each uniquely contributed to improving the lives of lung cancer patients," he said. "Your accomplishments and tireless devotion exemplify what our Heroes award represents."

Fatima Scipione, head of oncology patient advocacy and engagement at Takeda Oncology, also acknowledged the accomplishments made by the heroes at this event and beyond.

"Thank you to the Lung Cancer Heroes®, who are being recognized today, for your outstanding commitment and continuous dedication to this community, and for the difference you're making to improve the lives of others," Scipione said. "Each of you saw a need within the lung cancer community and used your own skills, your expertise, your time, your resources, your passion and your purpose to better the lives of people living with lung cancer and truly exemplify what it means to be a hero and a champion for others."

LEARN MORE ONLINE



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

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

Living Longer and Better Lives

As part of its "Speaking Out" video series, in partnership with the GO_2 Foundation for Lung Cancer, *CURE*® spoke with an expert on quality of life. By KRISTIE L. KAHL

WHILE TREATMENTS CONTINUE TO improve outcomes for patients with lung cancer, quality of life for this patient population is lower than for others with cancer.

Typically, symptoms like fatigue or loss of appetite, as well as pain or sleep disturbances, can affect a patient's physical and cognitive well-being. Moreover, these effects flow into the psychosocial side of a lung cancer diagnosis, possibly causing stress, anxiety or depression.

As part of its "Speaking Out" video series, *CURE*® spoke with Susan Smedley, national manager of community fundraising and endurance events at GO_2 Foundation for Lung Cancer, about physical and emotional quality-of-life and resources available for patients and their loved ones.

Q: How can side effects, either from treatment or the cancer itself, affect the day-to-day life of a patient with lung cancer?

A: In a myriad of ways, certainly physically, depending on the treatment. There can be side effects like fatigue, nausea, pain from the cancer itself, headaches if there has been metastasis to the brain, etc. The day-to-day, how you're feeling, can really be impacted, but also emotionally, feeling like you've lost touch with your life, with who you were before you heard those words, "You have lung cancer." Emotional (effects can include) anxiety, fear, just feeling separate and isolated, sadness, etc. And we find that those side effects, certainly the emotional ones, can continue even many years after treatment has ended.

Q: With all those different types of side effects, what are we doing to manage them in order to improve quality of life?

A: Quality of life certainly means different things to different people. The first place to start is your physical (quality of life), how you're feeling. And care providers have a lot of resources for managing nausea, for managing fatigue. But there are also other resources that are available. (GO_2 Foundation for Lung Cancer) has a whole section on our website around supporting people who've received a diagnosis, and provides different resources around managing those side effects.

I believe that there's more and more awareness that this is impacting people wanting to continue treatment, and it can really impact the outcome of someone's treatment. We want to make sure that people know, if you're feeling not good, please reach out to us at GO_2 Foundation. Our support line (1-800-298-2436 or support@go2foundation.org) can get you matched with resources to help you manage them, or your care team as well.

Q: How does maintaining a healthy lifestyle play a role in improving that quality of life?

A: It makes such a difference. And we're really interested in looking at how we, as an organization, can help support people to do that as well. (The American Cancer Society) has released guidelines basically saying that, for cancer patients of any type, they recommend at least 150 minutes of moderate exercise a week. That's two and a half hours. I think most people who haven't had a diagnosis aren't achieving that. And the reason that they're recommending that is movement helps to stimulate the different body systems, whether it be respiratory, lymphatic, cardiovascular, etc., to help strengthen »

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the body, help remove toxins, etc. Also, emotionally and mentally, movement helps.

Q: We talk a lot about the multidisciplinary approach to cancer care. Can you talk about palliative care and how that's playing a role in lung cancer now?

A: There are misnomers about palliative care that it only is for people who are at end of life, and that's simply not the case. Palliative care refers to a network of professionals who are an additional layer of support for someone going through treatment or for their family.

And that can be physical, maybe offering additional meds. It can also be encouraging movement. It can be offering support to children in the family, offering support to care providers, looking at the financial impact, looking at making plans for life shifts, just having some of those conversations.

As a lung cancer survivor myself, we think about these things anyway. And to not to have conversations about the elephant in the room can be really detrimental. And so palliative care can be professionals who are used to having some of those conversations regardless of where you're at in your treatment.

Q: Why is patient-physician communication important? And how can we help our patients improve that communication?

A: I really believe that empowering folks who've received a diagnosis and their loved ones with information is huge. You really want to be the driver in your own care. I mean, certainly you don't have all the skill sets, you haven't gone to medical school, but you're the expert on you. We want to make sure that people know what to expect, questions to ask.

We have lots of resources on our website. We also have our support line. One of my colleagues meets with people, looks at their treatment plan and helps them come up with questions (about) next steps. Educated patients live longer and better lives. We want to be that conduit for that information in layman's terms that I can understand.

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

cure® EDUCATED PATIENT® LUNG CANCER SUMMIT

Join us in March 2022 for the next Summit! Stay tuned for details to be announced.

CURE®'s Educated Patient® Lung Cancer Summit is a half-day virtual event seeking to educate, inform and challenge the thinking of patients with all stages of lung cancer, as well as caregivers, survivors and advocates.

SUMMIT CHAIR
Edward S. Kim, MBA, MD, FACP, FASCO
Physician-in-Chief, City of Hope Orange County
Vice Physician-in-Chief, City of Hope National Medical Center
City of Hope

Tentative Discussion Topics

- Lung cancer screening, staging and advances in diagnosis
- Targeted treatment options such as biomarker testing and targeted therapies
- Looking ahead to clinical trials and NSCLC and SCLC advancements

Subscribe to our eNewsletter at curetoday.com to stay up-to-date on the latest news in lung cancer.

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

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