

ATS DAILY BULLETIN



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Monday, May 20, 2019

Mindsets Direct Medical Decision-Making

If medicine is a science and based on facts and research, why do physicians disagree? Why is there controversy on recommended treatment plans for common diseases? If the experts can't agree, how can patients make the "right" decision?

The difficulty—and often uncertainty—surrounding medical decision-making was the topic of Sunday morning's ATS Lecture Keynote Series.

"Controversy in medicine is not new. What is new is the media coverage surrounding medical controversies," said Pamela I. Hartzband, MD, assistant professor at Harvard Medical School and attending physician in the Division of Endocrinology at Beth Israel Deaconess Medical Center, who shared the podium with Jerome E. Groopman, MD, professor of medicine at Harvard Medical School and chief of experimental medicine at Beth Israel Deaconess Medical Center in Boston.

The doctors wondered why medical experts come to different



Jerome Groopman, MD, and Pamela Hartzband, MD, defined the different mindsets that go into decision-making by patients as well as doctors.

conclusions about studies recommending or denouncing statins to reduce high cholesterol, how much Vitamin D an individual should take, the effect of salt on high blood pressure,

and if adults should take low-dose aspirin to stave off heart attacks or strokes. And what are patients to believe?

Traditionally, three different methods have been used in classic

medical decision analysis.

- **Linear scale.** Using a rating from 0-1 for decision-making. Zero is death and 1 is perfect health. You assign a number that represents see [DECISIONS](#) page 4

DLD Paves the Way for Future Science

Since 1969, the National Institutes of Health's Division of Lung Diseases (DLD) has facilitated the development of a robust and vibrant research

community, which has produced research findings that have changed practice—from the early findings about surfactant to the precision medicine trials of today, according to Gary Gibbons, MD, director of the National Heart, Lung, and Blood Institute (NHLBI), one of the NIH's largest institutions.

Dr. Gibbons will co-chair Monday's President's Symposium, which will commemorate the DLD's 50th anniversary. Speakers will highlight important scientific advances in

pulmonary health and disease and illustrate DLD's role in facilitating lung biology and disease research.

"The basic research of yesterday has created opportunities for groundbreaking clinical trials today," said Dr. Gibbons. "Throughout its 50-year history, the division has been a pioneer at NIH in creating opportunities at the leading edge of science."

For 50 years, the DLD has facilitated research advances by see [FUTURE SCIENCE](#) page 36



Gary Gibbons

President's Symposium: 50 Years of Progress in Pulmonary Science (B13)

9:15-11:15 a.m., Monday
Room D221/D225/D226 (Level 2), KBHCCD

DON'T MISS THESE EVENTS

Fellows Case Conference
9:15-11:15 a.m., Ballroom C Three-Four (Level 2), KBHCCD

Transforming Clinicians Into Effective Leaders: A Conversation With Dr. Jamie Stoller
10-11 a.m., Clinicians Center

Coffee & Connections
11 a.m.- 1:15 p.m., Exhibit Hall

Mini Symposium: Upper Airway Pathophysiology and Treatment in Sleep Disordered Breathing
2:15-4:15 p.m., Room C147/C148/C154 (Level 1), KBHCCD

Exhibit Hall Hours

Monday, May 20
10:30 a.m.-3:30 p.m.
Unopposed Hours: 1:15-2:15 p.m.

Tuesday, May 21
10:30 a.m.-3:30 p.m.
Unopposed Hours: 1:15-2:15 p.m.



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Growing Into Activism

Michael DeBaun, MD, MPH, the keynote at Saturday's ATS Diversity Forum, has a list of accolades. Professor of pediatrics and medicine, JC Peterson Endowed Chair, vice chair for clinical research in pediatrics, and founder and director of the Vanderbilt-Meharry Center of Excellence in Sickle Cell Disease at the Vanderbilt University Medical Center—it's a mouthful. At 59, he has the freedom to look back and advise the next generation of leaders about what diversity means in the medical community.

It's a balance, Dr. DeBaun said, between "individual activity and academic activism." He broke down his own career into phases, demonstrating for attending students and young professionals how he has grown into his own role as an academic activist.



An audience member poses a question.

"It's about choosing the right time and the right purpose," he said. It can be hard to focus as much on activism when you're still busy learning the ropes.

"When you work as an academic fellow, it's difficult to believe that, as a neophyte, you can walk in and effect change," Dr. DeBaun said.

Between 1996 and 2003, he estimates he was just learning the status quo. He observed the absence of programs for children with Sickle Cell Disease (SCD) as an assistant and associate professor at Washington University during those years. There was a lack of community awareness about the disease, particularly in the African American community.

Dr. DeBaun's academic activism began with making sure SCD patients and their families had a hospital-provided social worker, a resource that had been disproportionately lacking.

As time passed, he became increasingly agitated with the status quo. His self-described "mid-life crisis" hit in 2010.

"I was then unwilling to accept the status quo," said Dr. DeBaun. Care for patients with chronic diseases is limited to patients with access to that medical care. It's a luxury that many SCD patients can't afford. In 2010, he founded the Vanderbilt-Meharry Center of Excellence in Sickle Cell Disease to give patients in mid-Tennessee access to care.

He later expanded his SCD care and



Michael DeBaun, MD, MPH, had devoted his career to increasing awareness and treatment options for Sickle Cell Disease.

research to northern Nigeria, working to establish new maternity care for women with SCD in a clinic at the Korle-Bu Teaching Hospital in Ghana.

Dr. DeBaun attributes much of this career success and increased activism to self awareness.

"Know who you are, and be true to yourself," he told a student who asked how to become involved in activism. "That takes a lot."

He noted that activism can also be a gradual journey.

"You can always make a

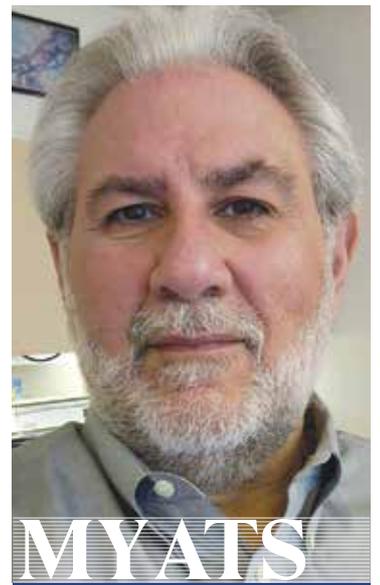
contribution, and it doesn't have to be in the way that I just described. It can be in many other ways," he said.

He said he believes that the next generation is going to take activism and diversity in the medical community to an entirely new level.

"When millennials go to medical school, they will continue to change the landscape. They'll be more sensitive," he said. "I'm hoping that [this community] will be more organic and less of an old boy's club." ●

“ When millennials go to medical school, they will continue to change the landscape. They'll be more sensitive.

– Michael DeBaun ”



MYATS

"The ATS has been a resource for education and interaction among colleagues to improve not only the aspects of patient care but also the unmet needs of patients that lead to better research."

Craig S. Conoscenti, MD, ATSF

Medical Expert, Interstitial Lung Disease; Program Lead for Chronic Fibrosing Interstitial Lung Disease; and Clinical Development and Medical Affairs
Boehringer Ingelheim Pharmaceuticals

KEYNOTE SERIES

Data Sharing and Breathlessness

The ATS Keynote Series continues today as speakers explore the mysteries of breathlessness in COPD and data sharing in the context of clinical trials.

This series highlights major advances, transformative findings, and important best practices in pulmonary, critical care, and sleep medicine from the perspective of a leader in the field. These state-of-the-art presentations take place at 8 a.m. each day, when no other programming is scheduled.

Data Sharing in the Context of Clinical Trials (K3)

Ballroom C One-Two (Level 2), KBHCCD

Jeffrey M. Drazen, MD, editor-in-chief of the *New England Journal of Medicine*, will describe the role of data gatherers and data scientists in



Jeffrey M. Drazen

clinical trials. He also will present the role of data statements and data repositories in maximizing the value obtained from the patients who put themselves at risk to participate in clinical trials.

Dr. Drazen is a senior physician at the Brigham and Women's Hospital in Boston, and professor of physiology at the Harvard School of Public Health. A specialist in pulmonology, Dr. Drazen maintains an active research program. He has published more than 300 articles on topics such as lung physiology and the mechanisms involved in asthma. He also has written editorials on data sharing in relation to data collection.

Unraveling the Mystery of Breathlessness in COPD (K4)

Ballroom C Three-Four (Level 2), KBHCCD

Denis E. O'Donnell, MD, professor of medicine at Queen's University



Denis E. O'Donnell

in Kingston, Ontario, Canada, will explain current constructs of the mechanisms of activity related dyspnea across the spectrum of COPD severity.

He also will review how new insights into these mechanisms can help develop a solid physiological rationale for management of this distressing symptom.

Dr. O'Donnell is a clinician-scientist and past chair of the Division of Respiratory and Critical

Care Medicine and director of the Respiratory Investigation Unit at Queen's University. He has been a senior author in more than 300 scientific peer-reviewed publications and has co-edited a book on dyspnea and a recent eBook on lung hyperinflation, mechanisms, and management. ●

Keynote Series Lineup

Tuesday: Developing the Evidence for Value-Based Care in Pulmonary Medicine (K5)

Enhancing Diversity and Inclusion in Academic Medicine (K6)

Wednesday: What Should Pulmonologists Know About Artificial Intelligence and Machine Learning? (K7)

ATS Daily Bulletin

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DECISIONS

Continued from page 1

the impact a side effect would have on your quality of life.

- **Time trade-off.** How many years of life would you be willing to give up, or trade-off, to avoid the side effect?
- **Standard gamble.** Imagine that there is a magic pill that can completely prevent a certain outcome, but in a certain percentage of cases, it causes instant death. Estimate what odds you'd be willing to take to completely avoid a certain outcome versus the chance that it might kill you right off the bat.

“Recent research in cognitive science has shown that these three methods are all severely flawed,” said Dr. Groopman. “The problem is that you cannot reliably forecast your life in the future. You cannot understand the impact that a certain outcome will have if you’ve never experienced it. Also, medical conditions are not static, they are dynamic. Illnesses change in an individual over time and also people adapt to their conditions.”

Using the philosophy of Sir William Osler, Drs. Groopman and Hartzband opted to “listen to the patient, because if you know how to listen, he’s telling you the answer.” They interviewed scores of patients and investigated how they made their medical decisions. Ultimately, they found common threads that allowed them to categorize different mindsets that lead patients to their medical decision-making. The mindsets are:

Minimalist or maximalist. A minimalist believes less medicine is often the best approach while a maximalist believes doing everything medically possible to achieve the best health is the best approach.

Naturalism orientation or technology orientation.

Naturalism defines someone who looks for natural solutions if they are available. Someone technology-oriented wants the latest and most advanced treatment available.

Believer or doubter. A believer is ready to confidently take medicine just as soon as the doctor prescribes it. A doubter will do more research, wondering if the treatment is worse than the disease.

They determined that patients, as well as doctors, have these mindsets.

“Doctors and experts have these mindsets, and it can impact the advice they give,” said Dr. Hartzband.

Ultimately, in making medical decisions, Drs. Groopman and Hartzband concluded you have to take into consideration your mindset and the patient’s mindset, as well as stories they hear related to their conditions. All of these support and direct their decision-making. ●

Learning and Sharing



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* Please refer to full prescriptive information at <http://svs.olympusamerica.com>

1. Criner GJ, Delage A, Voelker K. Late Breaking Abstract - Endobronchial Valves for Severe Emphysema – 12-month Results of the EMPROVE Trial. Eur Respir J. 2018;52(suppl 62). doi:10.1183/13993003.congress-2018.OA4928

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Students Walk in Patients' Footsteps

Student Scholars Program participants received a crash course in nonprofits in the lung disease community at Saturday's PAR Path.

The ATS Public Advisory Roundtable (PAR) consists of different organizations advocating for patients in the lung and airways disorders space. The PAR Path is a section of the Exhibit Hall that featured 14 different PAR group booths for student scholars to visit in six-minute increments on Saturday afternoon.

Donna Appel, executive director and founder of the Hermansky-Pudlak Syndrome Network Inc.,



came up with the idea last year to give students some facetime with nonprofit organizations—like a speed-dating event, she said.

"Certainly, in this day and age, patient centricity, patient engagement, and putting the patients in the drug development pipeline early is all part of their career and the skillset that they need to learn," said Ms. Appel.

PAR Path is only for participants in the Student Scholars Program now, but she said she hopes it can expand to all groups within the early career professional programs.

"I think it should be to the PhD groups, too, because they don't get a lot of patient contact and know who we are," Ms. Appel said. "We're researchers' cheerleaders. It'd be really great to have them down the row so we could say how important they are to us."

In the meantime, though, it's working smoothly for the Student Scholars.

The students learn which disease community each booth represents, the symptoms and characteristics of the disease as well as how to

diagnose, the focus of the nonprofit organization, and their top initiatives. Essentially, it's a crash course in nonprofits in the lung disease community.

"Each booth gets a monologue," Ms. Appel said. "They go through a monologue, because we don't want to make it threatening for students. We don't want them to have to come up with questions to ask us or make this awkward. I have every disease group describing the focus of their organization, and each organization is going through [the same] list with them."

"I think it's really awesome," said Michala Patterson, BS, of Chapel Hill, North Carolina. "As an undergraduate student, I haven't heard of most of this stuff. So now, going into the future of medical school and becoming a doctor, these experiences of talking with real patients are going to stick with me and really become something that is the foundation for my medical career. And I feel like that's what medicine should be in the first place—founded on patients." ●



Companies in the PAR Path include:

- Alpha-1 Foundation
- Allergy & Asthma Network
- ARDS Foundation
- Children's Interstitial Lung Disease Foundation, Inc.
- Foundation for Sarcoidosis Research
- Hermansky-Pudlak Syndrome
- The LAM Foundation
- Lung Transplant Foundation
- LUNgevity Foundation
- NTM Info and Research
- Pulmonary Fibrosis Foundation
- Primary Ciliary Dyskinesia Foundation (PCD)
- Scleroderma Foundation
- Tuberos Sclerosis Alliance



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Strategies for Teaching Modern Learners

Effective ways of teaching and disseminating knowledge have changed rapidly. The current climate of fast, ready-to-go access to information has altered how learners interact with content, and adult learning theories have changed the way content is delivered.

Frequently changing work hour restrictions, shifts in undergraduate medical curricula, and increased demands on attending physicians due to documentation and electronic health record challenges have all contributed to the need for new educational techniques that can keep up with the modern learner.

These and other educational issues will be explored during



Molly Hayes

this morning's Hot Topics symposium, which will provide participants with up-to-date, evidence-based best practices on how to effectively teach in 2019.

"I think many attendees will have heard about these topics, but what makes our session unique is that we will be offering tangible strategies that participants can take home and implement at their institutions," said session co-chair Margaret "Molly" Hayes, MD, assistant professor of medicine at Harvard Medical School in Boston.

