

Volume 9, Issue 1 SPRING 2020

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COVID-19 and Lung Cancer

Delivering reliable information and supporting our community

The health and well-being of the lung cancer community is a priority of ours. With so much uncertainty surrounding coronavirus COVID-19, we are committed to providing medically accurate and credible information about the virus as it becomes available.

LUNGevity is working with medical experts in the lung cancer community to develop resources specifically for people affected by lung cancer. A dedicated COVID-19





Dr. Zofia Piotrowska, MD, was our first expert in a series of webinars on COVID-19 and lung cancer

(www.LUNGevity.org/COVID-19) is continually being updated to include Q&As with experts answering questions posed by our community and video interviews with members of the Scientific Advisory Board and other medical experts. These resources are available in both English and Spanish.

Separately, LUNGevity is partnering with other lung cancer advocacy groups (GO2 Foundation for Lung Cancer, Lung Cancer Foundation of America, Lung Cancer Research Foundation, and LungCAN) to bring important updates to our

community on
COVID-19.
We will continue to
provide joint statements with updates,
based on recommendations by the World
Health Organization
(WHO) and the US
Centers for Disease

Control and Prevention (CDC), and what these updates mean for our community.

Most importantly, LUNGevity is here to help you navigate emotionally during these difficult times. Our Lung Cancer HELPLine (1-844-360-5864) offers free, personalized support for patients and caregivers at any time along your lung cancer journey. All of our patient services are also up and running, including the Lifeline Support Partner program, which matches lung cancer patients and caregivers to other lung cancer patients and caregivers who have walked the lung cancer path via continued on page 8

Only Four States Earn Top Grade on Lung Cancer Scorecard

In February 2020, LUNGevity released our first-ever Lung Cancer Scorecard, which graded individual states on policies that support access to optimal care for lung cancer patients on Medicaid. *continued on page 4*

REFLECTIONS FROM THE DESK OF THE PRESIDENT AND CEO

The outbreak of COVID-19 has brought unprecedented times: social distancing, sheltering in place, and much of the world at a standstill. As our new reality continues to unfold, I am encouraged by the teamwork that we are seeing to tackle the pandemic across all levels of society, but particularly in our community.

As you know, at LUNGevity we put patients first. I am proud to see our team at LUNGevity tirelessly sourcing and sharing information specific to people living with lung cancer. A new COVID-19 section on the website has expert webinars and Q&As in both English and Spanish.

I'm also proud to work closely with the other lung cancer advocacy organizations to create timely and reliable resources for our community, with weekly joint updates on the virus.

May is Lung Cancer HOPE Month. This May, I am filled with more hope than ever. Our community was able to accomplish so much in difficult times, and I look forward to seeing what we can accomplish in less uncertain times. I applaud our team and our constituents, who are integral to these continued steps forward. We have the greatest impact when we work together.

Thank you for your continued support.

Andrea E. Ferris

LUNGEVITY'S MISSION

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.

www.LUNGevity.org

Don't Miss Our Blogs!

Did you know that LUNGevity posts weekly blogs? They cover a variety of topics, including updates on research, advances in treatments and care, tips for healthy living and nutrition advice, and personal stories featuring members of our community, such as lung cancer survivors/patients, caregivers, volunteers, and fundraisers.

Check out LUNGevity.org/blogs every week to see what's new!

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Meet LUNGevity's Chief Health Equity and Diversity Officer



Jeanne M. Regnante

Jeanne Regnante has worked in healthcare advocacy and patient engagement for more than 35 years. Prior to joining LUNGevity, Jeanne served as the Senior Vice President of Community Engagement for the National Minority Quality Forum (NMQF) and Chair of the Diverse Cancer Community Working Group (CWG), which has 25 active public and private partners who work together to optimize cancer care, treatment, and inclusion in clinical trials for racial and ethnic minorities and medically underserved populations.

Q: Why is health equity important?

A: For decades, we've observed disparities in access to cancer care and treatment outcomes among racial, ethnic, and underserved populations. Health equity is about giving everyone, regardless of who they are, where they live, how much money they have, or how much education they have, an equal opportunity for the best possible outcomes.

Q: Tell me about your background and how this has shaped your beliefs.

A: I am driven by fairness, empathy, and collaboration in the work that I have done throughout my career. Through my work in global patient engagement and at NMQF, I've come to believe that patients, and those who care for them, are experts in their own disease. I also believe that long-held assumptions and prejudices can be erased. When they are eradicated, achieving impactful and sustainable health equity goals are possible.

