May 17-22, 2019 Dallas, TX

Let's discover together.

ATS DAILY BULLETIN

Where today's science meets tomorrow's care

Connect with ATS #ATS2019

Sunday, May 19, 2019

Collaborating for a Brighter Future

Polly Parsons, MD, ATSF, president of the American Thoracic Society, opened the 115th ATS International Conference Saturday afternoon by welcoming Mary E. Klotman, MD, dean of the Duke University School of Medicine and vice chancellor for Health Affairs, as the guest speaker.

An NIH funded investigator, Dr. Klotman focuses on the molecular pathogenesis of HIV-1. She and her team demonstrated that HIV resides in and evolves separately in kidney cells, a critical step in HIV-associated kidney disease. She said 25 years ago there was not much known about the connection between HIV and kidney disease. But today, thanks to input from many different team collaborators, it is all known.

"Teamwork is now a science," she said. Great solutions can be uncovered to knotty problems by building diverse cognitive teams, not necessarily like-minded individuals from the same background, she added.

"Diverse perspectives really contribute to success," she said. That includes diversity in perspectives, education, and culture.

One example she gave is MEDx at Duke, a collaboration of members from the Duke Schools of Medicine and Engineering where they developed a device that allows one nurse to turn a patient without getting hurt.

Dr. Klotman said the same principles of team science can be applied to clinical health systems and their academic institutions.

The Deep Care Management Project investigated ways to reduce costs. She said inpatient care accounts for 30 percent of Duke Connected Care total costs with primary admissions representing 90 percent of the cost burden.

By putting unusual teams of clinicians, researchers, data scientists, and health system providers together, she said they were able to take health records of Medicare patients and develop predictive algorithms to reduce unplanned admissions for at-risk patients.

Mary Klotman, MD, addressed how the intersection of diversity in collaboration can yield solutions to big problems.

She observed that diverse teamwork is forcing us to "redo" education.

"If we expect our physicians and scientists to work together in teams, we have to train them. We

see OPENING CEREMONY page 38

DON'T MISS THESE EVENTS

Clinical Year in Review 1
9:15-11:15 a.m., Hall A (Level 2), KBHCCD

Rapid Abstract Poster Discussion Session, NTM: Bench to Bedside
2:15-4:15 p.m., Ballroom A Four (Level 2), KBHCCD

Reception for PhDs & Other Basic Science Researchers
3-5 p.m., Science and Innovation Center

Lesbian, Gay, Bisexual, Transgender, and Questioning Allies (LGBTQ) Interest Group
6-8 p.m., Hyatt Regency Dallas, Cockrell

Using Big Data to Shape a New LHS

Imagine a health care system so advanced that it continuously gathers and analyzes the massive amount of data generated in the ICU to improve patient care in real time.

"When the system is optimized, patients can be confident that we're learning from the care we provide every day," said Vincent Liu, MD, research scientist at the Kaiser Permanente Division of Research in Oakland, California, and a co-chair of the session. "That means safer care and better outcomes for patients."

Vincent Liu

Dr. Liu is speaking of a Learning Health System (LHS) that leverages high-quality evidence, internal data and informatics, and systematic implementation to improve everyday patient outcomes in critical and other care settings.

"We care for hundreds, thousands, millions of patients each day," Dr. Liu noted, explaining the traditional approach to improving patient care can take a long time to get and implement results. "The LHS describes a feedback loop that uses data from our practices so we can make our care better with a relatively short lag time."

An LHS doesn't happen naturally, though. It requires investment and expertise from health care's top minds to get the system running. Much of it has to do with extracting big data from existing electronic health record systems (EHRs). "We're sitting on billions of data elements that are essentially

see BIG DATA page 35

Critical Care 2.0: Integrating Big Data, Clinical Trials, and Implementation Science to Create a Learning ICU System

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

Room C146 (Level 1), KBHCCD

Exhibit Hall Hours

Sunday, May 19
10:30 a.m.–3:30 p.m.
Unopposed Hours: 1:15–2:15 p.m.

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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GILEAD

ATS Pays Tribute to Scientists

Three scientists were recognized for their exceptional contributions to medicine and research during the opening ceremony on Saturday. Yvonne J. Huang, MD, received the Jo Rae Wright Award for Outstanding Science; Peter Sly, MD, DSc, received the World Lung Health Award; and Dona Upson, MD, received the Public Service Award.

JO RAE WRIGHT AWARD FOR OUTSTANDING SCIENCE

Dr. Huang's research on the role of the microbiome in airway disease phenotypes has led to new insights and hypotheses, and her cystic fibrosis expertise has contributed to understanding microbiome-disease-phenotype relationships across chronic inflammatory airway diseases.

She has co-led a number of investigations of the lower airway microbiome in asthma and COPD, including multicenter studies performed by the NHLBI-sponsored Asthma Clinical Research Network and AsthmaNet, and more recently in SPIROMICS. Currently, her laboratory at the University of Michigan is applying cross-disciplinary translational approaches, including in vitro, ex vivo and computational methods, to understand microbiome interactions that shape asthma and the COPD phenotype.

Dr. Huang has served on numerous committees and panels regarding microbiome science and respiratory disease, including for the National Academy of Science, Engineering, and Medicine. She received a Young Physician-Scientist Award from the American Society for Clinical Investigation, and the ATS-Allergy, Immunology & Inflammation Assembly Early Career Achievement Award.

WORLD LUNG HEALTH AWARD

Dr. Sly of Melbourne, Australia, has been an international leader in pediatric respiratory research for three decades, making major contributions to the understanding of how lung disease begins in early life. From a background in respiratory physiology and clinical pediatric respiratory medicine, Dr. Sly's research has been instrumental in understanding the major risk factors for the development of asthma and for the initiation and progression of lung disease in infants with cystic fibrosis.

Dr. Sly has been a prominent figure in international public health through his work with the World Health Organization, including his collaboration with the WHO Department of Public Health, Environment and Social Determinants and Health, as well as the establishment and direction of the WHO Collaborating Centre for Research on Children's Environmental Health in Perth and the WHO Collaborating Center for Children's Health and Environment in Brisbane.

His current research interests include preventing asthma, improving the detection of early lung disease in children with cystic fibrosis, and improving assessment of adverse environmental exposure in early life.

PUBLIC SERVICE AWARD

Dr. Upson has testified before Congress to increase VA research funding, and on the importance of clean air to children's health; and during local and state hearings. She received the American Lung Association's Clinton P. Anderson award "for outstanding work and commitment to the citizens of New Mexico" and the Volunteer of the Year award (Albuquerque) for chairing the Air Quality Board. Dr. Upson is working to educate clinicians and the public about electronic nicotine delivery systems, and recently contributed to the New Mexico PBS documentary, "VAPE."

Dr. Upson has been an active ATS member since 1988 and has served on numerous committees and councils in various positions. She co-founded the LGBTQ Interest Group and is currently serving her fourth year as chair for the Health Policy Committee and her second year as Section Editor for Health Policy and Financing for AnnalsATS. She works to provide education about electronic nicotine delivery systems and is involved in ATS-funded projects to develop clinical practice guidelines for the treatment of tobacco dependence and supplemental oxygen therapy. ●

Inspired to Learn

By Jess Mandel, MD
International Conference Committee Chair

Jess Mandel

On behalf of the American Thoracic Society International Conference Committee, welcome to Dallas and ATS 2019!

Since 1904, when the forerunner to the ATS held its first conference, the touchstone of this event has been the realization that progress in science and health is best achieved by sharing information. At ATS 2019, you'll find the leaders in pulmonary, critical care, and sleep medicine leading sessions and sharing their views. You'll also find tomorrow's leaders—some who haven't yet finished their training—presenting their research.

What ties them—and every one of us—together is a shared passion for this field and the belief that we can all learn from each other. Think, for instance, what those of us who trained in the last century can learn from early career professionals about integrating technology into our practices. Think how much more we learn from having participants from around the world. Solutions to world health problems depend on bringing perspectives from both resource-rich and resource-limited countries together.

Advances in our field also require learning from colleagues outside of pulmonary, critical care, and sleep medicine. This is why many of the sessions at ATS 2019 will include presenters from outside our field of medicine and, sometimes, from outside medicine itself.

The scope of the International Conference is inspiring but makes summarizing impossible. Nonetheless, I would like to offer a few highlights:

Big Data, machine learning, artificial intelligence, and data sharing are likely to change pulmonary, critical care, and sleep medicine and are topics that will be discussed at several sessions, including our keynote addresses.

The New England Journal of Medicine and the Journal of the American Medical Association will again present the latest groundbreaking research in respiratory and critical care medicine during two sessions today featuring the study authors and journals' editors.

The Basic Science Core topic, "Cell Fate Determination in Lung Health and Disease," will highlight a promising, and growing, area of research during symposia throughout the conference.