One Hot Topic will focus on social determinants of health (SDOH), the economic and social conditions that influence the health of people and communities. SDOH, according to the Centers for Disease Control and Prevention, are shaped by the amount of money, power, and resources that people have, and addressing them is a primary approach to achieving health equality.

"Social determinants of health is a hot topic these days with many variations on the definition,"

Dr. Hayes said. The presentation will investigate best practices for teaching SDOH, including different frameworks for teaching the concept along with currently available literature.

Another Hot Topic is free open access medical (FOAM) education. Does it help or hurt? Presenters will explore the best use of social media in education and the pros and cons of FOAM education.

"Many people use social media, specifically Twitter, as an educational platform—tweeting out lessons in the form of 'tweetorials,' questions with options to respond, and relevant papers with comments," said Dr. Hayes. "I myself have participated in interactive Twitter

chats to mentor people across the country."

Additional presentations will explore how to use active learning strategies to engage the learner, tips on using asynchronous learning to maximize teaching time, and assessment of competency.

Improving medical education teaching will theoretically improve the way its learners learn, and thus, patients will receive better care, Dr. Hayes said.

"Our goal as educators is to teach in the best way possible, using evidence-based methods where available so that our current trainees, who face many challenges in this modern era, will learn how to take excellent care of patients." ●

“ Many people use social media, specifically Twitter, as an educational platform—tweeting out lessons in the form of 'tweetorials,' questions with options to respond, and relevant papers with comments.

– Molly Hayes ”



MYATS

"ATS has a sense of 'home.' It's big, it's busy, and it's cutting edge, but the connectivity that is fostered with colleagues from around the world is at the root of what makes ATS special."

Andrew J. Halayko, PhD, ATSF
Professor and Canada Research Chair, Department of Physiology and Pathophysiology
University of Manitoba and Children's Hospital Research Institute of Manitoba.

Hot Topics in Medical Education: What's New in '19 (B12)

9:15-11:15 a.m., Monday

Dallas Ballroom G (Level 3), Omni Dallas Downtown

The next grant cycle begins on July 18, 2019!



YOUNG INVESTIGATOR PROGRAM
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Established in 2005, ENTELLIGENCE is a program for basic science, translational, and clinical research in the field of cardiopulmonary medicine. The program provides opportunities for individual young investigators to promote quality medical care and enhance patients' lives by supporting research in pulmonary hypertension related to expanding our knowledge of the pathways involved in pulmonary vascular pathobiology.

Award winners may receive a research grant of up to \$100,000 to fund a 1-year mentored project

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Review cycles completed: **13**
Awards distributed: **63**
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2. Submit a Letter of Intent (LOI) proposal with an introduction, background, hypothesis, objectives, and specific aims
3. If the LOI is selected, submit a full grant

The ENTELLIGENCE Young Investigator Program is supported through an educational grant from Actelion Pharmaceuticals US, Inc.

Guru Bars: Learning in 30 Minutes or Less

Guru Bars are short, lightning-learning sessions that allow you to collaborate with leaders on an array of subjects. Each session features a 10-minute outline of a problem statement, mitigating factors, and the host's perspective/solution. The sessions end with a challenge or question posed to participants, who discuss it for the remaining 10 minutes.

Each Guru Bar can accommodate 25 seated participants, with standing room around the perimeter, which allows for a dynamic and interactive discussion. Guru Bars are organized by categories of interest:

Guru Bars 1 and 2: Education/Awareness/Prevention or Diagnosis
Guru Bars 3 and 4: Treatment of Adherence/Compliance

Guru Bars will run every 30 minutes from 11 a.m. to 2 p.m. Monday and Tuesday in the Exhibit Hall (Level 2, Halls C-F).

Please see the Tuesday issue of the ATS 2019 *Daily Bulletin* for a list of that day's Guru Bars.

Education/Awareness/Prevention or Diagnosis

GURU BAR 1 11:30-11:50 a.m.

Novel Approaches to Lung Nodule Management: Percepta Bronchial Genomic Classifier

A clinically proven complement to lung cancer diagnostic bronchoscopies, the Percepta classifier down-classifies patients to low risk to avoid invasive procedures. A special clinician speaker will discuss the Percepta test and review patient cases.

Company: Veracyte, Inc.

12:30-12:50 p.m. Innovative Trial Design: How to Bring the Real World of IPF Management Into Phase 3 Programs

Galapagos is committed to being a valued scientific partner in the race to combat idiopathic pulmonary fibrosis (IPF). The current poor clinical prognosis for patients and a median survival at diagnosis of two to five years underscores the need for novel treatments and approaches to address the high unmet need in IPF.

Speaker: Paul Ford, MD, PhD, VP and TA, head of respiratory medicine, Galapagos
Company: Galapagos NV

1:30-1:50 p.m. Envisia Genomic Classifier—Improving Confidence in ILD Diagnosis

Learn how the Envisia classifier identifies a genomic UIP pattern utilizing transbronchial biopsy tissue for a more confident ILD diagnosis. Hear from a clinician on how the Envisia test is being used in practice.

Company: Veracyte, Inc.

GURU BAR 2 12-12:20 p.m. A Closer Lens on the Relationship Between COPD Exacerbations and Outcomes

Exacerbations are not only a common cause of hospital admissions in COPD patients, but they are also associated with significant impact in morbidity, mortality, and overall changes in quality of life. Explore the evidence regarding exacerbations and their life-changing impact on patients' lives.

Speaker: Antonio Anzueto, MD, University of Texas Health Science Center at San Antonio
Company: AstraZeneca

Treatment or Adherence/Compliance

GURU BAR 3 12:30-12:50 p.m.

Implementing Humidified High Flow on the General Care Floor

Confirm mechanisms of action and physiological effects. Outline role of humidified high flow on the general care floor in patients who have recently suffered an AECOPD. Practical application of humidified high flow on general care floor.

Speaker: James Gibbons, product manager

Company: Fisher & Paykel Healthcare

1:30-1:50 p.m. Diagnosis of Bronchiectasis and Subsequent Treatment Options

Alan Barker, MD, professor of medicine, pulmonary and critical care, Oregon Health & Science University, will present on the diagnosis and treatment

of bronchiectasis. Dr. Barker will briefly cover the pathogenesis of bronchiectasis and the chest imaging characteristics. The importance of confirming diagnosis of bronchiectasis using the gold standard of HRCT will be emphasized and best practices of working with your radiologist will be discussed. *Speaker:* Alan Barker, MD, professor of medicine, pulmonary and critical care, Oregon Health & Science University
Company: International Biophysics

GURU BAR 4 1-1:20 p.m. Robotic-Assisted Bronchoscopy With the Monarch™ Platform: Technical, Pre-Clinical, and Clinical Consideration

Auris will host a presentation by a physician currently using the Monarch Platform in U.S. cases. Visit Booth 613 to learn more about the Monarch Platform.

Speaker: Alexander Chen, MD, interventional pulmonologist, Washington University School of Medicine in St. Louis

Company: Auris Health ●

ADVANCING THE TREATMENT OF EOSINOPHILIC DISEASE

Join us for an engaging program exploring the role of eosinophils in disease management. We will examine key efficacy and safety data for a treatment that reduces eosinophils, including long-term data in patients with severe asthma. We will also discuss clinical approaches for identifying appropriate patient types that may benefit from a targeted treatment to reduce eosinophils. In addition, hear from a patient about their journey with eosinophilic disease and treatment.

Mario Castro, M.D., M.P.H.

Alan A. and Edith L. Wolff Professor of Pulmonary and Critical Care Medicine
 Professor of Medicine, Pediatrics, and Radiology
 Washington University School of Medicine

11:30 AM to 12:15 PM
 Monday, May 20, 2019

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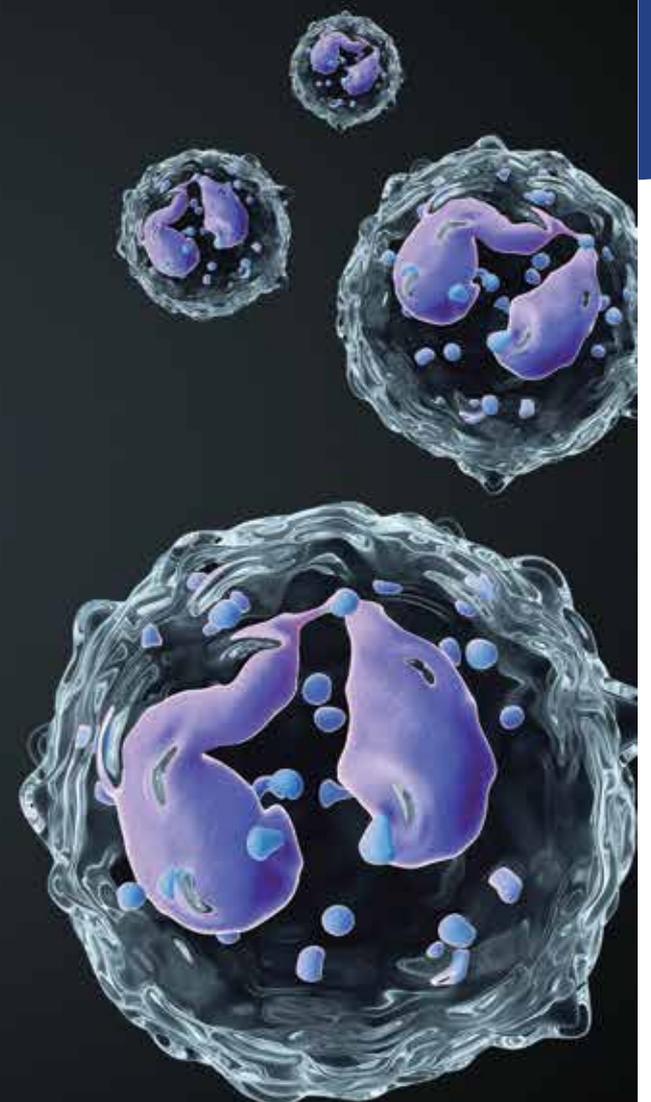
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A Treatment Option for Adult Patients With Refractory MAC Lung Disease

YOU'RE INVITED

- **Monday, May 20** from **11:30 AM-12:15 PM**
- **Theater 2, Exhibit Hall** at the Kay Bailey Hutchison Convention Center
- Speaker:

David E Griffith, MD

Professor of Medicine

WA and EB Moncrief Distinguished Professor,
Pulmonary Infectious Disease Section Chief

University of Texas Health Science Center at Tyler

SEARCH ONLINE FOR

MAC medication



An Industry Theater Presentation at the ATS 2019 International Conference. This presentation is sponsored by Insmid. Due to regulatory restrictions, this presentation is only available to attendees from the United States.

NP-US-01041A

Bringing Pulmonary Rehab to Patients With Non-COPD Disease

The newest medical research is putting a spotlight on the care and delivery of pulmonary rehabilitation in patients with non-COPD chronic respiratory disease. Although the evidence to support pulmonary rehabilitation is well established in the management of COPD, there is growing clinical interest in and an emerging evidence base for this treatment strategy in patients with non-



Claire Nolan

COPD chronic respiratory diseases. The evidence to support this intervention in some of the most common non-COPD chronic respiratory diseases, as well as strategies to tailor the education component of pulmonary rehabilitation for these conditions, will take center stage during today's session. Session Co-Chair Claire Nolan, BSc, MSc, PhD, senior research physiotherapist and pulmonary rehabilitation physiotherapy lead at the Royal Brompton and

Harefield NHS Foundation Trust in London, and Roger Goldstein, MD, a respiratory medicine specialist at West Park Healthcare Center in Toronto, will lead a panel of experts to explore the role pulmonary rehabilitation plays in the management of interstitial lung disease, asthma, pulmonary arterial hypertension, and lung transplantation.

"Pulmonary rehabilitation, a comprehensive intervention, is designed to improve the physical and psychological condition of people with chronic respiratory disease

and to promote the long-term adherence to health-enhancing behaviors," said Dr. Nolan. "It's important that we appropriately manage patients with non-COPD respiratory diseases in pulmonary rehabilitation and understand the educational needs of these populations."

When appropriately referring patients with these diseases to pulmonary rehabilitation, Dr. Nolan said the referring physician must be aware of what pulmonary rehabilitation involves, treatment inclusion and exclusion criteria, and optimal, ongoing medical management.

Underscoring the importance of serving the educational needs of people with non-COPD chronic respiratory disease, Dr. Nolan said they are similar to those patients with COPD. This includes teaching them how to manage breathlessness, nutrition, anxiety, and exercise. However, she said there are some differences that involve adapting care to the different non-COPD diseases, such as medication, oxygen use, and end-of-life care.

Moving forward, experts recommend increasing accessibility to pulmonary rehabilitation by considering the use of telehealth, implementing new technologies, securing funding to maintain existing pulmonary rehabilitation programs and create new ones, and providing solutions to the barriers of participation. Collaborative self-management strategies and methods for translating gains in exercise capacity into increased physical activity are equally important.

"The most important thing for physicians to remember is that pulmonary rehabilitation, an exercise and education program, is an integral component of the management of all patients with chronic respiratory diseases," Dr. Nolan said. ●

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See BTG at Booth #3622

Join us for an Industry Theater presentation at the ATS 2019 International Conference on:

Intervening in Pulmonary Embolism with EKOS Therapy
Tuesday, May 21, 12:30pm
Location – Mini Theater, Hall C

Presented by:
Gregory Piazza, MD, MS
 Assistant Professor of Medicine, Harvard Medical School
 Brigham and Women's Hospital, Boston, MA

This presentation is sponsored by BTG, and is open to all ATS 2019 International Conference attendees.

Pulmonary Rehabilitation in Non-COPD Chronic Respiratory Conditions (B86)

2:15-4:15 p.m., Monday

Trinity Ballroom 4/8 (Level 3), Omni Dallas Downtown

1. Tapson, Victor, et al., "A Randomized Trial of the Optimum Duration of Acoustic Pulse Thrombolysis Procedure in Acute Intermediate-Risk Pulmonary Embolism: The OPTALYSE PE Trial." JACC: Cardiovascular Interventions Jul 2018, 11 (14) 1401-1410.
 2. Sterling, K. "Long-term Results of the OPTALYSE PE trial" as presented at the International Symposium on Endovascular Therapy (ISET) meeting, Hollywood, FL, Feb 2018.

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INTERACTIVE CASE-BASED DISCUSSION



SEAN M. STUDER, MD

Chief of Medicine
NYU - Woodhull Medical Center
Brooklyn, NY

A CASE-BASED APPROACH TO PATIENT MANAGEMENT

An expert-led, case-based discussion of a patient on Esbriet® (pirfenidone), including diagnosis, treatment, and management throughout their journey.

MONDAY, May 20, 2019

1:30-2:00 p.m.



TADASHI ALLEN, MD

Assistant Professor Radiology
University of Minnesota
Minnesota, MN

UTILIZING RADIOLOGIC FINDINGS FOR DIFFERENTIAL DIAGNOSES

A radiologist-led discussion on identifying unique radiologic patterns and proper CT technique for various differential diagnoses.