I have worked with multiple stakeholders (healthcare providers, patient organizations, community leaders, health Insurance plan leaders, industry, patients, and caregivers) in diverse communities to address lung cancer screening rates for high-risk populations. Collaboration across all of these sectors is needed to address the many factors that influence health and to change the types of policies, practices, and systems that have kept inequity in place. I am dedicated to shining a light on cancer-center practices and the need for inclusion of diverse populations in cancer research in communities across the US.

Q: What are your duties in your new role?

A: My role is to represent LUNGevity as the trusted patient-organization partner with diverse and medically underserved lung cancer patients, including people at risk of lung cancer. Together, we can drive impactful, national and community-based solutions with all stakeholders to ensure greater access to healthcare throughout the care continuum.

I will also work to expand the Foundation's programs and services to better serve minority populations and underserved populations to ensure that all socially and economically underserved populations at risk of or diagnosed with lung cancer benefit from optimal care.

Q: What is your first goal as Chief Health Equity and Diversity Officer?

A: To engage with, listen to, and hear high-risk patient communities and those who care for them so that the choices that we make and the solutions that we offer as a Foundation are informed with them, not just for them. Those who are most affected by disparities must be engaged in the identification, design, implementation, and evaluation of promising solutions. For them, by them, and with them.

Q: What impact do you hope to have on lung cancer?

A: I believe that my engagement and inclusion of diverse populations and key stakeholders throughout healthcare will result in a better understanding of lung cancer and all its variants overall, and therefore will help everyone.

Q: What gives you hope in lung cancer?

A: Leaders in healthcare—providers, navigators, community leaders, researchers, educators, and policymakers—feel empathy for people. People want better health outcomes for themselves and their communities. At LUNGevity, we are dedicated to enabling all of them. I believe that building collaboration among stakeholders saves lives. When stakeholders get together to build on a diverse and inclusive culture of understanding and acceptance, only then will we have impact and save lives. This gives me great hope.

Are you interested in learning more about Jeanne's work, or would you like to talk more about health equity and diversity in lung cancer? You can reach Jeanne at jregnante@LUNGevity.org.

Nichelle Stigger Joins LUNGevity's Board of Directors



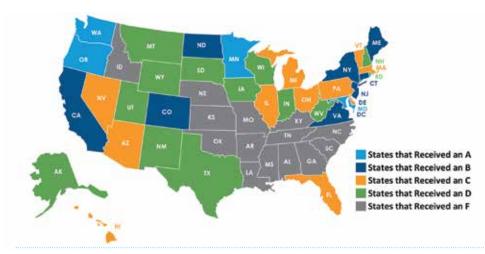
Nichelle Stigger

LUNGevity is honored that Nichelle Stigger, a lung cancer survivor-advocate, will be increasing her involvement with the Foundation and joining our Board of Directors.

Nichelle offers an indispensable perspective, as both a patient and a woman of color. Her personal mission to help other women of color survive cancer complements and amplifies LUNGevity's commitment to ensure all people diagnosed with lung cancer—irrespective of their geographic location, socioeconomic status, race, or ethnicity—have optimal cancer care and access to resources that can help them navigate their disease.

Nichelle's understanding of the challenges lung cancer patients face is invaluable on our Board, and we look forward to working with her to achieve LUNGevity's mission.

Read more about Nichelle at www. LUNGevity.org/meet-nichelle-stigger.



It is an imperative of LUNGevity to ensure all people diagnosed with lung cancer can benefit from optimal care irrespective of their income, race or ethnicity, or where they live.

Lung Cancer Scorecard continued from page 1

LUNGevity was joined by policymakers, healthcare providers, patients/survivors, and members of our community at a briefing on Capitol Hill to present the results of this study.

Dr. Mike Kolodziej from ADVI shared the results of the study with the Hill briefing attendees. He explained the importance of measuring metrics on a state level: "Often, state health policy is public health policy: very influential and very important."

To develop the Lung Cancer Scorecard, the Foundation examined the incidence and survival rates of lung cancer in all 50 states and Washington, DC. Next, the organization surveyed state Medicaid, the public health insurance program that provides healthcare coverage to low-income families or individuals, for their coverage policy for clinical care, including lung cancer screening, biomarker testing, and routine costs of clinical trials.

Four states—Maryland, Minnesota, Oregon, and Washington—received an "A" grade, while 14 states received an "F" grade.

Mutation-Specific Survivorship Summits to be Held in 2020/21

LUNGevity is proud to partner with several oncogene-specific patient support groups to bring a survivorship summit to each oncogene group.

The Summits offer those who have specific targetable mutation information on the basic research surrounding their oncogene type. Each type of lung cancer has specific treatment options, which may result in these patients having similar needs, lifestyles, and treatment journeys as others who share their mutation.