Experts will lead Year-in-Review sessions every day for adult and pediatric specialists, reviewing practice-changing studies and discussing clinical questions that remain unanswered.

An ATS Clinical Practice Guidelines session on Tuesday afternoon will give participants a chance to understand the strengths and limitations of the ATS's latest guidelines, as well as ask questions of guidelines developers.

Wherever you go during the conference, I'm confident that you'll find a collegial environment that inspires you to learn and to become an active participant in the important changes that will bring hope to pulmonary, critical care, and sleep patients around the world. ●

KEYNOTE SERIES

Decisions and Implementation Science

Artificial intelligence, data sharing, inclusiveness in medicine, and decision-making are a few of the themes you can expect from ATS 2019 keynote speakers. This diverse group of speakers will present cutting-edge research and their perspectives on a variety of topics highly relevant to the pulmonary, critical care, and sleep medicine community.

Keynotes are presented at 8 a.m. each day, when no other programming is scheduled.

Today's speakers will examine medical decision-making and implementation science.

When Experts Disagree: The Art of Decision-Making (K1)

Ballroom C One-Two (Level 2), KBHCCD

Two speakers will present the first lecture. They are Jerome E. Groopman, MD, professor of medicine at Harvard Medical School and chief of experimental medicine at Beth Israel Deaconess Medical Center in Boston, and Pamela I. Hartzband, MD, assistant professor at Harvard Medical School and attending physician in the Division of Endocrinology at Beth Israel Deaconess Medical Center.

Drs. Groopman and Hartzband will present the formula used in classic medical decision analysis and identify its limitations. They will also discuss the different mindsets that patients and doctors may bring to choosing among several treatment options.

Dr. Groopman is one of the world's leading researchers in cancer and

see KEYNOTE SERIES page 35

Jerome E. Groopman

Pamela I. Hartzband

ATS Daily Bulletin

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JAMA/NEJM Editors, Authors Discuss New Research

Be a part of the discussion as editors and authors present papers that were recently published in the Journal of the American Medical Association and the New England Journal of Medicine.

These interactive sessions provide a forum for attendees to have a question-and-answer period with the authors and editors, who select published papers to discuss at the conference based on their significance to the fields of critical care medicine (Session A84) and pulmonary medicine (Session A2).

These discussions are intended to provide insight into the papers, the selection process, and how research applies directly to each of these important fields of medicine.

Jeffrey Drazen, MD, will co-chair the morning session. Dr. Drazen is editor-in-chief of NEJM, a senior physician at the Brigham and Women's Hospital in Boston, and professor of physiology at the Harvard School of Public Health. George T. O'Connor, MD, will also co-chair this session. Dr. O'Connor is professor of medicine at Boston University School of Medicine and an associate editor for JAMA.

Howard Bauchner, MD, JAMA editor-in-chief, will co-chair the afternoon session. Dr. Bauchner is vice chair of pediatrics at the Boston University School of Medicine. He has published more than 125 papers in peer-reviewed journals. Dr. Drazen, MD, who co-chairs the morning session, will also co-chair this session. ●

NEJM and JAMA Discussion on the Edge: Reports of Recently Published Pulmonary Research (A2)
9:15 a.m.-11:15 a.m., Sunday
Room D163/D165/D170/D172 (Level 1), KBHCCD

JAMA and NEJM Discussion on the Edge: Reports of Recently Published Critical Care Research (A84)
2:15 p.m.-4:15 p.m., Sunday
Room D163/D165/D170/D172 (Level 1), KBHCCD

PAR Encourages Patient Empowerment

Taking charge of your own lung health was the theme of Saturday's ATS Public Advisory Roundtable (PAR) Meet the Experts panel. The PAR panel opened with a two-hour panel featuring five experts who explored pulmonary rehabilitation, oxygen therapy, clinical trials, and shared decision-making as they relate to lung health.

For patients with lung diseases, PAR Meet the Experts serves as an opportunity to learn more about their diseases—and themselves.

"I'm 22, and I don't know much about my own disease," said Jewella Sky of Joshua, Texas, who has primary ciliary dyskinesia. "I found out about it PAR through a small Facebook group I have with people with PCD worldwide. Someone posted on Facebook that this was going on in Dallas, and there's not a lot out there on PCD. I have some questions for my doctors now. Like, alright, I've learned all this stuff, so what can we do about this?"

Barb McManemin, from Dallas, came to hear from experts who specialize in her own disease, lymphangioleiomyomatosis (LAM).

"There were a number of different topics that they discussed," she said. "Something as simple as oxygen was really educational." Ms. McManemin said she learned different ways of delivering oxygen, as well as therapy for increasing pulmonary function on your own, whether at the office or at home. She is particularly interested in treatments that might benefit her in the future as she ages.

"Because my disease is a progressive disease, I won't get well," she said. "I've had it for two years, and I've been kind of in denial, so now it's time for me to get educated."

Presenters at PAR Meet the Expert included:

- Anne-Marie Russell, PhD, MScN, on "Shared Decision-Making: Partnership to Empower Patients"
- Daniel Croft, MD, MPH, on "Myths and Misconceptions: Managing Your Work and Home Space for Lung Health"
- Narelle Cox, PhD, on "Pulmonary Rehabilitation: What? Why? Who? Where?"
- Kathleen Lindell, PhD, RN, on "The Importance of Oxygen Therapy in Lung Disease"
- Kelly Chin, MD, on "Your Role in Clinical Trials"

Following the presentations, attendees broke out into five different ballrooms for discussion sessions covering:

- Allergy/Asthma
- chILD
- Hermansky Pudlak Syndrome
- LAM/Tuberous Sclerosis Complex
- Scleroderma
- Lung Transplant
- Primary Ciliary Dyskinesia
- Pulmonary Fibrosis
- Sarcoidosis ●

Sharp Intakes: RIS Unites Innovators and Investors

The second annual Respiratory Innovation Summit welcomed nearly 70 speakers and more than two dozen startup companies who previewed dozens of new therapies, drugs, devices, and diagnostics designed to treat respiratory disease.

Each of these innovators, investors, and clinicians is leading the fight to create powerful treatments for deadly and crippling diseases of the lungs and airways, and this event provides an opportunity to connect them during single-hour "spotlight" presentations.

Two dozen startups were given the opportunity to present to an audience that included entrepreneurs, investment banks, venture firms, large medical technology companies, and more—an intentional choice made with the hope of driving awareness and, ultimately, funding.

As she did last year, RIS Co-Chair Cecilia Gonzalo, partner at Oberland Capital, led off RIS with a call out to investors to commit more capital to this underfunded space. "We hope that this year's Respiratory Innovation Summit accomplished its mission of bringing together multiple stakeholders to advance innovation in the respiratory space to serve patients in need of new therapies," Ms. Gonzalo said.

This year's spotlights focused heavily on four main areas: airway disease, idiopathic pulmonary fibrosis and interstitial lung disease, interventional pulmonology, and artificial intelligence. Within each spotlight, clinicians gave a short overview of those areas and participated in panel discussions with start-up and industry executives.

Research Innovation Summit panel discussion on interventional pulmonology. From left: C. Matthew Kinsey, University Of Vermont; Jason Pesterfield, Veran Medical Technologies; Beran Rose, Pulmonx; Momen Wahidi, Duke University; and Dennis Wahr, Nuvaira.

Other discussions held during the day included:

- How Innovation Impacts Patient Perspectives
- How to Find—and Fund—Innovative Respiratory Ideas
- Emerging Medtech M&A and Fundraising Trends
- The Future of Financing Respiratory Start-Ups

The program has strong support from ATS leadership, including its Drug, Device, Discovery, and Development (Quad D) Committee. Tim Watkins, MD, MSc, who is chair of the DDDD committee and co-chair of RIS, said the program brought necessary attention to respiratory innovation.

"The strong showing at this year's RIS reflects the rising interest in new respiratory therapies," said Dr. Watkins, who also is director of clinical research in respiratory/inflammation therapeutics at Gilead Sciences. "We look forward to building on the momentum this year and increasing the size of the RIS community in 2020." ●

Product Presenters

This year's startup companies that presented at the Research Innovation Summit:

- 4Dx Limited
- Altavant
- Amiko
- ArtiQ
- AVISA
- Bellerophon Therapeutics
- Body Vision Medical
- Cohero Health, Inc.
- Eldec Pharmaceuticals
- FLUIDDA
- Gala Therapeutics
- HCmed Innovations
- Indalo Therapeutics
- Inscope Medical Solutions
- Lungpacer Medical, Inc.
- Nuvaira
- Optellum
- Pharmosa Biopharm Inc.
- Pliant Therapeutics
- Pulmocide
- Savara Inc.
- Sommetrics, Inc.
- Spire Health
- VIDA

OLYMPUS®

A Proven New Direction
in Severe Emphysema Treatment

The Olympus Spiration® Valve System

The Spiration Valve System (SVS) for bronchoscopic lung volume reduction is proven to improve lung function, reduce shortness of breath, and restore quality of life.[1] The SVS has demonstrated a strong risk benefit profile, with a low rate of serious pneumothorax and minimal risk of valve migration and expectoration.*

It also offers noninvasive patient selection, a short procedure time, and the assurance of Olympus' expertise in medical and respiratory technology.