MONDAY, May 20, 2019

11:30 a.m.-12:00 p.m.

A non-CME educational program sponsored by Genentech. Due to regulatory restrictions, this program is only available to attendees from the United States. Minnesota, New Jersey, Vermont, and Federal Entities (e.g., the Department of Defense and the Department of Veterans Affairs) have restrictions on receiving in-kind benefits (e.g., meals, valet parking) at company-sponsored events. You are accountable for understanding such restrictions and complying with them. If you are licensed in or affiliated with any of these states or federal agencies, Genentech policies may restrict you from consuming any portion of the Genentech-sponsored meal at this program or from receiving any other in-kind benefit from Genentech (e.g., valet parking) in connection with the program.



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Industry Theaters: Learning at Lunch

The learning doesn't stop at lunch. Grab a complimentary lunch and continue learning during Industry Theaters, Mini Theaters, and new Medium Theaters on Monday and Tuesday in the Exhibit Hall. You'll hear from supporting companies about the latest clinical updates related to pulmonary, critical care, or sleep medicine. Boxed lunches are provided by the ATS (while supplies last).

The theater locations are:
Industry Theater 1: Booth 116
Industry Theater 2: Booth 3249
Medium Theater: Booth 4549
Mini Theater: Booth 101

THEATER 1

11:30 a.m.-12:15 p.m.

Advancing the Treatment of Eosinophilic Disease

Join us for an engaging program exploring the role of eosinophils in disease management. We will examine key efficacy and safety data for a treatment that reduces eosinophils, including long-term data in patients with severe asthma. We will also discuss clinical approaches for identifying appropriate patient types that may benefit from a targeted treatment to reduce eosinophils. In addition, hear from a patient about a journey with eosinophilic disease and treatment.

Speaker: **Mario Castro, MD, MPH**, professor of medicine, Washington University School of Medicine

Company: GSK

1:15-2 p.m.

Mepolizumab: Choosing the Right Patient for Lasting Efficacy

Several biologics targeting the IL-5 pathway are now available to treat severe eosinophilic asthma. This Industry Theater will help HCPs navigate these options to make informed clinical decisions. The first presentation will discuss "Blood Eosinophils: A Simple Biomarker to Identify a Responder Patient," and review the patient profile most likely to benefit from treatment with mepolizumab. In the second presentation, titled "Mepolizumab: The Evidence of Lasting Efficacy to Support Clinician's Choice," we will focus on the latest long-term data available for mepolizumab, which has up to 4.5 years of consistent efficacy and safety data in severe asthma patients.

Speakers: **Emilio Pizzichini, MD, PhD**, professor, GSK and Universidade Federal de Santa Catarina; **Neil Barnes, FRCP**, professor, GSK; **Ian D. Pavord, FMedSci**, professor, University of Oxford

Company: GSK

THEATER 2

11:30 a.m.-12:15 p.m.

A Treatment Option for Adult Patients With Refractory MAC Lung Disease

Although patients with Mycobacterium Avium Complex (MAC) lung disease often achieve culture conversion on guideline-recommended therapy, many patients are refractory to treatment. Appropriate management of refractory MAC lung disease can be challenging for both physicians and patients, given the limited treatment options for refractory MAC patients.

This is an interactive program for U.S. health care professionals that will provide insight into the treatment of adult patients with refractory MAC lung disease.

Speaker: **David E. Griffith, MD**, professor of medicine, pulmonary infectious disease section chief, University of Texas Health Science Center

Company: Inmed

1:15-2 p.m.

Exploring Trends in COPD Treatment With Dual Bronchodilator and Triple Therapy Approaches

Join COPD experts as they provide an in-depth examination of some of today's important topics surrounding the management and treatment of patients with COPD using dual bronchodilator and triple therapy options. The panel will address commonly asked questions, review evolving approaches, and discuss clinical data.

Company: GSK

MEDIUM THEATER

12:20-1:05 p.m.

More Than an Airway Problem? Understanding Excessive Daytime Sleepiness in Obstructive Sleep Apnea (OSA)

Emerging science suggests that chronic intermittent hypoxia and sleep fragmentation caused by OSA may produce alterations to wake-promoting regions of the brain. One consequence of these changes may be excessive daytime sleepiness. This presentation will discuss the science related to potential brain changes and the diagnosis of excessive daytime sleepiness in OSA.

Speakers: **Richard K. Bogan, MD, FCCP, FAASM**, medical director, SleepMed of South Carolina; **Chitra Lal, MD, ATSF, D-ABSM, FCCP, FAASM, FACP**, associate professor of medicine, Medical University of South Carolina

Company: Jazz Pharmaceuticals

MINI THEATER

11:30 a.m.-12 p.m.

EVOLVE EBUS

As the oncologists demands EVOLVE by requesting additional tissue samples for full molecular testing, sarcoid, and lymphoma, we will discuss BSC's CoreDx™ Pulmonary Mini-Forceps (pending 510(k) clearance, not available for sale in the United States) as an internodal mini forceps biopsy. The CoreDx device may provide you with different experiences than today's EBUS-TBNA procedure which may potentially satisfy the demands of your oncologist and pathologist.

Speakers: **Momen Wahidi, MD**, interventional pulmonologist, Duke University; **Amit (Bobby) Mahajan, MD**, interventional pulmonologist, Inova Fairfax; **Chakravarthy Reddy, MD**, interventional pulmonologist, University of Utah

Company: Boston Scientific

12:30-1 p.m.

Comparison of Various Forms of Positive Airway Pressure Therapies for Sleep-Disordered Breathing in Heart Failure

Treatment of sleep disorders with servo ventilation has been questioned following past studies. Learn about recent clinical evidence that demonstrates the result of those studies may have been due to a device-effect and not a class-effect.

Speaker: **Salma Patel, MD, MPH**, assistant professor of medicine, UA Health Sciences

Company: Philips

1:30-2 p.m.

Breakthroughs in Diagnosing Respiratory Infections: Identifying Previously Missed Pathogens Using Explify® Respiratory, a Novel Next-Generation Sequencing (NGS) Based Test

Due to limitations in testing methods, pathogens are never identified in up to 60 percent of pneumonia cases. Explify® Respiratory is a metagenomics-based test that utilizes DNA/RNA sequencing and data analytics to identify pathogens conventional tests miss. Explify Respiratory can quickly and accurately identify more than 50,000 bacteria, fungi, viruses, and parasites—including more than 3,000 pathogens—to provide clinicians with more actionable information. This program will cover current limitations in diagnosing respiratory infections and the consequences, and how testing patients with Explify Respiratory can address these issues. Case studies will be presented demonstrating how Explify Respiratory has improved outcomes in clinical settings.

Speaker: **Robert Schlager, MD, PhD**, chief medical officer, IDbyDNA

Company: IDbyDNA •



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see **DONORS** page 17



orenitram[®]
treprostinil
EXTENDED-RELEASE TABLETS

In adult patients with pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity

IMPACT EARLIER

FC=functional class; WHO=World Health Organization.

INDICATION

Orenitram is a prostacyclin vasodilator indicated for treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity.

The study that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%). When used as the sole vasodilator, the effect of Orenitram on exercise is about 10% of the deficit, and the effect, if any, on a background of another vasodilator is probably less than this.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Orenitram is contraindicated in patients with severe hepatic impairment (Child Pugh Class C)

WARNINGS AND PRECAUTIONS

- Abrupt discontinuation or sudden large reductions in dosage of Orenitram may result in worsening of PAH symptoms
- Orenitram inhibits platelet aggregation and increases the risk of bleeding
- The Orenitram tablet shell does not dissolve. In patients with diverticulosis, Orenitram tablets can lodge in a diverticulum

DRUG INTERACTIONS / SPECIFIC POPULATIONS

- Concomitant administration of Orenitram with diuretics, antihypertensive agents, or other vasodilators increases the risk of symptomatic hypotension
- Orenitram inhibits platelet aggregation; there is an increased risk of bleeding, particularly among patients receiving anticoagulants

with Orenitram for your FC II/III patients

Visit Booth #3511 to learn more
or www.ImpactEarlier.com for additional information

- Co-administration of Orenitram and the CYP2C8 enzyme inhibitor gemfibrozil increases exposure to treprostinil; therefore, Orenitram dosage reduction may be necessary in these patients
- Pregnancy Category C. Animal reproductive studies with Orenitram have shown an adverse effect on the fetus. There are no adequate and well-controlled studies in humans
- It is not known whether treprostinil is excreted in human milk or absorbed systemically after ingestion. Because many drugs are excreted in human milk, choose Orenitram or breastfeeding
- Safety and effectiveness in patients under 18 years of age have not been established
- There is a marked increase in the systemic exposure to treprostinil in hepatically impaired patients

ADVERSE REACTIONS

- In the 12-week placebo-controlled monotherapy study, adverse reactions that occurred at rates at least 5% higher on Orenitram than on placebo included headache, diarrhea, nausea, flushing, pain in jaw, pain in extremity, hypokalemia, and abdominal discomfort

OREISlhcpJAN17

Reference: 1. Orenitram [package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2017.

Please see Brief Summary of Prescribing Information on the following page.

For Full Prescribing Information, visit www.orenitram.com, or call 1-877-UNITHER (1-877-864-8437).



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orenitram[®] treprostiniil

EXTENDED-RELEASE TABLETS

BRIEF SUMMARY

The following is a brief summary of the full prescribing information for Orenitram[®] (treprostiniil) Extended-Release Tablets. Please review the full prescribing information before prescribing Orenitram.

INDICATIONS AND USAGE

Orenitram is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. The study that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%). When used as the sole vasodilator, the effect of Orenitram on exercise is about 10% of the deficit, and the effect, if any, on a background of another vasodilator is probably less than this.

CONTRAINDICATIONS

Severe hepatic impairment (Child Pugh Class C).

WARNINGS AND PRECAUTIONS

Worsening PAH Symptoms upon Abrupt

Withdrawal—Abrupt discontinuation or sudden large reductions in dosage of Orenitram may result in worsening of PAH symptoms.

Risk of Bleeding—Orenitram inhibits platelet aggregation and increases the risk of bleeding.

Use in Patients with Blind-end Pouches—The tablet shell does not dissolve. In patients with diverticulosis, Orenitram tablets can lodge in a diverticulum.

ADVERSE REACTIONS

Clinical Trials Experience—Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. In a 12-week placebo-controlled monotherapy study (Study 1; WHO Group 1; functional class II-III), the most commonly reported adverse reactions that occurred in patients receiving Orenitram included: headache, diarrhea, nausea and flushing. Table 1 lists the adverse reactions that occurred at a rate on Orenitram at least 5% higher than on placebo. Orenitram patients in Table 1 for Study 1 (N = 151) had access to 0.25 mg tablets at randomization. Approximately 91% of such patients experienced an adverse reaction, but only 4% discontinued therapy for an adverse reaction (compared to 3% receiving placebo). The overall discontinuation rate for any reason was 17% for active and 14% for placebo.

Orenitram was studied in a long-term, open-label extension study in which 824 patients were dosed for a mean duration of approximately 2 years. About 70% of patients continued treatment with Orenitram for at least a year. The mean dose was 4.2 mg BID at one year. The adverse reactions were similar to those observed in the placebo-controlled trials.

The safety of Orenitram was also evaluated in an open-label study transitioning patients from Remodulin. The safety profile during this study was similar to that observed in the three pivotal studies.

Table 1. Adverse Reactions with Rates at Least 5% Higher on Orenitram Monotherapy than on Placebo

Reaction	Treatment (%)	
	Orenitram (N=151)	Placebo (N=77)
Headache	63%	19%
Diarrhea	30%	16%
Nausea	30%	18%
Flushing	15%	6%
Pain in jaw	11%	4%
Pain in extremity	14%	8%
Hypokalemia	9%	3%
Abdominal discomfort	6%	0%

Post-Marketing Experience—The following adverse reactions have been identified during post approval use of Orenitram: dizziness, dyspepsia, vomiting, myalgia, and arthralgia. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

DRUG INTERACTIONS

Antihypertensive Agents or Other

Vasodilators—Concomitant administration of Orenitram with diuretics, antihypertensive agents or other vasodilators increases the risk of symptomatic hypotension.

Anticoagulants—Treprostiniil inhibits platelet aggregation; there is increased risk of bleeding, particularly among patients receiving anticoagulants.

Effect of CYP2C8 Inhibitors—Co-administration of Orenitram and the CYP2C8 enzyme inhibitor gemfibrozil in healthy adult volunteers increases exposure to treprostiniil. Reduce the starting dose of Orenitram to 0.125 mg BID and use 0.125 mg BID increments every 3 to 4 days.

Effect of Other Drugs on Orenitram—Based on human pharmacokinetic studies, no dose adjustment of Orenitram is recommended when co-administered with either fluconazole, rifampin, sildenafil, bosentan or esomeprazole.

Warfarin—A drug interaction study was carried out with Remodulin co-administered with warfarin (25 mg/day) in healthy volunteers. There was no clinically significant effect of either medication on the pharmacokinetics of treprostiniil. Additionally, treprostiniil did not affect the pharmacokinetics or pharmacodynamics of warfarin. The pharmacokinetics of R- and S-warfarin and the international normalized ratio (INR) in healthy subjects given a single 25 mg dose of warfarin were unaffected by continuous subcutaneous infusion of treprostiniil at an infusion rate of 10 ng/kg/min.

USE IN SPECIFIC POPULATIONS

Pregnancy—*Pregnancy Category C*. Animal reproductive studies with treprostiniil diolamine have shown an adverse effect on the fetus. There are no adequate and well-controlled studies in humans.

Labor and Delivery—The effect of Orenitram on labor and delivery in humans is unknown. No treprostiniil treatment-related effects on labor and delivery were seen in animal studies.

Nursing Mothers—It is not known whether treprostiniil is excreted in human milk or absorbed systemically after ingestion. Because many drugs are excreted in human milk, choose Orenitram or breastfeeding.

Pediatric Use—Safety and effectiveness in pediatric patients have not been established.

Geriatric Use—Clinical studies of Orenitram did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic or cardiac function, and of concomitant disease or other drug therapy.

Patients with Hepatic Impairment—Plasma clearance of treprostiniil is reduced in patients with hepatic insufficiency. Patients with hepatic insufficiency may therefore be at increased risk of dose-dependent adverse reactions because of an increase in systemic exposure. Titrate slowly in patients with hepatic insufficiency, because such patients will likely be exposed to greater systemic concentrations relative to patients with normal hepatic function. In patients with mild hepatic impairment (Child Pugh Class A) start at 0.125 mg BID with 0.125 mg BID dose increments every 3 to 4 days. Avoid use of Orenitram in patients with moderate hepatic impairment (Child Pugh Class B). Orenitram is contraindicated in patients with severe hepatic impairment (Child Pugh Class C).

Patients with Renal Impairment—No dose adjustments are required in patients with renal impairment. Orenitram is not removed by dialysis.

OVERDOSAGE

Signs and symptoms of overdose with Orenitram during clinical trials reflect its dose-limiting pharmacologic effects and include severe headache, nausea, vomiting, diarrhea, and hypotension. Treat supportively.