The Summits will include clinicians and researchers with expertise in the specific oncogene, and will provide opportunities for patients and caregivers to interact with the experts and ask questions. The Summits will also provide opportunities for patients to connect with others who have had similar treatments, side effects,

and challenges, and to form a community that can advocate specifically for their type of lung cancer.

In 2020 and 2021, LUNGevity intends to host three Summits, each focused on a different mutation: ALK, KRAS, or EGFR. Partnering with patient groups on these Summits ensures that issues most important to them are addressed.

The Foundation is proud to help patients navigate their disease by giving them access to resources and experts in the field and providing a new sense of community.

For dates and locations for the 2020 Summits, check out our website at www.LUNGevity.org/oncogene-summits. Dr. Julie Brahmer, oncologist, lung cancer researcher, and LUNGevity Scientific Advisory Board member, spoke at the Hill briefing, stating, "We've never before seen the advancements that we're seeing in lung cancer survival for our patients, but we have such a long way to go. We have to be able to implement what we've actually found and truly make what we've seen equate to further improvements in survival for everybody."

The Lung Cancer Scorecard clearly illustrates the disparities in access to optimal healthcare for cancer patients in the US. The Scorecard establishes a baseline to measure improvements (or lack thereof) in how lung cancer care is delivered and to identify pain points and opportunities in the system that we can address to improve patient access to precision medicine treatments. We are excited to see the great advances we can make with the roadmap laid out in this report.

Find out more about our Lung Cancer Scorecard at LungCancerScore.org.

Fund to Support Patients Affected by COVID-19

LUNGevity established an emergency fund, Breathe Easier, to financially support lung cancer patients throughout the United States who have been impacted adversely by the novel coronavirus. or COVID-19.

Patients who are in active treatment who are in need of funds for critical basic needs, such as food and general household expenses, can apply for support. If an applicant qualifies, they will receive a one-time grant of \$500.

Patients can call the Lung Cancer HELPLine (844-360-5864), a free support phone service in partnership with Cancer Care, to apply for the Breathe Easier Gift Card.

IN LUNG CANCER RESEARCH

advances

HIGHLIGHTS FROM THE 6TH ANNUAL

AACR-IASLC International Joint Conference

LUNG CANCER — TRANSLATIONAL SCIENCE FROM THE BENCH TO THE CLINIC

Translational science, as defined by the National Center for Advancing Translational Sciences (NCATS—an NIH institute), is a "field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process (turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public—from diagnostics and therapeutics to medical procedures and behavioral changes." My simplified definition of translational science for lung cancer is "matching the science and biology of lung cancer with early detection, therapeutics, and survivorship."



I had the privilege of starting 2020 by attending the sixth annual AACR-IASLC International Joint Conference. This was the first time I attended this conference, which is held annually in San Diego.

Dr. Upal Basu Roy

Early Detection

Dr. Pierre Massion's (LUNGevity Scientific Advisory Board [SAB] member) presentation on biomarker signatures that can distinguish between early-stage indolent cancers (cancers that do not grow rapidly and have fewer mutations) and aggressive cancers (cancers that have a high likelihood of growing and metastasizing) reminded me that defining these molecular subtypes will be critical in deciding which of these cancers will need aggressive vigilance. Aggressive cancers tend to have mutations in the PIK3CG, ATM, APOB, EPPK1, EP300, and KMT2C genes. His presentation was complemented by an excellent talk by Dr. Jennifer Beane (LUNGevity 2012 Career Development Awardee) on immune signatures of pre-malignant lesions (PMLs). PMLs are patches of pre-cancerous lung cells. Her research shows that PMLs have lower numbers of cancer-fighting immune cells, suggesting that PMLs figure out ways to escape the immune system early on in cancer development. This finding lays the foundation for immunotherapy as a potential mode for early immunotherapy

intervention. Thanks to translational science, early detection is evolving to become precision-driven.

We also learned about research from the Women's Health Initiative. Dr. Sitapriya Moorthi from the Fred Hutchinson Cancer Research Center discussed how the cohort of never-smoking women in the Initiative is being studied to understand risk factors, such as exposure to secondhand smoke, occupational exposure to carcinogens, and hormones, on the development of lung cancer.