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Serious adverse events observed in the EMPROVE study include COPD exacerbations, pneumothorax, pneumonia and death[1]
* 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

 I svs.olympusamerica.com I OAIRES0319AD29703

Rounds Honored as ATS Foundation Champion and Benefactor

Throughout her career, Sharon I.S. Rounds, MD, has been a teacher, a mentor, a champion of diversity, and a pioneer. She has been a distinguished researcher and a leader. She's worked toward not only her own success, but to help others be successful, too.

For these reasons and more, the ATS Foundation identified Dr. Rounds as the recipient of the 2019 Breathing for Life Award—the highest honor given to an ATS member for philanthropy—during the 11th annual ATS Foundation Research Program Benefit on Saturday evening at Union Station in Dallas.

As ATS president in 2004-05, Dr. Rounds championed the formation of the ATS Foundation. In addition to being one of the most generous supporters of the Foundation, she served on the Foundation's board from 2012 until 2018.

Throughout her career, Dr. Rounds has pressed for more opportunities for women and minorities in the fields of pulmonary, critical care, and sleep medicine, both at Brown University, where she is a professor and associate dean for clinical affairs, and the ATS. Along with Alvin Thomas, MD, and Estelle Gauda, MD, she created the ATS Minority Trainee Development Scholarships program two decades ago.

"This is the history of the United States of America: We're only as good as our diversity," she said. "It makes us better health care professionals, and it makes our research more relevant to the needs of the community."

Elizabeth Harrington, PhD, considers Dr. Rounds a pioneer. She was among the few women "to do many things during her career in a very male dominated field," said Dr. Harrington, who is co-director with Dr. Rounds of the CardioPulmonary Vascular Biology Center for Biomedical Research Excellence.

At a time of life when many consider retiring, Dr. Rounds remains active as a mentor, researcher, and clinician. She also remains active in the ATS.

One might think that her many committee assignments and leadership roles within ATS are a way of paying the Society back for helping to launch her career. But Dr. Rounds, characteristically, offers a humbler explanation.

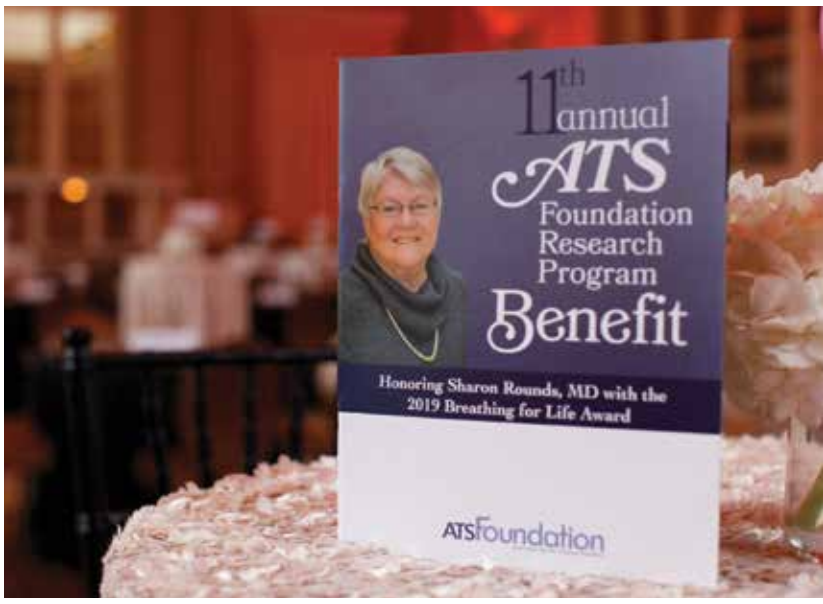
"I view my time contribution to ATS, not as work, but as fun," she said. "The ATS is interesting and engaging and keeps my mind off things that I might find boring."

The ATS Foundation is now accepting applications for the 2019-2020 Research Program grant cycle. Letters of intent are due by June 17, 2020.

The ATS Foundation extends a special thanks to GlaxoSmithKline, which supported this year's benefit at the Sapphire level for the first time. For the fifth year, Genentech supported the benefit at the Sapphire level, bringing its commitment to the next generation of researchers to a half-million dollars.

The Foundation also thanks: Mylan Inc./Theravance Biopharma at the Crystal Level; Mallinckrodt Pharmaceuticals, Novartis Pharma AG, and Sanofi Genzyme Regeneron at the Gold Level; AstraZeneca LP, Boehringer Ingelheim Pharmaceuticals, Inc., FREEMAN, Gilead Sciences, Inc., Insmed Incorporated, Sunovion Pharmaceuticals Inc., and Vertex Pharmaceuticals Inc., at the Silver Level; and Ascend Media, National Board for Respiratory Care, and Sunovion Pharmaceuticals Inc., at the Bronze Level.

For the most up-to-date list of generous donations from individuals, medical institutions, and corporate supporters of the ATS Foundation, visit **foundation.thoracic.org/benefit.** ●



BREATHING FOR LIFE AWARD RECIPIENTS

James F. Donohue, MD (2018)
David Center, MD (2017)
Sally Wenzel, MD (2016)
Marvin Schwarz, MD (2015)
William Busse, MD (2014)
Gerard Turino, MD (2013)
Talmadge King, Jr., MD (2012)
Louis Libby, MD (2011)
Sen. Mike Crapo (R-Idaho) (2010)
ATS PAR (2009)

Please join us for an Industry Theater exploring

A Treatment for Pulmonary Arterial Hypertension (PAH, WHO Group I): Targeting the Prostacyclin Pathway

The management of pulmonary arterial hypertension (PAH) continues to evolve, with targeting multiple pathways through sequential combination therapy now at the forefront of treatment strategies. This interactive, case-based theater will feature a PAH thought leader who will discuss a treatment for PAH, targeting the prostacyclin pathway.

12:20 – 1:05 PM CDT
Sunday, May 19, 2019
Presentation and Lunch

Medium Theater
The ATS 2019 Exhibit Hall
The Kay Bailey Hutchison Convention Center
Dallas

Featured Faculty:
Rajeev Saggar, MD
Executive Director, Lung Institute
Dir. of Pulmonary Hypertension and Fibrosis Programs, University of AZ
COM-Phoenix Banner University Medical Center-Phoenix
Phoenix, Arizona

For all attendees, please be advised that information such as your name and the value and purpose of any educational item, meal or other items of value you receive may be publicly disclosed. If you are licensed in any state or other jurisdiction, or an employee or contractor of any organization or governmental entity, that limits or prohibits any items of value from pharmaceutical companies, please identify yourself so that you (and we) are able to comply with such requirements.

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An Industry Theater presentation at the ATS 2019 International Conference. This presentation is sponsored by Actelion Pharmaceuticals US, Inc., a Janssen Pharmaceutical Company of Johnson & Johnson, and is open to all ATS 2019 International Conference attendees. This promotional educational activity is not accredited.

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Taking Credit: MOC and CME

Each year, the ATS Educational and the International Conference committees collaborate to ensure that International Conference symposia are eligible for Maintenance of Certification points.

ATS 2019 attendees are able to earn up to 54.5 American Board of Internal Medicine MOC Medical Knowledge points and 20 American Board of Pediatrics Part 2 MOC Self-Assessment points.

In addition to the adult and pediatric Core Curriculum there are 26 symposia that are eligible for MOC and will cover adult pulmonary, critical care, and sleep medicine as well as pediatric pulmonary symposia. The Adult and Pediatric Symposia eligible for MOC at the conference can be found at **http://conference.thoracic.org/program/moc.php**

HOW TO EARN MOC POINTS AT ATS 2019

During ATS 2019: Attend any or all of the MOC symposia you are interested in. These sessions will be highlighted in the Final Program.

After ATS 2019: Take the post-session test. All the tests are available on Wednesday, May 22, 2019, 4 pm CST and attendees can take the tests at no cost through July 31, 2019. Please note: audience response during a session does *not* count at the post-test.

HOW TO EARN CME ATS 2018

There are two separate pathways for claiming MOC and CME. In order to claim both CME and MOC you will need to follow steps for both. You must pass the MOC post-test to earn MOC and complete the CME evaluation to claim CME. Claiming one will not automatically transfer to the other. ●

"Through my membership in the ATS, the largest professional society in our field, I have been able to develop collaborations with amazing clinicians, educators, and researchers all across the country."