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Continued from page 14

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ADVANCING THE TREATMENT OF EOSINOPHILIC DISEASE

Join us for an engaging program exploring the role of eosinophils in disease management. We will examine key efficacy and safety data for a treatment that reduces eosinophils, including long-term data in patients with severe asthma. We will also discuss clinical approaches for identifying appropriate patient types that may benefit from a targeted treatment to reduce eosinophils. In addition, hear from a patient about their journey with eosinophilic disease and treatment.

Mario Castro, M.D., M.P.H.

Alan A. and Edith L. Wolff Professor of Pulmonary and Critical Care Medicine
Professor of Medicine, Pediatrics, and Radiology
Washington University School of Medicine

11:30 AM to 12:15 PM
Monday, May 20, 2019

Industry Theater #1
The Kay Bailey Hutchison Convention Center
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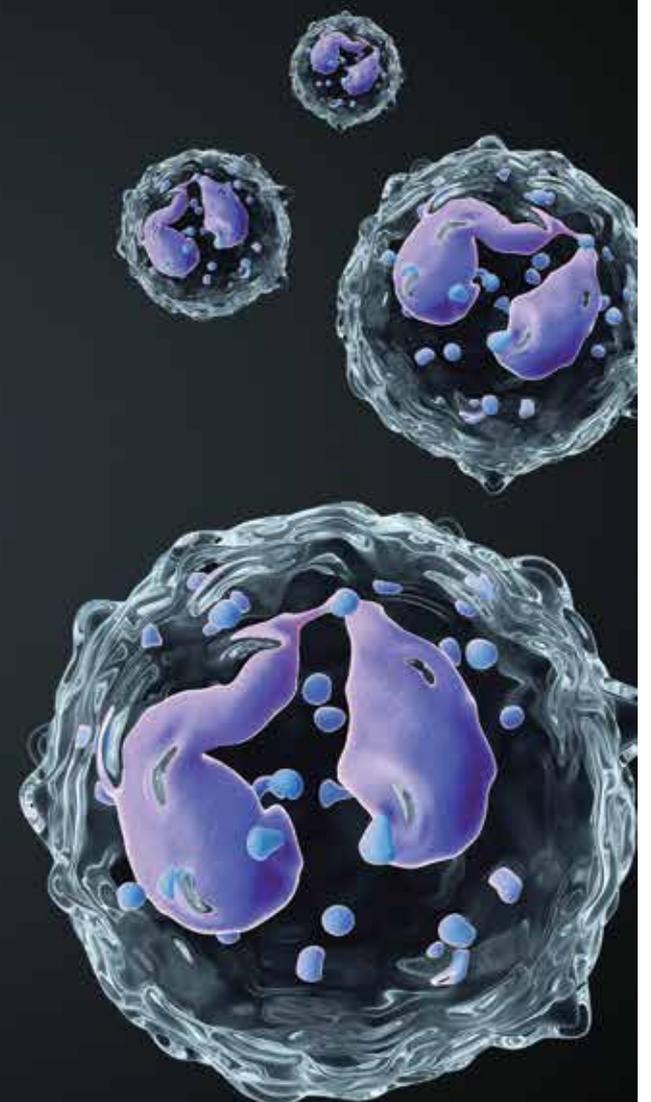
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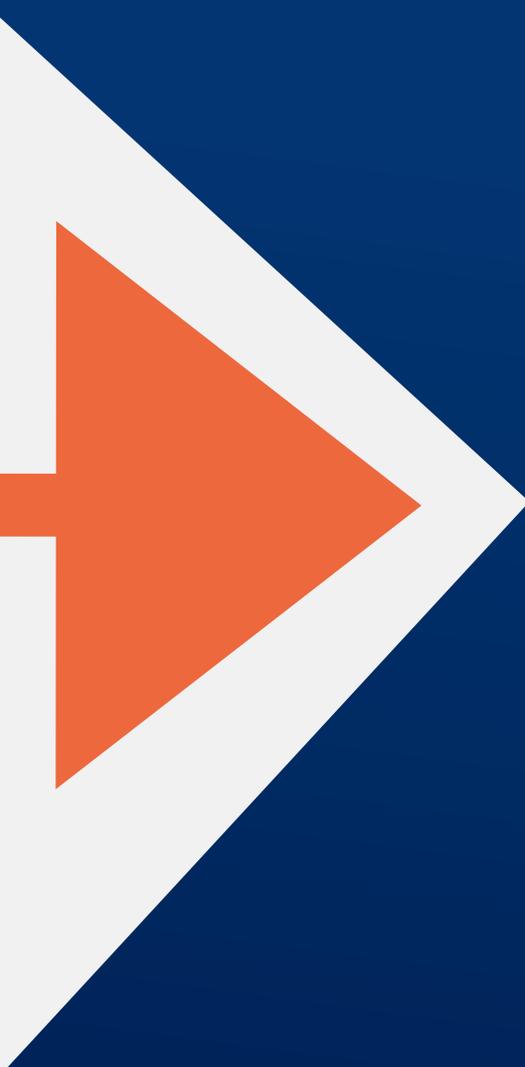


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Endobronchial Valves a New Option for Severe Emphysema

Lung volume reduction surgery (LVRS) has long been the only non-medical option for patients with severe emphysema who did not respond well to optimal medical therapy. The FDA has recently approved two minimally invasive endobronchial valves (EBV) that mimic the effects of LVRS and can be placed endoscopically as a new option for these patients.

“Endobronchial valves have been worked on since the late 1990s,” said Gerard J. Criner, MD, ATSE, professor of thoracic medicine and surgery at the Lewis Katz School of Medicine at Temple University in Philadelphia. “This is a great breakthrough for patients. Devices



Gerard J. Criner

and treatments that were previously only available as research tools are now available for selected patients.”

Dr. Criner will co-chair the ATS's most focused and comprehensive exploration of EBV technology and application during this morning's session, along with Daniela Gompelmann, MD, principal investigator at Translational Lung Research Center in Heidelberg, Germany, and Felix Josef Friedric Herth, MD, PhD, head of pneumology and critical care medicine at Heidelberg University in Germany. All three co-chairs have participated in EBV clinical studies and will present during the symposium.

EBVs are not new at ATS. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines first suggested the use of one-way endobronchial valves or coils as endoscopic options for lung volume reduction in 2017. ATS 2018 revealed the results of the pivotal LIBERATE study, which led to the FDA approval of the Zephyr

Endobronchial Valve (Pulmonx Corp) as well as the EMPROVE study, which led to FDA approval of the Spiration Valve System (SVS) (Olympus). Both trials showed statistically and clinically significant improvement in lung function and quality of life in patients with severe emphysema.

The two devices provide similar clinical benefits as LVRS but without strict surgical selection criteria or the perioperative morbidity and mortality associated with surgery. Zephyr uses small duckbill-shaped valves to occlude an emphysematous lobe while SVS uses umbrella-shaped valves.

Both valves are deployed to the bronchi using bronchoscopic guidance to dramatically reduce airflow to portions of the lung that are distal to the valve. Both valves allow movement of air and mucus in the proximal direction. The one-way flow results in lobar deflation, which leads to partial or full lobar atelectasis and effectively reduces hyperinflation by mimicking the mechanisms of LVRS to improve the function of the remaining lung tissue.

“Hyperinflation is probably

“ Devices and treatments that were previously only available as research tools are now available for selected patients.

– Gerard J. Criner

one of the most important pathophysiologic causes in people with severe emphysema that contributes to worsening lung function,” Dr. Criner said. “This is the most significant noninvasive method to reduce air trapping. If you can reduce air trapping and make the lungs smaller, you will improve lung and respiratory muscle function, cardiac function, and the patient's ability to walk and to exercise with less shortness of breath. These are meaningful physiological changes for our patients that are associated with an improved quality of life.”

EBVs are not for all severe emphysema patients. Patient selection criteria must ensure that patients have enough emphysematous destruction of the targeted lobe, have evidence of

little to no collateral ventilation to the target lobe, and are fit enough for an interventional procedure. Pneumothorax is the most important complication associated with endobronchial valve treatment with lobar occlusion in patients with little to no collateral ventilation. Patients require hospitalization post-treatment to monitor for this complication and appropriate measures need to be taken to treat a pneumothorax based on individual circumstances.

“This is a novel option for patients with severe emphysema,” Dr. Criner said. “And it is the first FDA-approved and commercially available intervention that can be done endoscopically, a less invasive tool for pulmonologists whose patients are still symptomatic despite optimal medical therapy.” ●

Endobronchial Valve Treatment in Patients With Advanced Emphysema: Its Time Has Come (B2)

9:15-11:15 a.m., Monday

Ballroom C One-Two (Level 2), KBHCCD

Please join us for an Industry-Organized Symposium at the ATS 2019 International Conference. A non-CME educational program sponsored by GSK open to all ATS 2019 International Conference attendees.



A Disease-State Presentation: Exploring Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Michael Wechsler, MD, MMSc

Professor of Medicine
Director, Asthma Program, National Jewish Health
Director, Cohen Family NJH Asthma Institute
Division of Pulmonary, Critical Care and Sleep Medicine
Department of Medicine
National Jewish Health and
University of Colorado School of Medicine



6:30 - 8 p.m.
Sunday, May 19, 2019



Hyatt Regency
Landmark Ballroom C

Dinner will be provided

This educational session will review the pathogenesis, clinical manifestations, classification criteria, diagnosis, and prognosis of EGPA.

This program is limited to Health Care Professionals (HCP) only. Some state laws prohibit manufacturers from providing meals or transfers of value to HCPs. Please do not accept any meal that violates the rules of states in which you are licensed to practice or the rules of your employer. GSK complies with all state and federal laws including transparent reporting and disclosure of payments and transfers of value to HCPs.

Confronting Obstacles in Critical Care Trials

Successful completion of critical care trials is fraught with barriers. These barriers may include engaging with surrogates, as patients often cannot consent. Patients' health can quickly take a turn for the worse and eliminate them from trials, resulting in missing data. Populations also are extremely heterogeneous.

"We also lack good intermediate endpoints, rendering phase II moderate-size studies nearly useless to perform in some cases," said Renee D. Stapleton, MD, PhD, ATSF, associate professor of critical care medicine/pulmonary disease at the



Renee D. Stapleton

University of Vermont Medical Center in Burlington. "We hope to address all of these issues in this session."

Dr. Stapleton is a chair of today's session on addressing the challenges that come with conducting randomized controlled trials in a critical care population, especially as they relate to recruitment, retention, and generalizability, and how they may contribute to the paucity of proven efficacious interventions in the ICU.

Using recent examples of critical care trials, this session will appeal to clinicians who seek greater insight on interpreting and applying literature to their patients.

"This session is devoted uniquely to critical care randomized trials and discussing troubleshooting their implementation and conduct, rather than focusing on interpreting the results of particular studies about a specific topic," said Dr. Stapleton.

Dr. Stapleton said the session also will provide a patient perspective, "which is always insightful and

reminds us why we do what we do."

Eileen Rubin, JD, executive director of the ARDS Foundation in Northbrook, Illinois, and acute respiratory distress syndrome survivor, will tell her story of what it was like participating in an ICU trial.

Dale M. Needham, MD, PhD, medical director of the Critical Care Physical Medicine and Rehabilitation Program and professor of medicine at John Hopkins University, will identify methods to engage patients over a long period of time to gather long-term outcomes.

"It's easy for participants to 'fall off the radar' once the critical illness is over, and Dr. Needham will discuss strategies to retain these participants," Dr. Stapleton said.

Additional presentations during the session will include how to nudge surrogate decision-makers toward participating in critical care trials, lessons learned from special issues in pediatric critical care trials, and the evolution of modern critical care trials from the past to the future.

"Critical care trialists will be able to utilize these strategies in their



day-to-day work to successfully implement, conduct, and complete critical care RCTs," said Dr. Stapleton.

Dr. Stapleton said attendees who do not conduct RCTs as part of their work can still use these lessons learned to help their colleagues enroll in trials, retain participants over time, and interpret published RCTs. ●

“It's easy for participants to 'fall off the radar' once the critical illness is over.

– Renee D. Stapleton



Challenges in Conducting and Interpreting ARDS and Sepsis Randomized Clinical Trials (B89)

2:15-4:15 p.m., Monday

Dallas Ballrooms A-C (Level 3), Omni Dallas Downtown

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The ATS is going live on Facebook during ATS 2019! Wake up each morning to join these presentations.

Monday, May 20, from 6:45 to 7:45 a.m. CT: Faculty Promotion and Tenure: Unraveling the Faculty Handbook (FD1)

Tuesday, May 21, from 6:45 to 7:45 a.m. CT: Using Digital Scholarship Strategically for Career Advancement (FD2)

Wednesday, May 22, from 6:45 to 7:45 a.m. CT: Negotiating for Your Future: Skills and Strategies for Success (FD3)

Art, Dogs Promote Wellbeing at IC

Learn to identify burnout and how to change things personally and professionally for the better. Explore the **Restoring Joy in Health Care** booth (#4733) to view the NAM Expressions of Wellbeing art installation or visit with a therapy dog to bring you back to center.

Want to take a deeper dive into preventing burnout and promoting wellbeing? Look for this programming.

Determinants of Burnout and Wellness Among Physicians and Trainees

Poster Discussion Session (C21)
Trinity Ballroom 5-7 (Level 3),
Omni Dallas Downtown

Tuesday, May 21
9:15-11:15 a.m.

Mindfulness for Optimizing Health Care Professional Wellbeing: Reducing Burnout

Scientific Symposium (SS301)
Greenville Avenue (Level 2),
Omni Dallas Downtown

Wednesday, May 22
6:45-7:45 a.m.



1.5 million
new users in one year

78%
increase
in high schoolers

48%
rise
in middle schoolers

Does Vaping Lead to Smoking?

There has been a 78 percent increase in the number of high school students who are using e-cigarettes, JUUL pods, or similar products, and a 48 percent rise in use among middle schoolers, according to a 2018 National Youth Tobacco Survey. Those percentages represent an increase of 1.5 million users in just one year. Health care professionals are increasingly alarmed by the statistics.

As new nicotine delivery systems evolved, two camps emerged. The first thought that these products offered a tool that could help highly addicted smokers quit, but the second noticed that young people seemed far more interested in those products than any group of smokers.

"There was never a reconciliation between those two camps," said Enid Neptune, MD, one of the chairs of today's session and an associate professor of medicine at Johns Hopkins Medicine in Baltimore, Maryland. "I don't think most of the public health community rejected either possibility." But the existence of those two groups has led to some

challenges, and those challenges will be the topic of this morning's session on adding a new generation.

Young people who use electronic nicotine delivery systems are twice as likely to take up smoking combustible cigarettes in the future, making the exponential rise in the number of young people using e-cigarettes an even greater concern said Dr. Neptune, who is co-chair of the AT'S Tobacco Action Committee. There may be fewer health harms to people who use electronic devices than there are associated with combustible cigarettes, but one thing that is often left out of the conversation is the fact that it's not an either/or proposition—there are people who consume nicotine both ways.