Therapeutics

The biggest impact of translational research has been seen in therapeutics, with 15 new lung cancer treatments FDA-approved in the last two years alone. There is much ongoing research, including work on drugging what has long been considered "the undruggable gene": KRAS. Currently, two new inhibitors, AMG510 and MRTX849, of KRAS G12C, the most common KRAS mutation (it is estimated to account for 12%-13% of lung adenocarcinomas), have shown promise in early-phase clinical trials. Dr. Sai-Hong Ignatius Ou from the University of California, Irvine discussed a new drug, RMC-4630, which blocks another protein, SHP2, which is central to signaling by the KRAS gene. A combination trial with AMG510 and RMC-4630 is being planned, based on the fact that inhibiting both these proteins will deliver a double punch to lung cancer cells. These types of intricate combination studies would have not been possible without progress in translational science.

Other types of lung cancers, such as squamous cell lung cancer and small cell lung cancer (SCLC), have also been traditionally difficult to target. Research from Dr. Eric Haura from Moffitt Cancer Center shows that squamous cell lung cancer can be subdivided into three types: inflamed (with more immune cells present within the tumor), redox (with more genomic alterations than previously identified), and mixed (with few genomic alterations). This suggests that these three groups may respond differently to treatments such as immunotherapy. Similarly, as shown by Dr. Anna Farago from Massachusetts General Hospital, the SCLC pie is being further divided into subtypes with unique therapeutic vulnerabilities, such as those responsive to immunotherapy, those responsive to PARP inhibitors and temozolomide, and those responsive to cell cycle inhibitors, such as aurora kinase inhibitors. *continued on page 7*

advances

Oncogene-driven Patient Groups: How Patients Are Driving Innovation and Change

The lung cancer research landscape has dramatically changed in the 15 years since the first discovery of mutations in the EGFR gene.

Our understanding of the molecular biology of adenocarcinoma, the most common type of non-small cell lung cancer, has led to the identification of "oncogenic driver mutations"— alterations in specific genes that can lead to the development of cancer. As of 2020, there are FDA-approved targeted therapies for five oncogenic drivers: ALK, BRAF, EGFR, NTRK, and ROS1. These targeted therapies have increased survival and quality of life for patients compared to traditional chemotherapy.

With this progress, some patients (and their caregivers) with specific oncogene-driven cancers have started to organize globally to build partnerships that seek to provide support, increase awareness and education, accelerate and fund research, and improve access to effective diagnosis and treatment. These strategic partnerships include patient advocacy groups such as LUNGevity Foundation, doctors and researchers, and industry partners to drive the research most meaningful to their communities.

These groups recognize that traditional funding and research models found in federal funding bodies, such as the National Cancer Institute and the Department of Defense, are limited in their ability to foster research in unique lung cancer subtypes. In short, these groups are challenging the status quo. LUNGevity Foundation has partnered with the ALK Positive patient group on translational science research grants and with the EGFR Resisters patient group on gathering patient-reported data to identify unmet needs of a unique patient-population.

We look forward to future partnerships with these and more oncogene-driven patient groups.

Partnership with EGFR Resisters

The EGFR Resisters is a grassroots, patient-driven community dedicated exclusively to changing EGFR-positive lung cancer into a manageable, chronic disease. This community of survivors and caregivers is made up of over 1,700 members in 30 countries who benefit from sharing knowledge and connecting with others who are experiencing similar journeys. Project PRIORITY (Patient Reported Initiative On Resistance, Incidence, Treatment studY), a collaboration between LUNGevity Foundation and the EGFR Resisters, aims to understand unmet needs of the global EGFR-positive lung cancer community.

Project PRIORITY was kicked off in April 2019 with an international, longitudinal survey aimed at understanding the diagnostic and treatment journey of EGFR-positive patients. Preliminary results (the study is ongoing) were presented at IASLC's 20th World Conference on Lung Cancer in Barcelona by Ivy Elkins, lung cancer survivor and co-founder of the EGFR Resisters, and additional findings were presented at the 2019 North America Conference on Lung Cancer by Jill Feldman, lung cancer survivor and co-founder of the EGFR Resisters.

The longitudinal component of the survey was started in March 2020 and will catalog information on treatment sequencing and the financial burden of a lung cancer diagnosis for EGFR patients.

In addition, the EGFR Resisters are partnering with LUNGevity Foundation to release the first-ever EGFR Lung Cancer Translational Research Award. The Request for Applications will be released in June 2020.