Michelle Sharp, MD, MHS

Post-Doctoral Fellow in Pulmonary and Critical Care
Johns Hopkins University School of Medicine

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Search for ATS (**@atscommunity**) on Snap Chat. Followers can check the "Our Story" page for behind-the-scenes pictures and conference videos.

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 Insmed. Due to regulatory restrictions, this presentation is only available to attendees from the United States.

NP-US-01041A

Enrich Learning With Non-CME Symposia

The ATS encourages Non-CME Symposia in conjunction with the 2019 International Conference. These programs complement the content offered by the ATS and provide an opportunity for attendees to further enrich their learning experiences. Please see the Tuesday issue of the ATS 2019 Daily Bulletin for a list of Tuesday Non-CME Symposia.

6:30-9:30 p.m.

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

Hyatt Regency Dallas, Landmark Ballroom C

Eosinophilic Granulomatosis with Polyangiitis (EGPA), formerly known as Churg-Strauss syndrome, is a rare vasculitis that often involves the respiratory tract, affects small-to-medium vessels, and is associated with asthma and eosinophilia. This educational session will review the pathogenesis, clinical manifestations, classification criteria, diagnosis, and prognosis of EGPA.

Speaker: **Michael Wechsler, MD, MMSc**, *professor of medicine, director of the asthma program at National Jewish Health, director of the Cohen Family NJH Asthma Institute, division of pulmonary, critical care and sleep medicine in the department of medicine at National Jewish Health and University of Colorado School of Medicine*

Company: GlaxoSmithKline

6:30-9:30 p.m.

A Multidisciplinary Case Study Approach: From Recognition to Progression of Fibrosing ILDs

Sheraton Dallas Hotel, Lone Star Ballroom A2-A4

This symposium will enlist an expert multidisciplinary panel detailing various clinical presentations of progressive fibrosing interstitial lung diseases. Case studies will be used and will focus on initial clinical presentations of various fibrotic ILDs, disease progression over time, and how identifying the progressive phenotype of ILD-associated diseases will help guide patient care decisions.

Speakers: **Gregory P. Cosgrove, MD, FCCP**, *assistant director of the interstitial lung disease program, endowed chair in interstitial lung disease at National Jewish Health;* **Flavia V. Castelino, MD**, *director of the scleroderma program, assistant professor of medicine at Massachusetts General Hospital, Harvard Medical School;* **Lida Hariri, MD, PhD**, *assistant pathologist, assistant professor of pathology at Massachusetts General Hospital, Harvard Medical School;* **Geoffrey D. Rubin, MD, MBA, FACR**, *George G. Gellar Distinguished Professor of Radiology at Duke University School of Medicine*

Company: Boehringer Ingelheim Pharmaceuticals, Inc.

6:30-9:30 p.m.

An Add-On Maintenance Treatment Option for Patients With Moderate-to-Severe Uncontrolled Asthma Driven by Type 2 Inflammation

Fairmont Dallas, International Ballroom

The session will begin with a presentation of an add-on maintenance treatment option for certain patients with moderate-to-severe asthma. The presentation will cover the approved indication, mechanism of action, and supporting clinical data. Following the session, our moderators will lead an interactive discussion of several hypothetical patient cases for whom this treatment option may be appropriate.

Speakers: **Geoffrey Chupp, MD**, *director at the Yale Center for Asthma and Airway Disease;* **Laren Tan, MD**, *assistant professor of internal medicine at Loma Linda University Medical Center*

Company: Sanofi Genzyme and Regeneron

6:30-9:30 p.m.

Bronchiectasis: Emerging Trends and Unmet Needs

Fairmont Dallas, Regency Ballroom

In this non-CME educational symposium, global non-cystic fibrosis bronchiectasis experts describe why awareness of the condition is growing, how to accurately identify patients with NCFB, and how to address symptoms within the framework of "treatable traits." They will present the latest research, clinical guidelines, and actionable information related to this under-recognized but critically important pulmonary condition.

Speakers: **Michael Polkey, MD**, *Royal Brompton Hospital in London, U.K.;* **Timothy Aksamit, MD**, *Mayo Clinic in Rochester, Minnesota;* **James Chalmers, MBChB, PhD**, *University of Dundee and Ninewells Hospital and Medical School in Dundee, U.K.;* **Tara Barto, MD**, *Baylor College of Medicine in Houston*

Company: RespirTech, a Philips Company

6:30-9:30 p.m.

Exploring Idiopathic Pulmonary Fibrosis With the Experts: A Multidisciplinary Program on the Diagnosis, Treatment, and Management of IPF

Sheraton Dallas Hotel, Austin Ballroom

Join us for an innovative symposium led by a multidisciplinary team of idiopathic pulmonary fibrosis (IPF) experts. In this interactive and case-based program, attendees will explore such topics as the importance of prompt diagnosis, the potential benefits and risks of treating patients with an FDA-approved IPF-specific therapy, and the steps for initiating and maintaining a comprehensive management plan.

Speakers: **Anne Whitney Brown, MD**, *director of clinical operations, Inova Advanced Lung Disease & Transplant Program, assistant professor of medicine, Virginia Commonwealth University School of Medicine Inova Fairfax Campus Falls Church, Virginia;* **Cedric Jamie Rutland, MD**, *Pacific Pulmonary Medical Group, assistant clinical professor of internal medicine, University of California, Riverside School of Medicine, Riverside, California;* **Jubal Watts Jr., MD,** *Radiology of Huntsville, Huntsville, Alabama*

Company: Genentech, A Member of the Roche Group

6:30-9:30 p.m.

In Pursuit of the Leaking Lymph: Nonmalignant Thoracic Lymphatic Disorders

Sheraton Dallas Hotel, Lone Star Ballroom B

Experts will discuss classification of pulmonary lymphatic disorders and evaluate new imaging and therapeutic approaches for the differentiation and treatment of these disorders. They will also assess pulmonary involvement in patients with lymphatic malformations. Interactive clinical case presentations will provide scientific pearls for integrating diagnostic and therapeutic algorithms into your practice.

Speakers: **Maxim Itkin, MD, FSIR**, *professor of radiology and pediatrics at the Center for Lymphatic Disorders at Perelman School of Medicine, University of Pennsylvania;* **Bruce K. Rubin, MD, MEngr, MBA, FRCPC**, *Jessie Ball duPont Distinguished Professor and chair in the department of pediatrics, professor of biomedical engineering, and physician in chief at Virginia Commonwealth University School of Medicine and Children's Hospital of Richmond at VCU;* **Christopher Towe, MD**, *assistant professor of pediatrics, pediatric pulmonary and pediatric lung transplant and director of rare lung diseases at Cincinnati Children's Hospital Medical Center*

Company: Vindico Medical Education, supported by an educational grant from Guerbet, LLC

6:30-9:30 p.m.

Nasal High Flow in the Critical Care Setting

Hyatt Regency Dallas, Landmark Ballroom A

This session highlights advances in improved care of respiratory failure and the clinical outcomes in critical care and emergency medicine using nasal high flow therapy. Clinical studies demonstrate that nasal high flow therapy may reduce escalation of care, reduce mortality rates, and improve symptomatic relief.

Speakers: **Nicholas Hill, MD**, *professor at Tufts University;* **Gregory Schmidt, MD**, *professor at the University of Iowa;* **Tomaso Mauri, MD, PhD**, *associate professor at the University of Milan*

Company: Fisher & Paykel Healthcare

6:30-9:30 p.m.

Systemic Sclerosis-Associated Interstitial Lung Disease: Expert Insights on Early Diagnosis and Optimal Management

Hyatt Regency Dallas, Marsalis Exhibit Hall A

A panel of expert faculty will offer insight to help clinicians achieve a greater understanding into the recognition, diagnosis, and management of systemic sclerosis and interstitial lung disease, including the latest clinical evidence with respect to emerging therapies.

Speakers: **Marilyn K. Glassberg, MD**, *director, interstitial lung disease program director, pulmonary diseases at interdisciplinary stem cell institute, professor of medicine, surgery, and pediatrics vice chair of medicine for diversity and innovation at the University of Miami School of Medicine;* **Aryeh Fischer, MD**, *associate professor of medicine division of rheumatology, division of pulmonary sciences and critical care medicine at the University of Colorado School of Medicine;* **Kristin B. Highland, MD, MSCR**, *associate program director for research and scholarly activity, pulmonary fellowship at the Cleveland Clinic*

Company: PVI, PeerView Institute for Medical Education, supported by educational grants from Boehringer Ingelheim Pharmaceuticals, Inc. and Genentech, a member of the Roche Group

Register: **PeerView.com/ILD19Dallas**

6:30-9:30 p.m.