"In a way, I think there's too much attention paid to that," said Dona Upson, MD, another session chair and a pulmonologist at New Mexico VA Health Care System in Albuquerque, New Mexico. "I think the overwhelming health impact is addiction to nicotine, and [the use of e-cigarettes] significantly increases

the number of youth who will go on to become addicted to combustible cigarettes."

Dr. Neptune agreed, adding, "What happens when highly addicted people remain highly addicted over 10 or 12 years? They move on to combustibles." The signals of the impact on youth were there from the beginning, according to Dr. Neptune. "It's not that what we're seeing today wasn't evident five years ago," she said.

"It's not surprising at all that the industry has marketed aggressively to youth," Dr. Upson said. "But it is surprising that the FDA and some of our colleagues believed that these devices could help people quit smoking without having a huge impact on youth."

The topic of nicotine addiction is happening more often; parents are asking pediatricians about it, adults want to know how children are affected by electronic delivery systems, and each year more health care professionals are asking for information about the health effects.

This symposium will allow attendees to develop an informed opinion regarding the use of e-cigarettes, as well as the information they need to educate fellows, residents, students, peers,

parents, and their patients.

In addition to information, they will gain some advocacy tools. When it comes to public health policy, physicians' opinions carry a great deal of legitimacy. "We hope that people who attend will go back home and get involved," said Dr. Upson. Both doctors commented that a new bill in Maryland that raises the age of purchase for combustible and vaping products was recently passed by the legislature and is awaiting the governor's signature.

This legislation, termed Tobacco 21, required aggressive advocacy by multiple stakeholders, including physicians.

There is also a concern for the future. "The JUULs are kind of a 1.0 device," said Dr. Neptune. "We may see a wave of these pods, which has the potential to expand and worsen the epidemic." ●

Addicting a New Generation: Juuling, Vaping, Heat Not Burn, Flavorings, and the Evidence for Why We Should Be Very Concerned (B9)

9:15-11:15 a.m., Monday
Room D220/D227 (Level 2),
KBHCCD

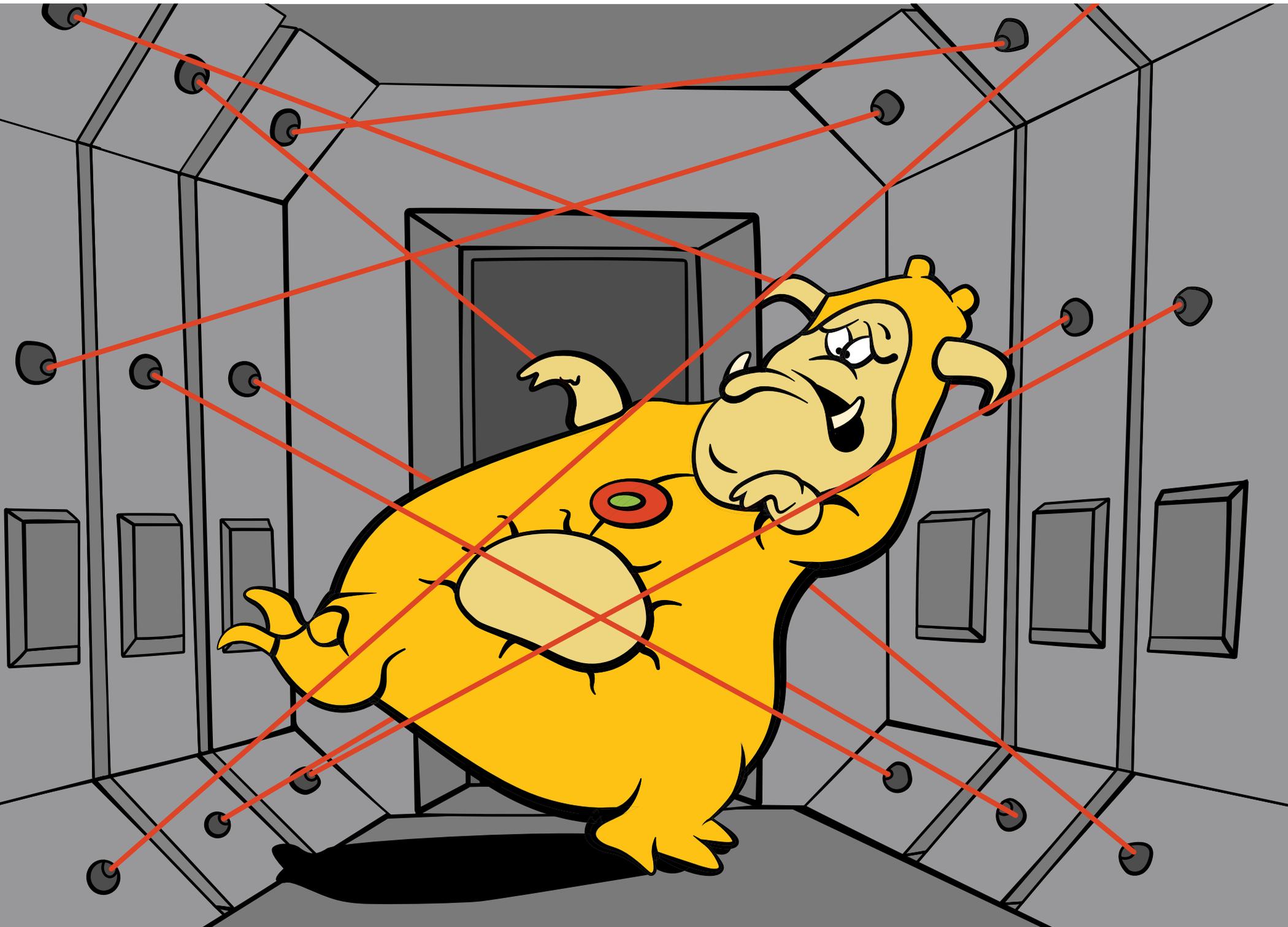


Enid Neptune



Dona Upson

Don't let pneumonia bugs evade detection.



Molecular diagnostics for pneumonia: An initial evaluation of the BioFire® FilmArray® Pneumonia Panel

Mini Theater | May 21, 2019 | 11:30 am–12 pm

Richard G. Wunderink, MD

Professor of Medicine (Pulmonary and Critical Care),
Feinberg School of Medicine, Northwestern University

A discussion of the current state of molecular diagnostics for pneumonia, including results from an initial clinical evaluation of the BioFire Pneumonia Panel.

An Industry Theater presentation at the ATS 2019 International Conference.
This presentation is sponsored by BioFire Diagnostics, and is open to all ATS 2019 International Conference attendees.

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Controversies in the Management of PE



Pulmonary embolism is one of the leading causes of preventable deaths among hospitalized patients. Advances in diagnostic and therapeutic techniques have expanded the number of potential therapies, and researchers are continuing to expand the evidence base and learn how to use these treatments. As a result, treatment decision-making has become more complex.



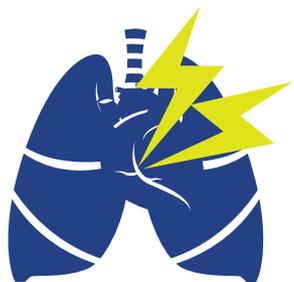
Parth Rali



Victor Tapson



Richard Channick



Teaming Up: The Parts of PERT

For optimal outcomes, managing PE now includes support from multiple disciplines including:

- Pulmonary and critical care medicine
- Interventional cardiology
- Interventional radiology
- Vascular medicine and surgery
- Hematology
- Emergency medicine
- Cardiac surgery

The optimum approach to managing PE now involves a multidisciplinary approach, with input from physicians in pulmonary and critical care medicine, interventional cardiology, interventional radiology, vascular medicine and surgery, hematology, emergency medicine, and cardiac surgery. The paradigm shift has led to increased attention to this life-threatening complication as well as to some controversies in management.

These controversies are brought to light in today's scientific symposium on managing acute pulmonary embolism, chaired by Parth Rali, MD; Victor Tapson, MD; and Richard Channick, MD. The debates in the symposium address lack of agreement in the approach to PE, including treatments recommended in guidelines developed by societies such as the American Heart Association, the European Society of Cardiology, and the American College of Chest Physicians.

"Even before we get involved in management, the guidelines differ somewhat in how PE is classified," said Dr. Rali, assistant professor of

thoracic medicine and surgery at Temple University in Philadelphia.

Another issue is that different specialties tend to follow specific guidelines. "Cardiologists follow the AHA and ESC guidelines, and pulmonologists follow the ACCP guidelines. This itself is enough to create confusion and lead to practice variation and procedural bias among clinicians," said Dr. Rali.

The treatment options for PE are based on risk categories of low, intermediate (submassive), and high (massive). But patient selection is also a key consideration. For example, aggressive treatment is needed for patients with massive PE, but recognizing the patient's bleeding risk is crucial because of the significantly higher risk of major bleeding associated with systemic thrombolytic therapy.

"Even these risk categories are heterogeneous," said Dr. Tapson of Cedars-Sinai Medical Center in West Hollywood, California. "A patient with high-risk PE may be receiving high-dose pressor therapy, for example, and still have inadequate hemodynamics, or a patient may be more mildly

hypotensive and perhaps need a different approach. Intermediate-risk PE is an even broader category."

"These treatment decisions and dilemmas are exactly why we established multidisciplinary pulmonary embolism response teams, or PERTs," added Dr. Channick of UCLA Medical Center in Los Angeles.

"It's a Catch-22," said Dr. Rali. "For every patient, you must consider the advantages and disadvantages for every modality of treatment. It's also why the PERT approach is of such great value."

Dr. Rali also noted that as the multidisciplinary approach to PE has evolved, the role of the thoracic surgeon has become even more important.

"Some patients may need embolectomy or bridge therapy with veno-arterial extracorporeal membrane oxygenation, both of which are performed by surgeons. Surgeons should be involved early, and there should be a plan and a back-up plan," said Dr. Rali.

The session's debate topics were selected to help clarify the core questions for most clinicians. One debate addresses catheter-directed

thrombolysis as the standard of care for submassive PE. With this relatively new modality of treatment, thrombolytic drugs are infused directly through a catheter positioned in the thrombosed pulmonary artery. Studies have shown that the approach seems to be safe in terms of risk of major bleeding (compared with full-dose systemic thrombolysis), but questions remain about the ideal timing, dosing, and duration. The lead authors for two pivotal trials of catheter-based thrombolysis—OPTALYSE-PE and SEATTLE II—will debate this issue.

"It is an exciting time in acute venous thromboembolism," said Dr. Tapson. "We need to continue to educate but, very importantly, also conduct high-quality clinical trials and expand the evidence base." ●

Pro/Con: The Conundrum of Managing Acute Pulmonary Embolism (B82)

2:15-4:15 p.m., Monday
Ballroom C One-Two (Level 2), KBHCCD

START BREAKING TRADITION

Instead of an ICS/LABA, start appropriate symptomatic patients with COPD on ANORO for dual bronchodilation

**Visit us at
GSK Booth
#3715**



Important Safety Information for ANORO ELLIPTA

WARNING: ASTHMA-RELATED DEATH

Long-acting beta₂-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in ANORO, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths. This finding with salmeterol is considered a class effect of all LABA.

The safety and efficacy of ANORO in patients with asthma have not been established. ANORO is not indicated for the treatment of asthma.

CONTRAINDICATIONS

- ANORO is contraindicated in patients with severe hypersensitivity to milk proteins or with hypersensitivity to umeclidinium, vilanterol, or any of the excipients.

WARNINGS AND PRECAUTIONS

- ANORO should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD.
- ANORO is NOT a rescue medication and should NOT be used for the relief of acute bronchospasm or symptoms. Acute symptoms should be treated with an inhaled, short-acting beta₂-agonist.
- ANORO should not be used more often or at higher doses than recommended or with another LABA (eg, salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs, like LABA.

ICS=inhaled corticosteroid.

Please see additional Important Safety Information for ANORO ELLIPTA throughout.

Please see Brief Summary of Prescribing Information, including Boxed Warning, for ANORO ELLIPTA following this ad.

ANORO ELLIPTA was developed in collaboration with INNOVIVA



ANORO was studied in patients with moderate or worse COPD.

ANORO is for the once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

ANORO is NOT for the relief of acute bronchospasm or for asthma.

**Go Ahead.
Get Started.**

ANORO ELLIPTA
(umeclidinium 62.5 mcg and vilanterol 25 mcg inhalation powder)

START WITH ANORO

FOR YOUR SYMPTOMATIC PATIENTS WITH COPD

Frank, age 58, professor, is a symptomatic patient with moderate COPD not yet on maintenance therapy and has had no exacerbations in the last 12 months. He is currently experiencing:

✓ **WHEEZING** ✓ **COUGH**

✓ **SHORTNESS OF BREATH LEADING TO:**

- Regular rescue medication use
- Pulling away from normal activities

Hypothetical patient story.

The GOLD 2019 Report

- **Continues to emphasize the role of LAMA/LABA for patients with COPD¹**
- **Does not include ICS/LABA as initial treatment for many patients¹**

GOLD=Global Initiative for Chronic Obstructive Lung Disease;
LAMA=long-acting muscarinic antagonist.

ANORO is not indicated to reduce COPD exacerbations.