Partnership with ALK Positive

ALK Positive is a group of 1,800+ ALK Positive patients and their caregivers in 42+ countries that provides information, support and research funding; they have partnered with LUNGevity Foundation to fund translational research that could, one day, save these patients' lives. The first Request for Applications (RFA) was issued in November 2017 and the ALK Positives, with input from world leaders in ALK-positive lung cancer research, funded three projects that aim to understand how immunotherapy can be used for ALK-positive patients. These projects, which will help uncover why immunotherapy has not been successful in treating ALK-positive lung cancer and test new immunotherapy approaches in ALK-positive lung cancer, include:

 Characterization of anti-ALK immunologic responses in ALK-positive NSCLC—Mark Awad, MD, PhD, Dana-Farber Cancer Institute

- Overcoming innate immune resistance in ALK-rearranged lung cancer—Justin Gainor, MD, Massachusetts General Hospital
- Targeting the complement pathway in ALK positive lung cancer—Raphael Nemenoff, PhD, University of Colorado Denver

The three awardees have made significant progress in their first year. The ALK Positives recently decided to provide a booster grant (an additional \$100,000) to Dr. Justin Gainor.

ALK Positive is also partnering with LUNGevity Foundation once again to fund their second RFA, totaling \$1 million. There are two paths to receive a 2020 Lung Cancer Research Award:

- ALK Positive Transformational Award: This award will be funded up to \$250,000 to \$500,000 over two years. Research in this award may include projects that incorporate patient samples.
- ALK Positive Clinical Trial Innovation Award: This award will be funded up to \$750,000 over two years. Research in this award includes clinical trials.

advances

RESEARCH PROGRESS REPORT

Cancer develops in a sequenced manner. Clusters of lung cells gain the ability to multiply faster than their neighboring normal cells by acquiring mutations. These clusters of cells are called "premalignant lesions" (PMLs). Some of these lesions may eventually become cancer. Knowledge about how some PMLs may develop into lung cancer is central to developing tools for cancer interceptioninterrupting the cancer development process and blocking progression to advanced metastatic disease. However, we have lacked effective lung cancer interception approaches due to our incomplete understanding of the earliest molecular events associated with the development of lung cancer, as well as the challenge in developing personalized tools for early detection and prevention.

The SU2C-LUNGevity Foundation-American Lung Association Lung Cancer Interception Dream Team (2018-2022), led by Drs. Avrum Spira and Steven Dubinett, is developing non-invasive diagnostic tools, such as nasal swabs, blood tests, and radiological imaging, to confirm whether lung abnormalities





r. Avrum Spira

Dr. Steven Dubinett

found on chest imaging are benign lung disease or lung cancer.

To protect against recurrence of earlystage disease that has already been successfully treated with surgery, the research team is also developing new blood tests that will help identify patients at the earliest stages of recurrence, enabling timely interventions, such as immunotherapy.

The Dream Team has seen fantastic progress since the inception of the award in 2017. They have characterized the immune cells surrounding PMLs versus those which surround lung cancer tissue. They found that there are fewer T-cells (specialized cancer-killing immune cells)

around the lung cancer tissue, suggesting that lung cancer, even in its earliest stage, figures out ways to escape recognition by the immune system. This knowledge will be central to the development of strategies to harness the immune system to control lung cancer in its early stages. In addition, the Dream Team has developed a non-invasive blood test that can detect circulating DNA (ctDNA—genetic material released from lung cancer cells) in the blood of lung cancer patients and predict whether a patient is likely to relapse after surgery for early-stage lung cancer.

Stay tuned for more updates!

AACR-IASLC International Joint Conference continued from page 5

Translational science is also integral to driving progress in lung cancer subtypes that have matched targeted therapies. Dr. Christine Lovly's (LUNGevity 2014 Career Development Awardee and LUNGevity SAB member) presentation on precision structural biology, used to understand how specific mutations affect the structure of cancer-causing protein in order to match a patient to the right treatment, was an elegant example of the strides we have made both in terms of technology to understand lung cancer and in biology to use these technologies. The success of her team in employing new tools of molecular biology and protein biochemistry to understand novel EGFR alterations (EGFR-KDD, or kinase domain duplication) and treat patients emphasizes the value in thinking outside the box when approaching treating lung cancer.

Survivorship

Patient advocates Janet Freeman-Daily (ROS1ders), Jill Feldman (EGFR Resisters), and Dr. Colin Barton (ALK Positive) discussed the importance of collaboration between patient groups, advocacy groups, clinicians, researchers, and industry partners with the goal of driving research and innovation in the lung cancer space. Patient groups help accelerate research by educating patients about clinical trials, help develop cancer models such as cell lines and PDXs, and drive collection of patient-reported real-world data.

I left the conference still thinking about a new concept shared by Dr. William Pao (one of the researchers who discovered the first mutation in the EGFR gene): precision phenotyping in lung cancer. This means combining big data obtained through electronic health records (and other similar systems) with the biology of lung cancer to cover the lung cancer spectrum from surveillance to early detection to more effective therapeutics to survivorship. This concept encapsulates the impact of translational science.