Uncontrolled Obstructive Airway Diseases: Treatment and Stepwise Management Approaches to Severe Asthma and Exacerbations in Chronic Obstructive Pulmonary Disease (COPD)

Hyatt Regency Dallas, Landmark Ballroom B

Learn treatment and early management approaches to severe asthma and exacerbations in COPD. A national panel of experts will discuss the burden and impact of severe asthma as well as the challenges associated with overreliance on oral corticosteroids (OCS).

Speakers: **Nicola Hanania, MD; Gene Bleecker, MD; Gary Ferguson, MD**

Company: AstraZeneca

JOIN US FOR A MULTIDISCIPLINARY DINNER SYMPOSIUM

6:30 – 8:30 P.M., SUNDAY, MAY 19, 2019

SHERATON DALLAS HOTEL, AUSTIN BALLROOM

400 North Olive Street, Dallas, TX 75201

ANNE WHITNEY BROWN, MD

Director of Clinical Operations
Inova Fairfax Campus
Falls Church, VA

CEDRIC JAMIE RUTLAND, MD

Pacific Pulmonary
Medical Group
Riverside, CA

JUBAL R. WATTS, JR., MD, FCCP

Radiology of Huntsville
Huntsville, AL

Join us for an innovative symposium led by a multidisciplinary team of experts. In this interactive and case-based program, attendees will explore such topics as the importance of prompt diagnosis, the potential benefits and risks of treating patients with Esbriet® (pirfenidone), and the steps for initiating and maintaining a comprehensive management plan.

An Industry-Organized Symposium at the ATS 2019 International Conference.

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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ESB/030519/0016b 04/19

Esbriet® (pirfenidone) tablets 267 mg 801 mg

ADVANCED LUNG DISEASE DESERVES

ADVANCED LUNG CARE SPECIALISTS.

At Northwestern Memorial Hospital, the #1 hospital in Illinois, our nationally ranked pulmonary program is leading the way in innovative lung care. Our advanced lung disease programs are led by multidisciplinary teams experienced in treating complex cases. So you can rest assured, even after most medical therapies have failed, we are your optimal partner in improving patient care. Alongside our entire Northwestern Medicine family, we're committed to our relentless pursuit of better medicine.

For more information or to refer a patient, visit **nm.org/nmhats**

BEST HOSPITALS U.S.News & WORLD REPORT NATIONAL PULMONOLOGY 2018-19

BEST HOSPITALS U.S.News & WORLD REPORT HONOR ROLL 2018-19

BEST HOSPITALS U.S.News & WORLD REPORT NATIONAL RANKED IN 11 SPECIALTIES 2018-19

Northwestern Memorial Hospital

BETTER Northwestern Medicine®

Four Honored for Outstanding Efforts in Medicine

The ATS will recognize four physicians and researchers for their remarkable contributions to medicine during Sunday's Awards Session, featuring the Amberson Lecture and the presentation of the Trudeau Medal and two Distinguished Achievement Awards.

AMBERSON LECTURE

Jahar Bhattacharya, MD, DPhil., will deliver this year's Amberson Lecture on "Lung Injury as Seen Through the Lens of the Alveolus." He is professor of medicine and director of lung research at Columbia University in New York. The Amberson Lecture recognizes exemplary professionalism, collegiality, and citizenship through mentorship and leadership in the ATS community.

In his lecture, Dr. Bhattacharya plans to cover several key points including:

- Visualizing the onset of alveolar injury
- Macrophage-epithelial interactions in alveolar immunity
- Alveolar mitochondria in injury resolution

Dr. Bhattacharya said the goal of his lecture is to convey unique alveolar mechanisms of evolution and resolution of immunity. "The ATS membership will learn about new mechanistic approaches to therapy for lung injury."

Dr. Bhattacharya's live lung studies led to the discovery of a new class of lung macrophages, now called sessile alveolar macrophages (SAMs), that communicate Ca^{2+} with the lung epithelium via GAP junctions to suppress immunity during endotoxin challenge. His group has recently demonstrated that *S. aureus* stabilize in the lung in alveolar niches, accounting for the severity of lung injury in an infection model. His work has had implications for basic understanding of lung vascular biology, cellular physiology, immunity, and the pathogenesis and repair of acute lung injury.

EDWARD LIVINGSTON TRUDEAU MEDAL

The recipient of this year's Edward Livingston Trudeau Medal is Jacob I. Sznajder, MD. The Trudeau Medal recognizes lifelong major contributions to prevention, diagnosis, and treatment of lung disease through leadership in research, education, or clinical care. Dr. Sznajder is professor of medicine and cell and molecular biology at Northwestern University Feinberg School of Medicine in Chicago. His research has focused on the mechanisms of lung injury and edema clearance, effects of hypercapnia and hypoxia, and signal transduction pathways in the lungs. Dr. Sznajder is passionate about the training of physician/scientists and researchers of diverse backgrounds. For more on Dr. Sznajder, see his profile on page 27.

DISTINGUISHED ACHIEVEMENT AWARDS

John Hansen-Flaschen, MD, ATSF, and Meir Kryger, MD, will receive this year's Distinguished Achievement Awards.

Dr. Hansen-Flaschen is a professor of medicine at the University of Pennsylvania in Philadelphia. He served from 1990 to 2015 as the third chief of the Pulmonary, Allergy, and Critical Care Division at the university, where he also founded the multidisciplinary Paul Harron Lung Center in 2007.

Dr. Hansen-Flaschen redirected his scholarship to an exploration of the burdens endured by patients and family members in ICUs. At a time when many people thought the practice was tantamount to euthanasia, he was the first at the University of Pennsylvania to palliatively withdraw mechanical ventilation in the presence of family members and with full medical record documentation. The practice took hold locally and was reported in a series of newspaper articles published in 1983 that won a Pulitzer prize for the Philadelphia Inquirer. Dr. Hansen-Flaschen expanded on that experience to write about and advocate for routine, active engagement of intensivists in family-centered palliative care of patients near the end of life. He was also one of the first to draw the attention of medical intensivists to the benefits and perils of intravenous sedation and analgesia for the palliative management of acute respiratory failure.

Meir Kryger, MD, is a professor of medicine at Yale School of Medicine in New Haven, Connecticut, who has been treating patients with sleep disorders for more than 40 years. He has also worked as professor of medicine at the University of Manitoba in Canada, and was director of the Sleep Disorders Center at St. Boniface Hospital Research Center, the first clinical laboratory studying patients with sleep breathing problems in Canada. He described what is probably the first case of sleep apnea in North America while a trainee at the Royal Victoria Hospital in Montreal, Canada.

Dr. Kryger is chief editor of The Principles and Practice of Sleep Medicine, a textbook that is now in its sixth edition, and the Atlas of Clinical Sleep Medicine. He has published more than 200 peer reviewed articles and book chapters. His next project is called Dreaming in Color, which explores how artists look at sleep. ●

Awards Session (G2)
4:30-5:30 p.m., Sunday
Hall A (Level 2), KBHCCD

Join the Conversation #ATS2019

Enhance your International Conference experience by keeping connected through social media. Or join the conversation even if you can't make it to Dallas. Each day, the ATS promotes the conference on a variety of social media platforms. Staying social could even land you a prize.

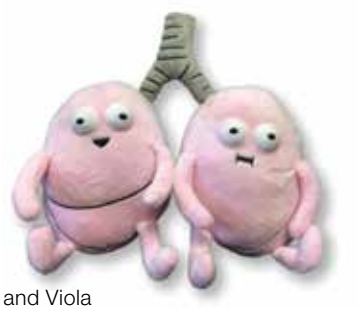
THE OFFICIAL HASHTAG IS #ATS2019.

Tweet **#ATS2019** and pick-up a ribbon IRL in the Kay Bailey Hutchison Convention Center Dallas in Lobby F (Level 2) next to Assisted Registration, to highlight your online participation! Make sure to print your Twitter handle on your badge, and add it to your ATS member page.

GET IN ON THIS YEAR'S INSTAGRAM CONTEST. HERE ARE THE RULES:

1. Follow **@atscommunity** on Instagram.
2. Comment on photos of Al and Viola with your best captions.
3. The ATS will choose up to three captions each day to win a prize!

Winners will be notified on Instagram. Contestants must be attending ATS 2019. Pick up your prizes at the Membership Booth in Lobby F, May 17-18, or the ATS Center (Exhibit Hall, booth 2726), May 19-22.



Al and Viola

Bonus: Run into Al and Viola at the conference? Take a selfie with them and post it to your Instagram! Look for your shot to be regrammed to the ATS IG page.

PREFER SNAPCHAT TO INSTAGRAM?