In GSK pivotal studies for ANORO, an exacerbation was defined as acute worsening of symptoms of COPD requiring the use of any treatment beyond study drug or rescue albuterol. This includes the use of antibiotics and/or systemic corticosteroids and/or emergency treatment or hospitalization.²

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

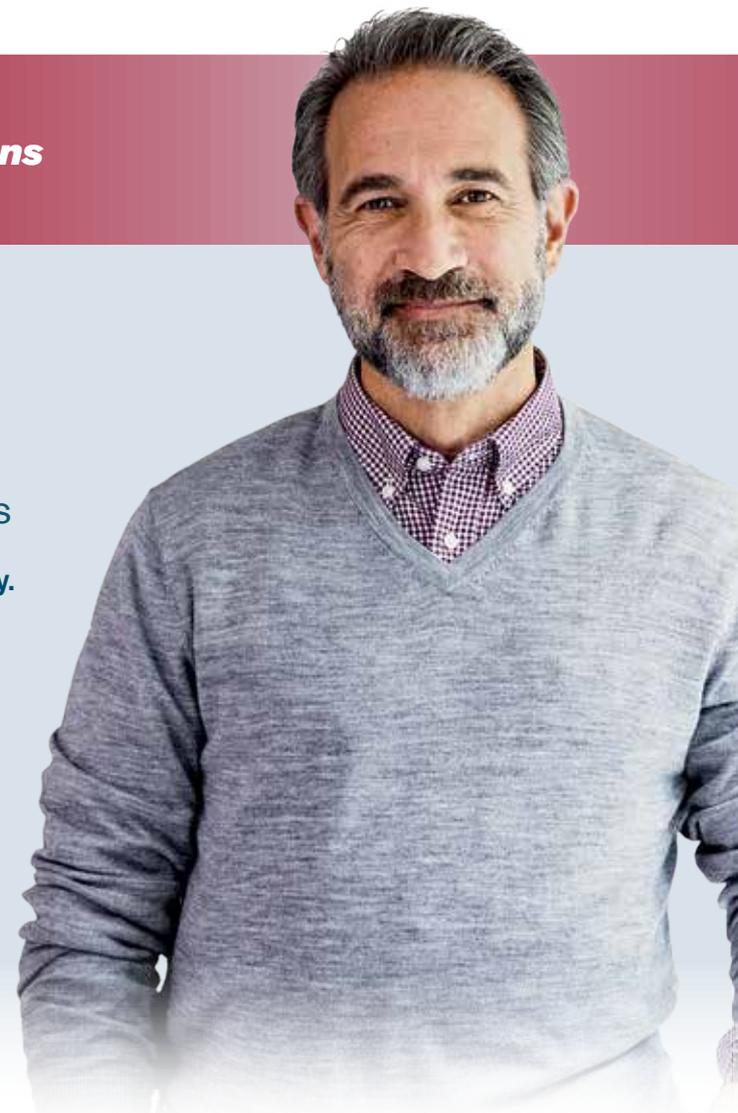
- Caution should be exercised when considering the coadministration of ANORO with long-term ketoconazole and other known strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleanomycin, voriconazole) because increased cardiovascular adverse effects may occur.
- If paradoxical bronchospasm occurs, discontinue ANORO and institute alternative therapy.
- Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of ANORO. Discontinue ANORO if such reactions occur.
- Vilanterol can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, or symptoms. If such effects occur, ANORO may need to be discontinued. ANORO should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.
- Use with caution in patients with narrow-angle glaucoma. Instruct patients to contact a healthcare provider immediately if signs or symptoms of acute narrow-angle glaucoma develop.
- Use with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to contact a healthcare provider immediately if signs or symptoms of urinary retention develop.
- Be alert to hypokalemia and hyperglycemia.

ADVERSE REACTIONS

- The most common adverse reactions ($\geq 1\%$ and more common than placebo) reported in four 6-month clinical trials with ANORO (and placebo) were: pharyngitis, 2% ($< 1\%$); sinusitis, 1% ($< 1\%$); lower respiratory tract infection, 1% ($< 1\%$); constipation, 1% ($< 1\%$); diarrhea, 2% (1%); pain in extremity, 2% (1%); muscle spasms, 1% ($< 1\%$); neck pain, 1% ($< 1\%$); and chest pain, 1% ($< 1\%$).
- In addition to the 6-month efficacy trials with ANORO, a 12-month trial evaluated the safety of umeclidinium/vilanterol 125 mcg/25 mcg in subjects with COPD. Adverse reactions (incidence $\geq 1\%$ and more common than placebo) in subjects receiving umeclidinium/vilanterol 125 mcg/25 mcg were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

Please see additional Important Safety Information for ANORO ELLIPTA throughout.

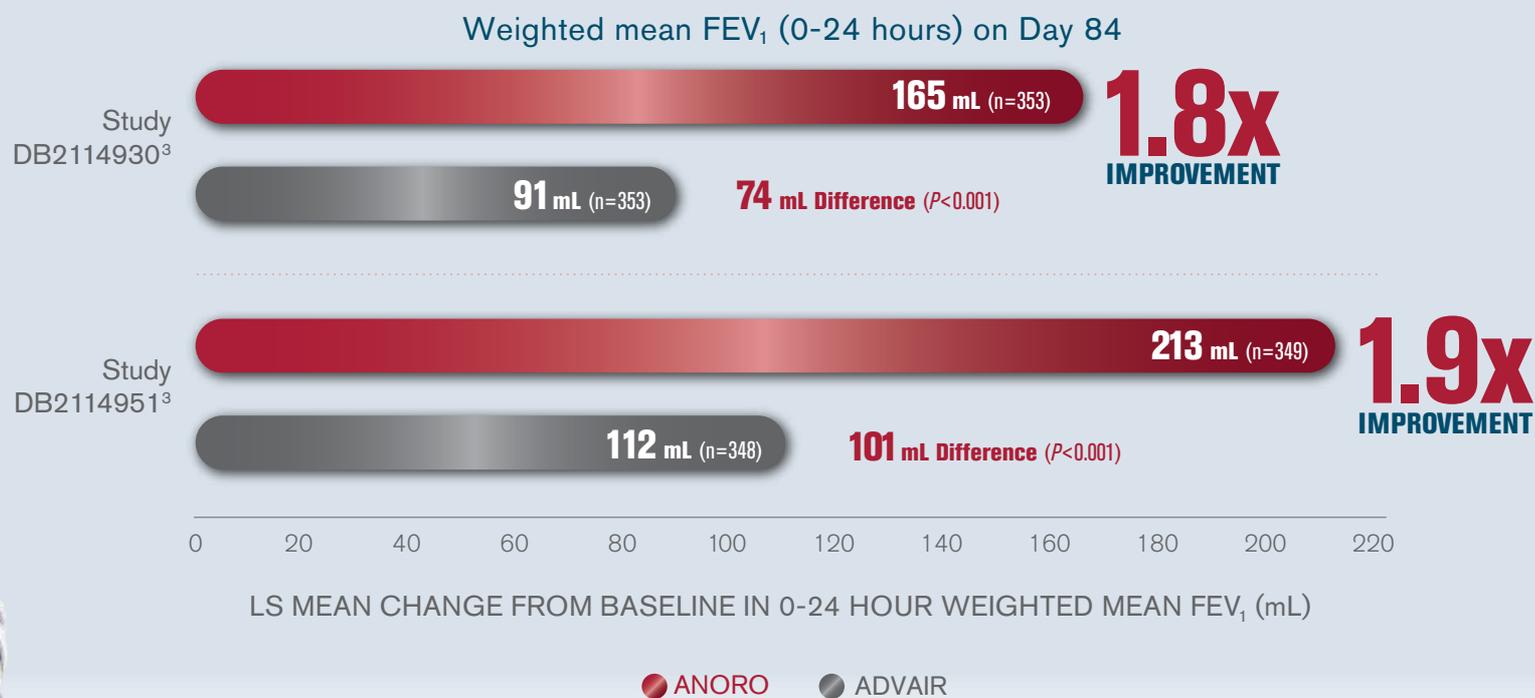
Please see Brief Summary of Prescribing Information, including Boxed Warning, for ANORO ELLIPTA following this ad.



START WITH ANORO

FOR SUPERIOR IMPROVEMENT IN LUNG FUNCTION VS AN ICS/LABA³

NEARLY **2X** THE LUNG FUNCTION IMPROVEMENT VS ADVAIR³



The indication for ANORO differs from the indication for ADVAIR in that ANORO is not indicated for reducing COPD exacerbations.

Studied in patients with moderate to severe COPD (GOLD 2 or 3).³

Description of studies^{2,3}

The efficacy and safety of a once-daily dose of ANORO ELLIPTA and a twice-daily dose of ADVAIR DISKUS 250 mcg/50 mcg were evaluated in two 12-week, multicenter, randomized, double-blind, double-dummy, parallel-group studies in patients (mean age range: 63 to 64 years) with COPD with no exacerbations (COPD symptoms requiring oral corticosteroids, antibiotics, and/or hospitalization) in the previous year. At screening, patients had a mean postbronchodilator FEV₁ range of 49.4% to 49.5% predicted. The studies were not powered to compare the safety profiles of the products.

Primary endpoint: Weighted mean FEV₁ (0-24 hours postdose) on Day 84.

FEV₁=forced expiratory volume in 1 second; LS=least squares.

Important Safety Information (cont'd)

DRUG INTERACTIONS

- Caution should be exercised when considering the coadministration of ANORO with ketoconazole and other known strong CYP3A4 inhibitors as increased systemic exposure to vilanterol and cardiovascular adverse effects may occur. See prior Warning and Precaution regarding CYP3A4 inhibitors.
- ANORO should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval, or within 2 weeks of discontinuation of such agents, because they may potentiate the effect of vilanterol on the cardiovascular system.
- Use beta-blockers with caution as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.
- Use with caution in patients taking non-potassium-sparing diuretics, as ECG changes and/or hypokalemia associated with these diuretics may worsen with concomitant beta-agonists.
- Avoid coadministration of ANORO with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects.

References: 1. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2019 report. www.goldcopd.org. Accessed February 15, 2019. 2. Data on file, GSK.

3. Donohue JF, Worsley S, Zhu C-Q, et al. Improvements in lung function with umeclidinium/vilanterol versus fluticasone propionate/salmeterol in patients with moderate-to-severe COPD and infrequent exacerbations. *Respir Med*. 2015;109(7):870-881, Appendix B.

Learn more at StartWithANORO.com

ANORO ELLIPTA was developed in collaboration with INNOVIVA

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UCVJRNA190001 March 2019
Produced in USA.



**Go Ahead.
Get Started.**

ANORO ELLIPTA
(umeclidinium 62.5 mcg and vilanterol 25 mcg inhalation powder)

ANORO ELLIPTA**BRIEF SUMMARY****(umeclidinium and vilanterol inhalation powder), for oral inhalation**

The following is a brief summary only; see full prescribing information for complete product information.

WARNING: ASTHMA-RELATED DEATH

Long-acting beta₂-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in ANORO ELLIPTA, increase the risk of asthma-related death. Data from a large placebo-controlled US trial that compared the safety of another LABA (salmeterol) with placebo added to usual asthma therapy showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of LABA [see Warnings and Precautions (5.1)].

The safety and efficacy of ANORO ELLIPTA in patients with asthma have not been established. ANORO ELLIPTA is not indicated for the treatment of asthma.

1 INDICATIONS AND USAGE

ANORO ELLIPTA is a combination anticholinergic/long-acting beta₂-adrenergic agonist (anticholinergic/LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Important Limitations of Use: ANORO ELLIPTA is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

4 CONTRAINDICATIONS

The use of ANORO ELLIPTA is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to umeclidinium, vilanterol, or any of the excipients [see Warnings and Precautions (5.6), Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS**5.1 Asthma-Related Death**

Data from a large placebo-controlled trial in subjects with asthma showed that LABA may increase the risk of asthma-related death. Data are not available to determine whether the rate of death in patients with COPD is increased by LABA.

A 28-week, placebo-controlled, US trial comparing the safety of another LABA (salmeterol) with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in subjects receiving salmeterol (13/13,176 in subjects treated with salmeterol vs. 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25, 15.34]). The increased risk of asthma-related death is considered a class effect of LABA, including vilanterol, one of the active ingredients in ANORO ELLIPTA.

No trial adequate to determine whether the rate of asthma-related death is increased in subjects treated with ANORO ELLIPTA has been conducted. The safety and efficacy of ANORO ELLIPTA in patients with asthma have not been established. ANORO ELLIPTA is not indicated for the treatment of asthma.

5.2 Deterioration of Disease and Acute Episodes

ANORO ELLIPTA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. ANORO ELLIPTA has not been studied in subjects with acutely deteriorating COPD. The initiation of ANORO ELLIPTA in this setting is not appropriate.

ANORO ELLIPTA should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. ANORO ELLIPTA has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting beta₂-agonist. When beginning treatment with ANORO ELLIPTA, patients who have been taking oral or inhaled, short-acting beta₂-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs and to use them only for symptomatic relief of acute respiratory symptoms. When prescribing ANORO ELLIPTA, the healthcare provider should also prescribe an inhaled, short-acting beta₂-agonist and instruct the patient on how it should be used. Increasing inhaled, short-acting beta₂-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated.

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If ANORO ELLIPTA no longer controls symptoms of bronchoconstriction; the patient's inhaled, short-acting beta₂-agonist becomes less effective; or the patient needs more short-acting beta₂-agonist than usual, these may be markers of deterioration of disease. In this setting a reevaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of ANORO ELLIPTA beyond the recommended dose is not appropriate in this situation.

5.3 Excessive Use of ANORO ELLIPTA and Use with Other Long-acting Beta₂-agonists

ANORO ELLIPTA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using ANORO ELLIPTA should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

5.4 Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors

Caution should be exercised when considering the coadministration of ANORO ELLIPTA with long-term ketoconazole and other known strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased cardiovascular adverse effects may occur [see Drug Interactions (7.1), Clinical Pharmacology (12.3) of full prescribing information].

5.5 Paradoxical Bronchospasm

As with other inhaled medicines, ANORO ELLIPTA can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs following dosing with ANORO ELLIPTA, it should be treated immediately with an inhaled, short-acting bronchodilator; ANORO ELLIPTA should be discontinued immediately; and alternative therapy should be instituted.

5.6 Hypersensitivity Reactions

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of ANORO ELLIPTA. Discontinue ANORO ELLIPTA if such reactions occur. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder products containing lactose; therefore, patients with severe milk protein allergy should not use ANORO ELLIPTA [see Contraindications (4)].

5.7 Cardiovascular Effects

Vilanterol, like other beta₂-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, or symptoms [see Clinical Pharmacology (12.2) of full prescribing information]. If such effects occur, ANORO ELLIPTA may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiographic changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Therefore, ANORO ELLIPTA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

5.8 Coexisting Conditions

ANORO ELLIPTA, like all medicines containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis and in those who are unusually responsive to sympathomimetic amines. Doses of the related beta₂-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

5.9 Worsening of Narrow-Angle Glaucoma

ANORO ELLIPTA should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

5.10 Worsening of Urinary Retention

ANORO ELLIPTA should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

5.11 Hypokalemia and Hyperglycemia

Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Beta-agonist medicines may produce transient hyperglycemia in some patients. In 4 clinical trials of 6-month duration evaluating ANORO ELLIPTA in subjects with COPD, there was no evidence of a treatment effect on serum glucose or potassium.

6 ADVERSE REACTIONS

LABA, such as vilanterol, one of the active ingredients in ANORO ELLIPTA, increase the risk of asthma-related death. ANORO ELLIPTA is not indicated for the treatment of asthma. [See Boxed Warning and Warnings and Precautions (5.1).] The following adverse reactions are described in greater detail in other sections:

- Paradoxical bronchospasm [see Warnings and Precautions (5.5)]
- Cardiovascular effects [see Warnings and Precautions (5.7)]
- Worsening of narrow-angle glaucoma [see Warnings and Precautions (5.9)]
- Worsening of urinary retention [see Warnings and Precautions (5.10)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The clinical program for ANORO ELLIPTA included 8,138 subjects with COPD in four 6-month lung function trials, one 12-month long-term safety study, and 9 other trials of shorter duration. A total of 1,124 subjects have received at least 1 dose of ANORO ELLIPTA (umeclidinium/vilanterol 62.5 mcg/25 mcg), and 1,330 subjects have received a higher dose of umeclidinium/vilanterol (125 mcg/25 mcg). The safety data described below are based on the four 6-month and the one 12-month trials. Adverse reactions observed in the other trials were similar to those observed in the confirmatory trials.