Patients, advocates, and researchers came together at the AACR-IASLC International Joint Conference to collaborate, strategize, and learn from each other.

LUNG CANCER IN THE NEWS

The understanding of lung cancer and its treatment is moving at an unprecedented pace; LUNGevity is here to help you stay on top of the latest findings. Check out some exciting highlights from advances in lung cancer from the last year!

Largest percentage drop in cancer mortality

The American Cancer Society reported in January the greatest single-year drop in US cancer mortality since reporting began. The number of cancer deaths dropped by 2.2% between 2016 and 2017, with half of the drop attributable to the reduction in the percentage of people who smoke and improvements in lung cancer treatment. You can view the full report on the American Cancer Society's website.

NELSON trial confirms benefits of LDCT screening

In 2011, the US National Lung Screening Trial found that patients at high risk for lung cancer (based on age and smoking history) who were screened with a low-dose computed tomography (LDCT) scan had a 20% lower chance of dying of lung cancer than those who were screened with a chest x-ray. Based on those results, LDCT has been recommended in the US since then for high-risk populations. The long-awaited and recently released NELSON (Dutch-Belgian Randomized Lung Cancer Screening) trial, also conducted among high-risk patients, again revealed a positive impact. Compared to patients who were not screened, mortality from lung cancer dropped by about 33% among women and 24% among men. These results confirm the benefits of LDCT screening among certain populations. Those at high risk should speak with their healthcare team about an LDCT screening.

Additional treatment available for small cell lung cancer

Atezolizumab (Tecentrig®) was the first immunotherapy drug, in combination with the chemotherapy drugs carboplatin and etoposide, approved as a first-line treatment for patients with extensive-stage (metastatic) small cell lung cancer (SCLC). Now, another immunotherapy-chemotherapy combination has proved itself to improve overall survival as well. In the phase 3 CASPIAN clinical trial, durvalumab (Imfinzi®) was paired with etoposide-platinum chemotherapy and showed that median overall survival among previously untreated extensive-stage SCLC patients increased from 10.3 months, among those who were treated only with the chemotherapy drugs, to 13.0 months among those who were treated with the durvalumab/chemotherapy combination. This combination was given Priority Review by the US Food and Drug Administration, and was approved in March. With two immunotherapy/chemotherapy combination treatments proving to be effective, they are likely to be the new standard of care for the treatment of extensive-stage SCLC.

NSCLC treatment advances

Osimertinib provides better outcomes to EGFR-positive patients in clinical trial: Recent results from the phase III FLAURA trial indicate that lung cancer patients with locally advanced or metastatic EGFR-positive non-small cell lung cancer (NSCLC) have longer overall survival when initially treated with osimertinib (Tagrisso*) than with either of two other tyrosine kinase inhibitors, erlotinib (Tarceva*) and gefitinib (Iressa*).

Atezolizumab receives additional FDA approval: In December, the FDA gave approval to the immunotherapy drug atezolizumab (Tecentriq®) for the first-line treatment of adult patients with metastatic non-squamous NSCLC in combination with two chemotherapy drugs, nab-paclitaxel and carboplatin.

Priority review given to nivolumab-ipilimumab combination:

Based on data from part 1 of the phase 3 CheckMate-227 clinical trial, the FDA in January gave priority review status to the combination of two immunotherapy drugs, nivolumab (Opdivo*) and ipilimumab (Yervoy*), for the first-line (initial) treatment of lung cancer patients with metastatic or recurrent NSCLC without either an EGFR or an ALK mutation.

COVID-19 and lung cancer continued from page 1

phone or email. Our online communities are also a great way to connect with others and share information. Please **visit www.LUNGevity.com/support** to learn how you can participate in the great conversations happening among our community members or request services.

Finally, to ensure the health of our community, we decided to postpone or make virtual many of our events and programs this spring, including our keynote International Lung Cancer Survivorship Conference (ILCSC) which has been rescheduled for **August 21-23**, **2020**. For those who have registered for the ILCSC, we are conducting virtual meet-ups to help build our community and provide support; we are also posting expert webinars to keep you informed until we can meet together.

While COVID-19 has prevented us from gathering in person as a community this spring, it has not and will not stop us in our mission to improve outcomes for people diagnosed with lung cancer. You can access all of our information about the COVID-19 virus at www.LUNGevity.org/COVID-19. Follow us on Facebook, Twitter, and Instagram for real-time updates and new expert videos and articles.