Simply scan this code to follow ATS (or search **@atscommunity**). Followers can check the "Our Story" page for behind-the-scenes pictures and conference videos.

THE ATS IS GOING LIVE ON FACEBOOK DURING ATS 2019!

Sunday, May 19, from 1 to 2 p.m. CT: How to Deal With Professional Conflicts

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) ●

ATS Walking Challenge: Get Moving

The ATS Walking Challenge is back as part of the ATS 2019 International Conference. Walk, stay active, or compete with colleagues all while helping the ATS Foundation Research program. The top three overall steppers win a prize and three randomly selected participants reaching the 30,000 step goal win a prize.

The ATS Walking Challenge supports the ATS Foundation Research Program in a big way. For every participant who walks 30,000 steps during ATS 2019, Mylan makes a donation of $100 to the ATS Foundation, up to $50,000.

Register today at the ATS Walking Challenge Booth located in Lobby D (Level 2) at the Kay Bailey Hutchison Convention Center.

Guru Bars: Lightning Learning Sessions

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 run every 30 minutes from 11 a.m. to 2 p.m. Sunday through Tuesday in the Exhibit Hall (Level 2, Halls C-F).

Education/Awareness/Prevention or Diagnosis

GURU BAR 1

11:30-11:50 a.m.

Best Practices in PFT Data Quality and Interpretation

Incongruences between pulmonary function test results, other respiratory diagnostic exams, and/or symptoms adversely affect clinical decisions in millions of cases where pulmonary functions testing is indicated each year. Learn how new best practices can eliminate these incongruences and provide diagnostic confidence in the PFT data you receive from your labs.

Speaker: **Tad Scheiblich, BS, MBA**, *director, clinical applications, nSpire Health*

Company: nSpire Health

12:30-12:50 p.m.

Bronchoscopic Lung Volume Reduction With the Spiration Valve System

Join us as we discuss the Spiration Valve System, an innovative endobronchial therapy that offers patients with severe emphysema a customized, minimally invasive treatment option for lung volume reduction with a favorable risk-benefit profile. Patients treated with the Spiration Valve System in clinical trials experienced improvements in breathlessness, lung function, and quality of life. For complete benefit and risk information, please visit **svs.olympusamerica.com.**

Speaker: **Gerard J. Criner, MD**, **ATSF**, *founding chair and professor of thoracic medicine and surgery of Temple University Health System*

Company: Olympus America Inc.

1:30-1:50 p.m.

Fluoroscopic Navigation Technology: Solving for CT to Body Divergence

As pioneers of ENB procedures, we take our responsibility of transforming lung cancer from a deadly disease to a managed condition seriously. That's why we continue to create technologies that help enable a better outcome for patients—including our latest innovation: Fluoroscopic Navigation Technology. Our new software algorithms use multiple fluoroscopic images which provide enhanced visualization of soft tissue objects like lung lesions, accurate modeling of 3-D distances on 2-D images, local registration to help compensate for local CT-to-Body divergence, updated catheter position relative to nodule, and the ability to visualize smaller nodules. Join us and Dr. Krish Bhadra in the discussion.

Speaker: **Krishnendu Bhadra, MD**, *interventional pulmonologist, CHI Memorial Medical Group*

Company: Medtronic

GURU BAR 2

12-12:20 p.m.

A New Therapeutic Option for Oral Corticosteroid Dependent Asthma

Our speaker will lead an interactive discussion of a hypothetical case with moderate to severe oral corticosteroid dependent asthma. The speaker will describe the data supporting an add-on maintenance treatment option that may reduce and possibly even eliminate the needs for the corticosteroids.

Speaker: **Cedric "Jamie" Rutland, MD**, *assistant clinical professor of internal medicine, University of California Riverside*

Company: Sanofi Genzyme and Regeneron

1-1:20 p.m.

Olympus Peripheral Solution—The Power to Bring the Periphery Closer

Join us for a discussion about the Olympus Peripheral Bronchoscopy Solution, which incorporates state-of-the-art bronchoscopes and devices that expand your possibility to reach more distal peripheral lesions better than before. The revolutionary BF-MP190F ultra-slim bronchoscope combined with the radial EBUS probe and the PeriView FLEX TBNA needle, enhance access and improve sampling capabilities bringing the periphery closer.

Speakers: **Alexander Chen, MD**, *assistant professor of medicine and surgery, director of interventional pulmonology, Washington University School of Medicine;* **Ali Sadoughi, MD**, *director of interventional pulmonology and bronchoscopy, assistant professor of medicine, Montefiore Medical Center*

Company: Olympus America Inc.

Treatment or Adherence/Compliance

GURU BAR 3

11:30-11:50 a.m.

Minimizing Patient Escalation With Effective Nasal High Flow

Confirm mechanisms of action and physiological effects. Outline role of nasal high flow with minimizing patient escalation. Practical application of nasal high flow.

Speaker: **Chris Hutchinson**, *senior product manager*

Company: Fisher & Paykel Healthcare

12:30-12:50 p.m.

Optimizing Post-Extubation With Effective Nasal High Flow

Confirm mechanisms of action and physiological effects. Outline role of nasal high flow with optimizing post-extubation. Practical application of nasal high flow.

Speaker: **Chris Hutchinson**, *senior product manager*

Company: Fisher & Paykel Healthcare

1:30-1:50 p.m.

COPD Exacerbations: Beyond Inhaler Treatment

Learn more about an available treatment option for patients with uncontrolled COPD continuing to exacerbate on current bronchodilator therapy. Enhance your knowledge and discuss an alternative to help prevent COPD exacerbations.

Speaker: **Sanjay Sethi, MD,** *VA WNY Healthcare System*

Company: AstraZeneca

GURU BAR 4

12-12:20 p.m.

Corecath: A Novel Way of Debulking Airways

As pioneers of ENB procedures, we take our responsibility of transforming lung cancer from a deadly disease to a managed condition seriously. That's why we continue to create technologies that help enable a better outcome for patients—including our latest innovation: the CoreCath™ 2.7S device. This electrosurgical device lets you remove soft tissue obstructions in the upper airways and tracheobronchial tree by debulking, coagulating, and evacuating surgical smoke with integrated suction. This multiple-application tool provides electrosurgical hemostasis and may be delivered through the working channel of a flexible bronchoscope, and is designed to reduce the number of tools in a procedure. Join us and Dr. Mahajan in the discussion.

Speaker: **Amit "Bobby" Mahajan, MD, FCCP, DAABIP**, *medical director of interventional pulmonology, Inova Heart and Vascular Center*

Company: Medtronic

1-1:20 p.m.

Robotics and the Future of Lung Cancer Diagnosis: A Community Hospital's Experience With the Monarch Platform

Stephen Kovacs, DO, FCCP, will host a presentation about his current use of the Monarch Platform in U.S. cases. Visit Booth 613 to learn more about the Monarch Platform.

Speaker: **Stephen Kovacs, DO, FCCP,** *co-director, UPMC Hamot Comprehensive Lung Center, UPMC*

Company: Auris Health ●

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

orenitram®
treprostinil
EXTENDED-RELEASE TABLETS

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

IMPACT EARLIER

with Orenitram for your FC II/III patients

Visit Booth #3511 to learn more

or www.ImpactEarlier.com for additional information

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
- 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

OREISIhcpJAN17

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).

United Therapeutics CORPORATION

orenitram®
treprostinil
EXTENDED-RELEASE TABLETS

BRIEF SUMMARY

The following is a brief summary of the full prescribing information for Orenitram® (treprostinil) 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

	Treatment (%)	
Reaction	**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—Treprostinil 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 treprostinil. 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 treprostinil. Additionally, treprostinil 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 treprostinil at an infusion rate of 10 ng/kg/min.

USE IN SPECIFIC POPULATIONS

Pregnancy—*Pregnancy Category C.* Animal reproductive studies with treprostinil 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 treprostinil treatment-related effects on labor and delivery were seen in animal studies.

Nursing Mothers—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.

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 treprostinil 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.

United Therapeutics Corporation, Research Triangle Park, NC 27709
Rx only
January 2017
www.orenitram.com
OREBShcpJAN17

United Therapeutics CORPORATION

Networking Events Offer a Global Connection

The ATS International Conference is where science and health care intersect. It's our aim to provide you with abundant opportunities to connect and engage with colleagues on the latest research and scientific breakthroughs and best practices in patient care. We're planning a number of special events and learning opportunities beyond the conference. Consider adding these events to your itinerary.

ATS FOUNDATION DONOR APPRECIATION SUITE

As a way to thank donors, the ATS Foundation will again feature its ATS Foundation Donor Appreciation Suite located in Hall B (Level 2) of Kay Bailey Hutchison Convention Center Dallas. Conference attendees who contribute $250 or more between June 2018 and May 2019 are invited to the suite to enjoy complimentary breakfast, refreshments, free Wi-Fi, concierge services, and private meeting rooms (be sure to reserve these ahead of time).