6-Month Trials

The incidence of adverse reactions associated with ANORO ELLIPTA in Table 1 is based on four 6-month trials: 2 placebo-controlled trials (Trials 1 and 2; n = 1,532 and n = 1,489, respectively) and 2 active-controlled trials (Trials 3 and 4; n = 843 and n = 869, respectively). Of the 4,733 subjects, 68% were male and 84% were white. They had a mean age of 63 years and an average smoking history of 45 pack-years, with 50% identified as current smokers. At screening, the mean postbronchodilator percent predicted forced expiratory volume in 1 second (FEV₁) was 48% (range: 13% to 76%), the mean postbronchodilator FEV₁/forced vital capacity (FVC) ratio was 0.47 (range: 0.13 to 0.78), and the mean percent reversibility was 14% (range: -45% to 109%).

Subjects received 1 dose once daily of the following: ANORO ELLIPTA, umeclidinium/vilanterol 125 mcg/25 mcg, umeclidinium 62.5 mcg, umeclidinium 125 mcg, vilanterol 25 mcg, active control, or placebo.

Table 1. Adverse Reactions with ANORO ELLIPTA with ≥1% Incidence and More Common than Placebo in Subjects with Chronic Obstructive Pulmonary Disease

Adverse Reaction	ANORO ELLIPTA (n = 842) %	Umeclidinium 62.5 mcg (n = 418) %	Vilanterol 25 mcg (n = 1,034) %	Placebo (n = 555) %
Infections and infestations				
Pharyngitis	2	1	2	<1
Sinusitis	1	<1	1	<1
Lower respiratory tract infection	1	<1	<1	<1
Gastrointestinal disorders				
Constipation	1	<1	<1	<1
Diarrhea	2	<1	2	1
Musculoskeletal and connective tissue disorders				
Pain in extremity	2	<1	2	1
Muscle spasms	1	<1	<1	<1
Neck pain	1	<1	<1	<1
General disorders and administration site conditions				
Chest pain	1	<1	<1	<1

Other adverse reactions with ANORO ELLIPTA observed with an incidence less than 1% but more common than placebo included the following: productive cough, dry mouth, dyspepsia, abdominal pain, gastroesophageal reflux disease, vomiting, musculoskeletal chest pain, chest discomfort, asthenia, atrial fibrillation, ventricular extrasystoles, supraventricular extrasystoles, myocardial infarction, pruritus, rash, and conjunctivitis.

12-Month Trial

In a long-term safety trial, 335 subjects were treated for up to 12 months with umeclidinium/vilanterol 125 mcg/25 mcg or placebo. The demographic and baseline characteristics of the long-term safety trial were similar to those of the placebo-controlled efficacy trials described above. Adverse reactions that occurred with a frequency of greater than or equal to 1% in the group receiving umeclidinium/vilanterol 125 mcg/25 mcg that exceeded that in placebo in this trial were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during postapproval use of ANORO ELLIPTA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to either their seriousness, frequency of reporting, or causal connection to ANORO ELLIPTA or a combination of these factors.

Cardiac Disorders

Palpitations.

Eye Disorders

Blurred vision, glaucoma, increased intraocular pressure.

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis, angioedema, and urticaria.

Nervous System Disorders

Dysgeusia, tremor.

Psychiatric Disorders

Anxiety.

Renal and Urinary Disorders

Dysuria, urinary retention.

Respiratory, Thoracic, and Mediastinal Disorders

Dysphonia, paradoxical bronchospasm.

(continued on next page)

7 DRUG INTERACTIONS

7.1 Inhibitors of Cytochrome P450 3A4

Vilanterol, a component of ANORO ELLIPTA, is a substrate of CYP3A4. Concomitant administration of the strong CYP3A4 inhibitor ketoconazole increases the systemic exposure to vilanterol. Caution should be exercised when considering the coadministration of ANORO ELLIPTA with ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleanomycin, voriconazole) [see *Warnings and Precautions (5.4), Clinical Pharmacology (12.3) of full prescribing information*].

7.2 Monoamine Oxidase Inhibitors and Tricyclic Antidepressants

Vilanterol, like other beta₂-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias.

7.3 Beta-adrenergic Receptor Blocking Agents

Beta-blockers not only block the pulmonary effect of beta-agonists, such as vilanterol, a component of ANORO ELLIPTA, but may also produce severe bronchospasm in patients with COPD. Therefore, patients with COPD should not normally be treated with beta-blockers. However, under certain circumstances, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents for these patients; cardioselective beta-blockers could be considered, although they should be administered with caution.

7.4 Non-Potassium-Sparing Diuretics

The electrocardiographic changes and/or hypokalemia that may result from the administration of non-potassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, such as vilanterol, a component of ANORO ELLIPTA, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of ANORO ELLIPTA with non-potassium-sparing diuretics.

7.5 Anticholinergics

There is potential for an additive interaction with concomitantly used anticholinergic medicines. Therefore, avoid coadministration of ANORO ELLIPTA with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects [see *Warnings and Precautions (5.9, 5.10), Adverse Reactions (6)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects

Pregnancy Category C. There are no adequate and well-controlled trials of ANORO ELLIPTA or its individual components, umeclidinium and vilanterol, in pregnant women. Because animal reproduction studies are not always predictive of human response, ANORO ELLIPTA should be used during pregnancy only if the potential benefit justifies the potential risk to fetus. Women should be advised to contact their healthcare providers if they become pregnant while taking ANORO ELLIPTA.

Umeclidinium: There was no evidence of teratogenic effects in rats and rabbits at approximately 50 and 200 times, respectively, the MRHDID (maximum recommended human daily inhaled dose) in adults (on an AUC basis at maternal inhaled doses up to 278 mcg/kg/day in rats and at maternal subcutaneous doses up to 180 mcg/kg/day in rabbits).

Vilanterol: There were no teratogenic effects in rats and rabbits at approximately 13,000 and 70 times, respectively, the MRHDID in adults (on a mcg/m² basis at maternal inhaled doses up to 33,700 mcg/kg/day in rats and on an AUC basis at maternal inhaled doses up to 591 mcg/kg/day in rabbits). However, fetal skeletal variations were observed in rabbits at approximately 450 times the MRHDID in adults (on an AUC basis at maternal inhaled or subcutaneous doses of 5,740 or 300 mcg/kg/day, respectively). The skeletal variations included decreased or absent ossification in cervical vertebral centrum and metacarpals.

Nonteratogenic Effects

Umeclidinium: There were no effects on perinatal and postnatal developments in rats at approximately 80 times the MRHDID in adults (on an AUC basis at maternal subcutaneous doses up to 180 mcg/kg/day).

Vilanterol: There were no effects on perinatal and postnatal developments in rats at approximately 3,900 times the MRHDID in adults (on a mcg/m² basis at maternal oral doses up to 10,000 mcg/kg/day).

8.2 Labor and Delivery

There are no adequate and well-controlled human trials that have investigated the effects of ANORO ELLIPTA during labor and delivery.

Because beta-agonists may potentially interfere with uterine contractility, ANORO ELLIPTA should be used during labor only if the potential benefit justifies the potential risk.

8.3 Nursing Mothers

ANORO ELLIPTA

It is not known whether ANORO ELLIPTA is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when ANORO ELLIPTA is administered to a nursing woman. Since there are no data from well-controlled human studies on the use of ANORO ELLIPTA by nursing mothers, based on the data for the individual components, a decision should be made whether to discontinue nursing or to discontinue ANORO ELLIPTA, taking into account the importance of ANORO ELLIPTA to the mother.

Umeclidinium

It is not known whether umeclidinium is excreted in human breast milk. However, administration to lactating rats at approximately 25 times the MRHDID in adults resulted in a quantifiable level of umeclidinium in 2 pups, which may indicate transfer of umeclidinium in milk.

Vilanterol

It is not known whether vilanterol is excreted in human breast milk. However, other beta₂-agonists have been detected in human milk.

8.4 Pediatric Use

ANORO ELLIPTA is not indicated for use in children. The safety and efficacy in pediatric patients have not been established.

8.5 Geriatric Use

Based on available data, no adjustment of the dosage of ANORO ELLIPTA in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out.

Clinical trials of ANORO ELLIPTA for COPD included 2,143 subjects aged 65 years and older and 478 subjects aged 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger subjects.

8.6 Hepatic Impairment

Patients with moderate hepatic impairment (Child-Pugh score of 7-9) showed no relevant increases in C_{max} or AUC, nor did protein binding differ between subjects with moderate hepatic impairment and their healthy controls. Studies in subjects with severe hepatic impairment have not been performed [see *Clinical Pharmacology (12.3) of full prescribing information*].

8.7 Renal Impairment

There were no significant increases in either umeclidinium or vilanterol exposure in subjects with severe renal impairment (CrCl less than 30 mL/min) compared with healthy subjects. No dosage adjustment is required in patients with renal impairment [see *Clinical Pharmacology (12.3) of full prescribing information*].

10 OVERDOSAGE

No case of overdose has been reported with ANORO ELLIPTA.

ANORO ELLIPTA contains both umeclidinium and vilanterol; therefore, the risks associated with overdosage for the individual components described below apply to ANORO ELLIPTA. Treatment of overdosage consists of discontinuation of ANORO ELLIPTA together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medicine can produce bronchospasm. Cardiac monitoring is recommended in cases of overdosage.

10.1 Umeclidinium

High doses of umeclidinium may lead to anticholinergic signs and symptoms. However, there were no systemic anticholinergic adverse effects following a once-daily inhaled dose of up to 1,000 mcg umeclidinium (16 times the maximum recommended daily dose) for 14 days in subjects with COPD.

10.2 Vilanterol

The expected signs and symptoms with overdosage of vilanterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms of beta-adrenergic stimulation (e.g., angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, insomnia, hyperglycemia, hypokalemia, metabolic acidosis). As with all inhaled sympathomimetic medicines, cardiac arrest and even death may be associated with an overdose of vilanterol.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

ANORO ELLIPTA

No studies of carcinogenicity, mutagenicity, or impairment of fertility were conducted with ANORO ELLIPTA; however, studies are available for the individual components, umeclidinium and vilanterol, as described below.

Umeclidinium

Umeclidinium produced no treatment-related increases in the incidence of tumors in 2-year inhalation studies in rats and mice at inhaled doses up to 137 and 295/200 mcg/kg/day (male/female), respectively (approximately 20 and 25/20 times the MRHDID in adults on an AUC basis, respectively).

Umeclidinium tested negative in the following genotoxicity assays: the in vitro Ames assay, in vitro mouse lymphoma assay, and in vivo rat bone marrow micronucleus assay.

No evidence of impairment of fertility was observed in male and female rats at subcutaneous doses up to 180 mcg/kg/day and inhaled doses up to 294 mcg/kg/day, respectively (approximately 100 and 50 times, respectively, the MRHDID in adults on an AUC basis).

Vilanterol

In a 2-year carcinogenicity study in mice, vilanterol caused a statistically significant increase in ovarian tubulostromal adenomas in females at an inhalation dose of 29,500 mcg/kg/day (approximately 7,800 times the MRHDID in adults on an AUC basis). No increase in tumors was seen at an inhalation dose of 615 mcg/kg/day (approximately 210 times the MRHDID in adults on an AUC basis).

In a 2-year carcinogenicity study in rats, vilanterol caused statistically significant increases in mesovarian leiomyomas in females and shortening of the latency of pituitary tumors at inhalation doses greater than or equal to 84.4 mcg/kg/day (greater than or equal to approximately 20 times the MRHDID in adults on an AUC basis). No tumors were seen at an inhalation dose of 10.5 mcg/kg/day (approximately 1 time the MRHDID in adults on an AUC basis). These tumor findings in rodents are similar to those reported previously for other beta-adrenergic agonist drugs. The relevance of these findings to human use is unknown.

Vilanterol tested negative in the following genotoxicity assays: the in vitro Ames assay, in vivo rat bone marrow micronucleus assay, in vivo rat unscheduled DNA synthesis (UDS) assay, and in vitro Syrian hamster embryo (SHE) cell assay. Vilanterol tested equivocal in the in vitro mouse lymphoma assay.

No evidence of impairment of fertility was observed in reproductive studies conducted in male and female rats at inhaled vilanterol doses up to 31,500 and 37,100 mcg/kg/day, respectively (approximately 12,000 and 14,500 times, respectively, the MRHDID in adults on a mcg/m² basis).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

Asthma-Related Death

Inform patients that LABA, such as vilanterol, one of the active ingredients in ANORO ELLIPTA, increase the risk of asthma-related death. ANORO ELLIPTA is not indicated for the treatment of asthma.

Not for Acute Symptoms

Inform patients that ANORO ELLIPTA is not meant to relieve acute symptoms of COPD and extra doses should not be used for that purpose. Advise patients to treat acute symptoms with an inhaled, short-acting beta₂-agonist such as albuterol. Provide patients with such medicine and instruct them in how it should be used.

Instruct patients to seek medical attention immediately if they experience any of the following:

- Decreasing effectiveness of inhaled, short-acting beta₂-agonists
- Need for more inhalations than usual of inhaled, short-acting beta₂-agonists
- Significant decrease in lung function as outlined by the physician

Tell patients they should not stop therapy with ANORO ELLIPTA without healthcare provider guidance since symptoms may recur after discontinuation.

Do Not Use Additional Long-acting Beta₂-agonists

Instruct patients not to use other medicines containing a LABA. Patients should not use more than the recommended once-daily dose of ANORO ELLIPTA.

Instruct patients who have been taking inhaled, short-acting beta₂-agonists on a regular basis to discontinue the regular use of these products and use them only for the symptomatic relief of acute symptoms.

Paradoxical Bronchospasm

As with other inhaled medicines, ANORO ELLIPTA can cause paradoxical bronchospasm. If paradoxical bronchospasm occurs, instruct patients to discontinue ANORO ELLIPTA and contact their healthcare provider right away.

Risks Associated with Beta-agonist Therapy

Inform patients of adverse effects associated with beta₂-agonists, such as palpitations, chest pain, rapid heart rate, tremor, or nervousness.

Worsening of Narrow-Angle Glaucoma

Instruct patients to be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

Worsening of Urinary Retention

Instruct patients to be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

ANORO and ELLIPTA are registered trademarks of the GSK group of companies.

ANORO ELLIPTA was developed in collaboration with INNOCIVA



GlaxoSmithKline
Research Triangle Park, NC 27709

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The ATS 2019 International Conference

Join us to learn more about the

EVOLVING UNDERSTANDING OF INFLAMMATORY MEDIATORS IN ASTHMA

Mario Castro, MD, MPH

Alan A. and Edith L. Wolff Professor of
Pulmonary and Critical Care Medicine
Professor of Medicine, Pediatrics, and Radiology
Washington University School of Medicine
St. Louis, MO

This presentation is sponsored by Novartis, and is open to
all ATS 2019 International Conference attendees.

Tuesday, May 21

1:15 PM TO 2:00 PM

**The Kay Bailey Hutchison
Convention Center Dallas**

The ATS 2019 Exhibit Hall, Theater 1

Boxed lunches will be provided by The
American Thoracic Society (ATS)

COME VISIT US AT

**Novartis booth #1500
at the ATS 2019
Exhibit Hall**

SUBMIT YOUR QUESTIONS

at the Novartis Booth for the opportunity to
have them answered personally by Dr. Castro
during the presentation. Select questions will be
used for discussion.