Revising Lung Cancer Clinical Trial Eligibility Criteria: Why It Matters

Since its inception in 2016, the LUNGevity Scientific and Clinical Roundtable (SCRT) initiative has explored key topics and worked to develop actionable steps to make lung cancer clinical trials accessible to more patients and more efficient. The eight past meetings of the SCRT have provided opportunities to engage leaders from the FDA, the European Medicines Agency (EMA), other international regulatory agencies, industry leaders, clinicians, and patients.

One of the key topic areas of focus has been clinical trial eligibility criteria and how they may impede access to trial participation. Eligibility criteria typically consist of both inclusion criteria and exclusion criteria. Inclusion criteria include demographic, clinical, geographic, and other such characteristics. Exclusion criteria, among those who meet the inclusion criteria, include additional characteristics that could increase a trial participant's risk for severe side effects or a negative outcome or that could interfere with the conduct of the study; these render the person ineligible to participate in the trial.

As newer drugs are being developed with unique mechanisms of action, it is imperative that clinical trial design co-evolves with the biology of the disease. Low rates of adult patient participation are a persistent issue in cancer clinical trials and continue to be a barrier to efficient drug development. Routine use of overly restrictive exclusion criteria contributes to this problem by limiting participation in studies, thus creating significant clinical differences among the study cohort and the realworld cancer patient population. These outdated exclusions also unnecessarily restrict opportunities for many patients to access potentially promising new therapies during clinical development.

Multiple efforts are underway to broaden eligibility criteria, allowing more patients to enroll in studies and generating more robust data about the impact of novel therapies in the population at large. Focusing specifically on lung cancer as a case study, a working group consisting of

members of the LUNGevity's Scientific and Clinical Roundtables identified 14 restrictive and potentially outdated exclusion criteria that appear frequently in lung cancer clinical trials. The working group provided recommendations on when such criteria should be used and when it may be suitable to relax or eliminate these criteria. As part of the project, the group also evaluated data from multiple recent lung cancer studies to ascertain the extent to which these 14 criteria appeared in study protocols and played a role in excluding patients.

The recommendations by the working group have been summarized in a manuscript entitled "Expanding access to lung cancer clinical trials by reducing the use of restrictive exclusion criteria: Perspectives of a multi-stakeholder working group" that has been accepted for publication in the journal *Clinical Lung Cancer*. LUNGevity Foundation will continue to work with clinical trial sponsors to incorporate these recommendations into their trials.

Clinical trials, studies that test how new methods of screening, prevention, diagnosis, or treatment of a disease work in people, are a critical component of the drug development process. They also can be a source of access to life-saving treatments, such as new drugs or combinations of new drugs while they are still in the drug development process and not approved by the FDA.

FIRST OF ITS KIND

Pre-analytics Precision Medicine Meeting

LUNGevity has partnered with leaders in the pathology space to help create a standardized approach to tissue and blood acquisition, transportation, handling, and processing for all cancers. These steps are commonly referred to as "pre-analytics."

The delivery of precision medicine is not only dependent on conducting comprehensive biomarker testing, but also reliant on the molecular pathologist having access to high-quality tissue and blood to perform the molecular analysis.

In December, lead pathologist Dr. Carolyn Compton, Arizona State University, with support from LUNGevity, convened a meeting of stakeholders in pre-analytics in precision medicine. The two-day meeting was held in Washington, DC with leaders from government, academia,

medical societies, industry and advocacy across cancers. This "Do-Tank" is working toward adoption of consistent pre-analytics standards for biospecimens.

LUNGevity is proud to have worked on this landmark initiative to create a foundation to enable the promise of precision medicine for all cancer patients.

Have you talked to your doctor about comprehensive biomarker testing?
Learn more about testing at www.lungevity.org/biomarker-testing.



















1) Face of Hope awardee Dr. Avrum Spira receives his award 2) Gala Dinner Chair Rosemary Marquardt (second from left) and friends 3) LUNGevity board members (from left: Michael Parisi, Lynne Doughtie, and Michael Marquis) attend Gala 4) Gala Vice Chair Brent Barnhart (second from right) with friends 5) LUNGevity's Inhale for Life: Clinical Trial video launches at Gala 6) Lung cancer survivor and advocate Matt Riga shares his story 7) Gala attendees participate in the Saving Lives auction 8) Lung cancer survivors at the Gala 9) Corporate Leadership awardee Novartis Oncology

7TH ANNUAL

CELEBRATION OF HOPE GALA

The 7th annual Celebration of Hope Gala in New York City was held in November 2019 and was a great success. Leaders of business, philanthropy, and science gathered for an inspiring evening to raise funds for LUNGevity's research, education, and support programs.