EARLY CAREER PROFESSIONALS

If you are a graduate or medical student, medical resident, clinical or postdoctoral fellow, or junior faculty member, these networking opportunities are for you.

The Center for Career Development, located in Hall B (Level 2) of Kay Bailey Hutchison Convention Center Dallas, will offer a complimentary breakfast each day at 7 a.m. and a Professional Networking Hour from 4 to 5 p.m. with free cocktails and appetizers. Each day during the conference, the CCD features informal workshops aimed at enhancing the professional development of early career professionals. You can learn more about CCD scheduled activities at **conference.thoracic.org/program/early-career-professionals/ccd.php**

ATS WOMEN'S AND DIVERSITY FORUMS

Take the opportunity to support women and diversity during two separate luncheon forums. The Diversity Forum takes place on Sunday and the Women's Forum will be on Monday. Both forums, which take place in the Hyatt Regency, Landmark D Ballroom, are free and include a plated lunch. Pre-registration is required, but there are usually seats available at the door on a first-come, first-served basis.

CLINICIANS CENTER

All clinicians are invited to meet, network, relax, refresh, and learn in the Clinicians Center and Learning Lab, located in Hall B (Level 2) of Kay Bailey Hutchison Convention Center Dallas. The Center is open Sunday through Wednesday. Every morning, coffee and a light breakfast will be available from 7 to 9 a.m. Educational programs kick off on Sunday. On Monday, May 20, don't miss the ATS Outstanding Clinician Award Reception.

INTERNATIONAL PARTICIPANTS CENTER

All international attendees are invited to stop by the International Participants Center, open Sunday through Wednesday in Hall B (Level 2) of Kay Bailey Hutchison Convention Center Dallas. Use the Center to connect with colleagues, network, or just relax while enjoying complimentary snacks, coffee, and soda.

Don't miss the reception to recognize international attendees and honor this year's International Trainee/MECOR award recipients on Tuesday, May 21, at the Center.

SCIENCE AND INNOVATION CENTER

Scientists and researchers looking to network, learn, and relax should plan some time in the Science and Innovation Center, open Sunday through Wednesday in Hall B of Kay Bailey Hutchison Convention Center Dallas. A complimentary breakfast will be served in the SIC each morning at 7 a.m. and light refreshments will be served each day at noon.

If you need to catch up on basics before attending a symposium, you can attend an SIC 101 series presentation. Look for a complete list of these online in the Resource Center at **conference.thoracic.org/attendees/resource-centers**. ●

Helping Lungs Self-Repair After Injury

Ten years ago, pulmonologists understood that a damaged adult lung could repair itself under certain circumstances via the plasticity of well-defined progenitor cells that sense when resident cells are damaged.

Although it was known in the medical community that progenitor cells in the lung move out to repair and repopulate portions of damaged lung, ongoing research suggests that progenitor cells are doing more than previously thought.

Gregory P. Downey, MD, ATSF, a pulmonologist at National Jewish Health in Denver, and one of the session's co-chairs, explained that it's now known that progenitor cells can move back and forth between the junctions of the airways and air sacs within the lung to repopulate damaged cells. Such knowledge is opening up many avenues through which researchers can manipulate experimentally and therapeutically to help the lung repair itself after injury.

This research is aided by cell fate determination, through which researchers gain the ability to tag specific cells and follow the cell's fate. Based on the cell's change over time, an inference can be made that the cell started out as "Cell Type X" and later turned into "Cell Type Y."

"Finding the signaling pathways and mechanisms to promote the healthy repair [of the lung] may provide a window in addressing some pretty important diseases of the lung," said Bruce D. Levy, MD, ATSF, of Brigham and Women's Hospital in Boston, a session co-chair.

"This session was designed with a broad audience in mind," Dr. Levy said. "Any provider—in particular those interested in COPD, pulmonary vascular disease, and those interested in translational research—(will find value here)." Additional conditions of interest include pulmonary fibrosis, pulmonary infections, ARDS, and LAM.

Although there is still much research to be completed before clinical interface, the topics within the symposia will be relevant to next-step translational research that will lead to the therapeutic interventions relevant to clinical care. Basic scientists, clinical translational scientists, and providers caring for patients will be brought up to date on the restorative repair processes that occur in the lung.

Dr. Levy explained the dream of such research is to treat patients who have suffered a maladaptive repair process by being able to go in and regenerate those portions of the lung that have been injured. Another possibility includes the ability to extract cells from the body to create cell structures like organoids, which could be helpful when reintroducing the cells back into the patient to repair areas of lung damage and recapture normal function.

"Attendees can certainly get involved and identify people working on topics within this complex subject matter that's relevant to their projects or interests," Dr. Levy said. ●

Gregory P. Downey

Bruce D. Levy

> "Finding the signaling pathways and mechanisms to promote the healthy repair (of the lung) may provide a window in addressing some pretty important diseases of the lung."
>
> – Bruce D. Levy

Cell Fate Determination in the Lung in Health and Disease: Location and Neighbors Matter (A5)

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

Ballroom D Two (Level 3), KBHCCD

Basic Science Core Sessions

Don't miss these other sessions in the Basic Science Core, all taking place in Ballroom D Two (Level 3), KBHCCD.

Sunday
2:15-4:15 p.m.
Living and Dying by Lipids: Resolving Inflammation and Tempting Cell Fate (A85)

Monday
9:15-11:15 a.m.
Til Death Do Us Part: Cell Fate and Obstructive Lung Disease (B5)

2:15-4:15 p.m.
They've Got the Beat: Cilia in Development and Disease (B85)

Tuesday
9:15-11:15 a.m.
Discovering the Role of Stem Cell Fate in Lung Injury and Fibrosis (C5)

Pro/Con:

Managing OSA and PAP Therapy

When it comes to choosing the most appropriate treatment for a patient with sleep-disordered breathing, clinicians must make controversial choices. For example, the evidence regarding the benefit of long-term continuous positive airway pressure (CPAP) therapy for asymptomatic patients is unclear. Similarly, there is debate among physicians about the best therapeutic approach for patients who have heart failure and central sleep apnea, as well as those who have obesity hypoventilation syndrome (OHS).

Babek Mokhlesi

Sushmita Pamidi

Neomi Shah

These controversies will take center stage as a series of debates during Sunday morning's session. Short, 10-minute presentations on the pros and cons of each controversy will allow thorough discussion of controversial topics. "We believe that the ATS attendees will be interested in hearing ongoing controversies in the field of sleep-disordered breathing," said Babek Mokhlesi, MD, MSc, professor of medicine at the University of Chicago.

"These talks will highlight the latest data and will help provide a clinical perspective on what the important issues are to consider when managing sleep apnea patients with cardiovascular disease and obesity hypoventilation syndrome, and how the field should move forward with respect to future clinical trial design," said Sushmita Pamidi, MD, assistant professor at McGill University in Montreal, Quebec, Canada.

The first round of debate will focus on whether moderate to severe obstructive sleep apnea (OSA) should be treated in order to improve cardiovascular outcomes. Although observational studies have consistently reported an independent association between OSA and cardiovascular disease, more recent research raises questions.

"The largest randomized clinical trial to date, the SAVE trial, failed to demonstrate a statistically significant benefit from CPAP for recurrent CVD events," says Neomi Shah, MD, MPH, MS, associate division chief at Icahn School of Medicine at Mount Sinai in New York City. A systematic review and meta-analysis reached a similar conclusion: The use of CPAP compared to no treatment or sham treatment didn't demonstrate a lower risk of cardiovascular events or death in patients with sleep apnea. "This topic is important as we are in an urgent need to determine the role of OSA treatment in the primary and secondary prevention of cardiovascular disease events," said Dr. Shah.

The second round of debate will consider the treatment of ambulatory patients with obesity hypoventilation syndrome. Should they be treated first with CPAP or with non-invasive ventilation? The same pro/con format will give attendees information supporting each treatment choice.

"When should one treatment modality be chosen over the other has remained a matter of controversy," said Dr. Mokhlesi.

The presenters will explore the most recent published clinical trial on the treatment of OHS, co-authored by Dr. Mokhlesi, which aimed to compare the long-term effectiveness of treating OHS with non-invasive ventilation or CPAP. The researchers found that the two treatments have similar long-term results; however, given that the cost and complexity of CPAP is less than that of non-invasive ventilation, CPAP may be the most appropriate first treatment until more studies can be conducted.

The third area of controversy will be PAP therapy in patients with central sleep apnea and heart failure. "Since the results of the SERVE-HF trial have been published, the management of central sleep apnea in heart failure is not standardized and often requires a discussion among sleep providers to determine best management," said Dr. Shah.