Outstanding Scientists to Present Research

Recognition Awards for Scientific Accomplishments are presented each year to four scientists to recognize outstanding scientific contributions in basic or clinical research that enhance the understanding, prevention, and treatment of respiratory disease or critical illness. Individuals who are considered for the award are recognized for either scientific contributions throughout their careers or for major contributions at a particular point in their careers. Awardees will each make a 25-minute presentation of their research.

Recognition Awards for Scientific Accomplishments (G3)

2:15-4:15 p.m., Monday
Ballroom A Three (Level 2), KBHCCD



Joanna Floros, PhD, ATSF

Evan Pugh University Professor in Cellular and Molecular Physiology
Departments of Pediatrics and Obstetrics and Gynecology
Pennsylvania State University

Dr. Floros will present Surfactant Protein A Genetic Variants: So What? Interplay of Genetic Variability, Sex, and Oxidative Stress. She first became interested in the pulmonary surfactant field and surfactant proteins while at Harvard.

Because most (if not all) pulmonary diseases are characterized by derangement of host defense and/or surfactant function, these proteins are relevant to various pulmonary diseases. Dr. Floros's primary focus is surfactant protein A (SP-A), an innate immune molecule, which, in humans, has been identified with extensive genetic and epigenetic variability.

Her current research, using a variety of approaches, is on the function and regulation of the human SP-A variants and how these may change in response to environmental cues and/or as a function of sex.



Nicholas W. Lukacs, PhD

Godfrey D. Stobbe Professor of Pathology Scientific Director
Mary H. Weiser Food Allergy Center
University of Michigan Medical School

Dr. Lukacs will present Respiratory Infections and Asthma: The Role of the Microbiome. The Lukacs Lab is focused on the innate and acquired immune responses in allergen- and respiratory virus-induced diseases, as well as the role that the gut microbiome has on development of the early life immune system. Studies in the laboratory have explored the function and activation of DC and T cells during infections and the differential modulation of the immune and pathologic responses that lead to exacerbated disease progression.

Translational collaborations include studies examining severe respiratory syncytial virus (RSV)-induced disease with infants in the pediatric ICU as well as the development of food and airborne allergen responses in inner-city birth cohorts linked to microbiome and metabolic profiles.



Prabir Ray, PhD

Professor of Medicine and Immunology
Endowed Chair of Lung Immunology in Medicine
University of Pittsburgh School of Medicine

Dr. Ray will present Infection and Immunity in the Lung. Early in his career at Yale University, Dr. Ray pioneered the development of inducible cell-specific transgenic mice to show the important role of the growth factor KGF in protection from lung epithelial cell death during lung injury.

Currently, his research interest encompasses immunoregulatory mechanisms of lung inflammation as they relate to disease inception and resolution in the context of infections by bacteria and viruses. His findings in this area may explain the link between respiratory virus-induced severe illness in early life and the predisposition to asthma in later life.

In ongoing translational research, his laboratory is investigating differential response to RSV infection in infants that causes severe illness in some but mild illness in others.



Theodore J. Standiford, MD

Professor of Internal Medicine Chief, Division of Pulmonary and Critical Care Medicine
Michigan Medicine
University of Michigan

Dr. Standiford will present Lung Innate Immunity: From Chemokines to Toll Receptors and Beyond. The thrust of basic and translational research in Dr. Standiford's laboratory has focused on exploring immune responses in the lung.

His research has identified the importance of pathogen recognition receptors in mucosal immunity and has defined how downstream pathogen recognition receptor signaling is regulated by both immunological and epigenetic mechanisms.

His laboratory has uncovered basic mechanisms of experimental lung injury in response to infectious and non-infectious insults. In human studies, Dr. Standiford has investigated mechanisms of lung injury in sepsis and ARDS and performed trials to assess the effect of growth factor administration on outcome of patients with ARDS. ●

Exhibit Hall Exploration

Attendees seized the opportunity on Sunday to visit the more than 200 exhibitors at ATS 2019, participate in hands-on demos, network with colleagues, and learn in the Guru Bars and Industry Theaters.



BEAR Cage 2019: Meet the Finalists

Three early career investigators are vying for a \$10,000 cash prize during the ATS BEAR Cage competition on Monday afternoon. Each will “pitch” his or her proposal to a panel of translational science experts, which will ultimately select the winner.

The fifth annual Building Education to Advance Research (BEAR) Cage competition, which follows a Shark Tank-style of presentation, will award \$10,000 to the top presentation and \$2,500 each to the two runners-up.

This year's finalists and their proposals are:



MYATS

“The sincere desire for collaboration between ATS and industry makes ATS a trendsetter.”

Courtney Crim, MD

Clinical Associate Professor of Medicine, Division of Pulmonary and Critical Care Medicine
University of North Carolina at Chapel Hill

Group Director, Clinical Development
GlaxoSmithKline, Inc.



“Functional Lung MRI”
Adrienne Campbell-Washburn, PhD

National Heart, Lung, and Blood Institute

Q What made you become a scientist/researcher?

My undergraduate degree is in physics. I was excited about the idea of using something as theoretical as physics to have an immediate, practical impact, like improving human health. I had the opportunity to pursue some summer research projects in medical physics—and that was it, I was hooked.

Q Why should the panel award you the top prize?

My new imaging technologies will provide a comprehensive assessment of lung anatomy, function, and physiology in a single session, free of ionizing radiation. The MRI machine I am developing is also quieter, safer for patients with implants, and more cost-effective. I think my work could truly change the way we evaluate lung disease in the clinic, in addition to increasing access to advanced imaging world over.

Q How will you spend the prize money if you win?

Probably to travel. I've lived in the U.S. for six years, and there are still so many national parks to see!



“Targeting Pulmonary Protease Activity With an HDL-Binding Protease Inhibitor Peptide”
Scott M. Gordon, PhD

University of Kentucky

Q What made you become a scientist/researcher?

I have always had a passion for nature and biology. As an undergraduate, I majored in biology but had no serious career path in mind until I had a fantastic experience working in a research lab that gave me absolute clarity on my career goals.

Q Why should the panel award you the top prize?

I believe I have developed a novel and creative approach to fulfilling a real medical need that exists in a large population of pulmonary patients. I am excited about its progress so far and the potential for actually improving quality of life for these patients.

Q How will you spend the prize money if you win?

First, I would take my family on a decent vacation as a thank you for their understanding and support over the last year while I have been building my independent research lab. Then, I would try to make a small dent in the pile of student loans that paid for the education that has allowed me pursue a career that I absolutely enjoy.



“Steerable Electromagnetic Navigation Guided Endobronchial Radial Ultrasound With Biopsy Needle”
Jasleen Pannu, MD

Ohio State University

Q What made you become a scientist/researcher?

A profound curiosity of why things work the way they do and what can be done to make them better. Encouragement from mentors and the growing field of interventional pulmonology has kept my inquisitiveness alive.

Q Why should the panel award you the top prize?

My idea addresses a growing community need. If successfully implemented, it can be a cost-effective, easy-to-use, and efficient tool for biopsy of lung nodules

Q How will you spend the prize money if you win?

I will use it to invest further into building a collaboration between biomedical engineering and interventional pulmonology at my institution. ●

BEAR Cage

1-3 p.m., Monday

Science and Innovation Center (Level 2), KBHCCD



PRODUCT SHOWCASE

Are your patients short of breath with a dry, hacking cough? It could be **pulmonary fibrosis.**

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Visit booth 4076 to learn about managing chest congestion in stable chronic bronchitis patients and claim your Starbucks \$5 giftcard!

25
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QUESTION OF THE DAY

Which respiratory disease will be cured or eliminated in your lifetime?



Rachel Putman, MD, MHS
Boston

Cystic fibrosis.
It is one of the only monogenetic diseases in pulmonary, and we've been able to make progress in gene therapy. There have been a ton of advancements.

Lee Brooks, MD
Voorhees, New Jersey

None.
In the mid-1980s, when the gene for cystic fibrosis was discovered, I remember talking to the parents of a newborn with CF, telling them that I believed the disease would be eliminated in her lifetime. I was wrong.

Shekhar Venkataraman, MD
Pittsburgh

Cystic fibrosis.
I'm a pediatrician, so I would lean toward CF. We know all of the genetic mutations, and there are promising stem cell therapies that could be applicable.

Louella Amos, MD
Milwaukee

Cystic fibrosis.
A lot of money is going into it and a lot of people have it, so the research focus is there.

Sameer Avasarala, MD
Cleveland

Asthma.
There have been great strides in asthma treatment, especially with new biologicals, and they are becoming more mainstream than just using inhalers.

Are We There Yet?

IPPF

Tips to Better MANAGEMENT

TUESDAY
MAY 21 | 6:30–9PM

HYATT REGENCY DALLAS | MARSALIS EXHIBIT HALL A

Join us for an interactive **“What would YOU do?”** enhanced learning experience focused on shared decision-making



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Miller School of Medicine
University of Miami



Lisa H. Lancaster, MD
Vanderbilt University
Medical Center



Fernando J. Martinez, MD, MS
New York Presbyterian Hospital/
Weill Cornell Medical Center

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A MECC-Organized Symposium at the ATS 2019 International Conference. All ATS 2019 International Conference attendees are invited to attend this Non-CME educational program sponsored by The France Foundation and supported by grants from Boehringer Ingelheim Pharmaceuticals, Inc. and Genentech, Inc.

Step Up to the ATS Walking Challenge



You still have time to participate in the ATS Walking Challenge. Free wireless activity trackers are available on a first-come, first-served basis at the ATS Walking Challenge Booth, located in Lobby D (Level 2) at the convention center. The ATS Walking Challenge Mobile App also supports attendees who prefer to use their own FitBit, Jawbone or

iPhone/Android smartphone step counters.

You can watch the results unfold in real time on leaderboards in the Mylan booth (4333), or at the ATS Walking Challenge booth. The top 3 overall steppers win a prize and three randomly selected participants reaching the 30,000 step goal win a prize. Prizes are awarded at 9 a.m. Wednesday at the Walking Challenge booth in

Lobby D. (You must be present to win as prizes are not shipped)

Don't forget, the ATS Walking Challenge also supports the ATS Foundation Research Program. For every participant who walks 30,000 steps during ATS 2019, Mylan makes a donation of \$100 to the ATS Foundation, with a total maximum donation of \$50,000 to fund new research awards in pulmonary, critical care, and sleep medicine. ●

FUTURE SCIENCE

Continued from page 1

creating opportunities to overcome barriers and make breakthroughs on the causes, diagnosis, prevention, and treatment of lung diseases and sleep disorders, said Dr. Gibbons. In the early years, this was coupled with strategic training programs to prepare the researchers for the future.

“Even today, DLD takes a multidisciplinary approach to discovering treatments and improving care for patients who have lung diseases and sleep disorders by creating connections between stakeholders and scientists,” he said.

Most key scientific advances in pulmonary health and disease since the DLD's creation can be seen in lower mortality from neonatal respiratory diseases and acute lung injury, improved survival in patients with cystic fibrosis, new treatments for people with asthma and COPD, and better understanding of health risks for individuals who have sleep apnea, said Dr. Gibbons.

“We have a much greater understanding at a molecular level about the heterogeneity of a disease, positioning us for more tailored, precise treatments with less untoward effects,” he said. “We are hopeful

that this greater understanding will create opportunities to detect lung diseases in their earliest stages, before symptom development, and allow us to intervene to prevent disease progression.”

Going forward, the DLD will continue to foster discovery, said Dr. Gibbons. Guided by the NHLBI's Strategic Vision established in 2016, the DLD has set four strategic priorities: Prevention, Regeneration, Precision Medicine, and Implementation.

“Although pulmonary disease remains a major challenge, there are also tremendous future possibilities, including a cure for cystic fibrosis with gene-editing technologies and exciting research in sleep and circadian rhythms, such as discovering how sleep may protect against heart disease,” said Dr. Gibbons. “New bioengineering approaches open the real possibility of regenerating or rebuilding a new lung. The DLD is also spearheading an exciting, new asthma network, called PreCISE, to test more advanced, precision approaches to severe asthma management, which could serve as a model for testing precision approaches to the management of other lung diseases.” ●

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if it were right in front of your face?

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TODAY'S TOP TWEETS #ATS2019

After caring for patient after patient with acute lung injury/ARDS due to pneumonia, I couldn't read enough of the work of Prof. Bhattacharya and others @ColumbiaMed. I couldn't think of someone more worthy to present the Amberson Lecture at #ATS2019.



@pneuma_md

Speaker after speaker at the marijuana session at #ATS2019: "We desperately need more high quality research" as legalization spreads rapidly.

@NJHealth



The Dream Team of Persian Sleep Experts #ATS2019 #Sleep @SleepKid

@leilagozal



Dr. Pi Chun Cheng from @ChildrensPhila presented an interesting case of exogenous lipoid pneumonia in a teen who was wearing 5 coats of lip gloss several times daily, showing the value of the patient history in pulm medicine! #ATS2019 #FOAMPULM #FOAMCC @RAMirahmadi

What ATS really should have arranged is a screening of the game of thrones finale @atscommunity #ATS2019. Nothing brings you together like the battle for thrones! @virenkaul

@Re_innervated



Dr. Jacqueline Kruser talks about the unmet needs in end-of-life care in patients in the ICU at ATS 2019 #CriticalCare #LungDisease #Lungs #Pulmonary #ATS #ATSchat #ATS2019

@tmmRESPIRATORY



Congratulations to @PACCM Fellowship Associate Program Director @KevenRobinson6 who won the Rising Star Award from the Allergy, Immunology, and Inflammation Assembly at #ATS2019 @AlcornLab @morrissa1668 @ChildrensPgh @atscommunity

@PACCM_fellows

@drmarkware: Most cannabis policy changes have happened because patients pushed for it. Industry came secondarily #ATS2019

@drstanbrook



I need a miniature version of these lungs for my future office! @MayoPCCM @GallodeMoraesMD @KaraDupuy #pulmnerd #ATS2019

@aeaganMD

Instagram

Join the #ATS2019 photo Instagram Challenge



Applications Now Being Accepted



Gilead Sciences Research Scholars Program In Cystic Fibrosis

The program supports innovative scientific research that will advance knowledge in the field of cystic fibrosis, and provides support for 3 junior faculty researchers in Canada, Europe, or the United States for a 2-year period. Each award will be funded up to USD130,000, to be paid in annual installments of up to USD65,000.

Awards are subject to separate terms and conditions

SCIENTIFIC REVIEW COMMITTEE

Applications will be reviewed by a committee comprised of internationally recognized experts in basic and clinical research in the field of cystic fibrosis

**Application Deadline:
Friday, August 9, 2019, 11:59 PM Eastern Daylight Savings**

For more information and to apply for an award, please visit:

<http://researchscholars.gilead.com>

Click on the CF program logo



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