The event was once again chaired by LUNGevity board member Lynne Doughtie, CEO of KPMG, and Dinner Chairs Rosemary and Jim Marquardt. Brent Barnhart, Vice President, UBS, was this year's Vice Chair.

Each year, LUNGevity honors individuals

and organizations whose commitment to improve outcomes for lung cancer patients is making a difference. Novartis Oncology received the LUNGevity Hope Award for Corporate Leadership for its tireless efforts in the science that improves life. LUNGevity also honored Avrum Spira, MD, MSC, member of the LUNGevity Scientific Advisory Board, Professor of Medicine, Pathology and Bioinformatics at Boston University School of Medicine and Global Head of the Lung Cancer Initiative at Johnson & Johnson, with the Face of Hope Award for his ongoing work on behalf of all people

affected by lung cancer and the meaningful change his efforts are making.

Attendees included 24 lung cancer survivors as well as doctors, researchers, national sponsors who supported the event, and other esteemed guests.

With the help of returning emcee Dave Price, weather anchor for NBC 4 New York, and lung cancer survivors Amanda Kouri and Matt Riga, LUNGevity raised the highest amount for lung cancer to date for this annual Gala, during the *Saving Lives* auction.

Join us at the 9th annual Celebration of Hope in Washington, DC, on September 30, 2020, and the 8th annual Celebration of Hope in New York City on November 5, 2020.



Raising Awareness of Clinical Trials

The third installment in LUNGevity's impactful awareness campaign *Inhale for Life*—which brings awareness, information, and hope to the lung cancer community and general public—focuses on the importance of participating in clinical trials.

Inhale for Life: Clinical Trials encourages patients to ask their doctors if a clinical trial could be right for them. The campaign, which uses videos that highlight the personal journey and experience of patients who have participated in clinical trials, was launched in November as part

of Lung Cancer Awareness Month and ran through March 2020 on social media.

The *Inhale for Life* series, which began in 2017, can be viewed on the LUNGevity website. Previous campaigns focused on general lung cancer awareness and the importance of biomarker testing.

Stay tuned for the next campaign in the *Inhale for Life* series, *Inhale for Life: Right Track*, which will encourage patients to seek out the right team, right tests, and right treatment.

LUNGevity Receives \$1,000,000 Bequest

LUNGevity was recently the recipient of a generous gift given through a donor's estate. We are honored that this donor trusted the Foundation to use his funds to make a difference in lung cancer and the community we serve. This bequest is now part of the donor's lasting legacy and will support LUNGevity's mission well into the future.

Bequests are one of the essential sources of funding for the Foundation. They help ensure our programmatic goals are met: funding impactful research into early detection and treatment of lung cancer; providing support, community, and education for patients and their loved ones; and continuing to drive change on behalf

of those affected by lung cancer. They also help us better plan for our future as an organization and invest additional resources into initiatives and programs that do the most good.

Are you interested in adding LUNGevity to your will or trust? LUNGevity has resources to help guide you through the process. No gift is too large or too small to make a tangible impact on lung cancer. If you have already designated LUNGevity in your estate plans, please let us know so that we can thank you and keep you updated on our activities.

Learn more about how you can create a lasting legacy and the benefits for you and your family at https://LUNGevity.plannedgiving.org/



Team LUNGevity Expands to Include Series of Rock 'n' Roll Races!

Team LUNGevity, LUNGevity's endurance sports program, now has entries to several Rock 'n' Roll races across the country. We are proud to offer entries to Rock 'n' Roll races in Nashville, TN, Atlantic City, NJ, Virginia Beach, VA, and Philadelphia, PA. This is in addition to the already impressive list of official races, which includes the Bank of America Chicago Marathon and TCS New York City Marathon.

Last year, Team LUNGevity offered entries in six official races, had runners participating in ten DIY (Do It Your Way) events, in which runners pick their own events, and over 100 runners total! This year, we expect the team to grow to 125 runners, who will have the choice to run one of 12 official races or a DIY event of their choice.

Join the team! Are you already competing in an endurance event, or are you looking to sign up for one? Join the athletes of Team LUNGevity, who complete endurance events across the US and around the world, to help improve outcomes for lung cancer patients.





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The International Lung Cancer Survivorship Conference has a new date: August 21-23, 2020

Join us for this celebration of 10 years of hope!

While we can't physically be together until August, you can join us for our virtual meet-ups! Online video meet-ups are a great way to connect with other survivors. Those who register for the conference are invited to sit in on virtual expert sessions for a taste of all the great sessions happening at ILCSC this year! Join once or multiple times to meet new people and see old friends.

Register for the conference and be on the lookout for weekly sign-up emails.

Learn more and register at www.LUNGevity.org/ilcsc