Dr. Pamidi agreed. "We expect attendees will be able to improve their understanding of the clinical trials to date, including the nuances of the study protocols and patient populations included in the studies, and see how this evidence applies to their clinical practice."

PAP for All or PAP for Few: Controversies in Management of Sleep-Disordered Breathing (A6)

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

Room C155-C156 (Level 1), KBHCCD

MYATS

"The ATS really focuses on two very important things: how to bring the most quality, high-yield, beneficial content to their membership, and how to improve the health of all humans, worldwide."

Laura E. Crotty Alexander, MD, ATSF

Associate Professor of Medicine
University of California, San Diego

Staff Physician
VA San Diego Healthcare System

> "This topic is important as we are in an urgent need to determine the role of OSA treatment in the primary and secondary prevention of cardiovascular disease events."
>
> **– Neomi Shah**

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Get Involved in the Society's Assemblies and Sections

Enhance your ATS 2019 International Conference experience by getting more involved. There is no better way to do that than to participate in your assembly and/or section activities.

The Society's assemblies and sections will hold their annual membership meetings Sunday and Monday at the Hyatt Regency Dallas Hotel.* All ATS 2019 attendees are encouraged to attend these meetings. (See the schedule below for specific times and locations of assembly membership meetings, receptions, section meetings, and assembly dinners.)

ASSEMBLY MEMBERSHIP MEETINGS

The Assembly Membership Meetings provide updates on assembly activities from each assembly's leadership. These meetings give members the opportunity to provide input on future direction and get involved in assembly and networking activities. Voting results for the assembly's future leaders also will be announced.

These meetings will all be 4:30 to 7 p.m. Monday, May 20, with the exception of the Assembly on Behavioral Science and Health Services Research and the Assembly on Pediatrics, which will meet Sunday, May 19.

*All membership meetings, receptions, and dinners will take place at the Hyatt Regency Dallas Hotel.

SUNDAY
5:30-7:30 p.m.

Pediatrics
Chair: Stephanie Davis, MD, ATSF
Reunion Ballroom A-B (Lobby Level)

6:30-8:30 p.m.

Behavioral Science and Health Services Research
Chair: J. Darryl Thornton, MD, MPH
Reunion Ballroom A-B (Lobby Level)

MONDAY
4:30-7 p.m.

Allergy, Immunology, and Inflammation
Chair: Bethany Moore, PhD, ATSF
Reunion Ballroom E-F (Lobby Level)

Clinical Problems
Chair: MeiLan Han, MD, MS
Landmark Ballroom A (Lobby Level)

Critical Care
Chair: John P. Kress, MD
Marsalis Hall B (Exhibition Level)

Environmental, Occupational, and Population Health
Chair: Howard Kipen, MD, MPH
Reunion Ballroom G-H (Lobby Level)

Nursing
Chair: Linda Chlan, PhD, RN
Reunion Ballroom C (Lobby Level)

Pulmonary Circulation
Chair: Karen Fagan, MD
Landmark Ballroom D (Lobby Level)

Pulmonary Infections and Tuberculosis
Chair: Kristina A. Crothers, MD
Reunion Ballroom A-B (Lobby Level)

Pulmonary Rehabilitation
Chair: Richard Casaburi, MD, PhD
Cumberland E-H (Exhibition Level)

Respiratory Cell and Molecular Biology
Chair: Melanie Koenigshoff, MD, PhD
Marsalis Hall A (Exhibition Level)

Respiratory Structure and Function
Chair: Gwen Skloot, MD
Landmark Ballroom C (Lobby Level)

Sleep and Respiratory Neurobiology
Chair: Sanjay Patel, MD
Landmark Ballroom B (Lobby Level)

Thoracic Oncology
Chair: M. Patricia Rivera, MD
Pegasus Ballroom A-B

SECTION MEETINGS

SUNDAY
6-8 p.m.

Section on Genetics and Genomics
Chair: Michael H. Cho, MD, MPH;
Co-Chair: Anthony N. Gerber, MD, PhD
Reverchon AB (Atrium Level)

TUESDAY
4:30-6:30 p.m.

Section on Medical Education
Chair: Henry E. Fessler, MD;
Co-Chair: W. Graham Carlos, MD, MSCR, ATSF
Cumberland A-C (Exhibition Level)

Section on Terrorism and Inhalation Disasters
Chair: Sven Eric Jordt, PhD
Windsor (Atrium Level)

ASSEMBLY DINNER

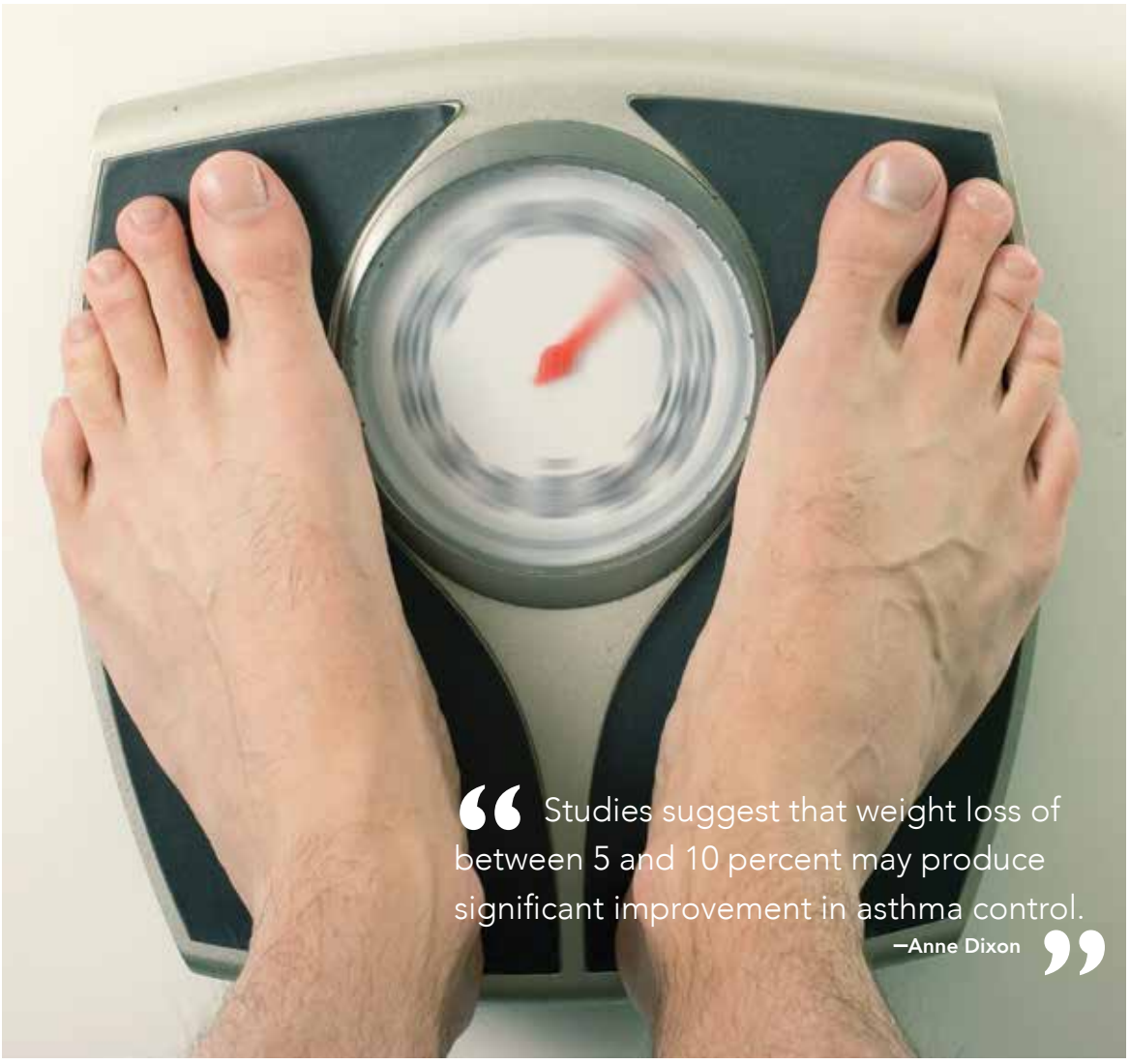
SUNDAY
7:30-10:30 p.m.

Pediatrics
Reunion Ballroom E-F (Lobby Level)

ASSEMBLY RECEPTIONS

MONDAY
7-10 p.m.

Sleep and Respiratory Neurobiology
Cumberland K-L (Exhibition Level)



The Obesity, Asthma Equation

Obesity has long been recognized as a significant risk factor for asthma. Nearly 60 percent of patients with severe asthma are obese, presenting a host of treatment challenges. In general, obese patients do not respond as well to conventional asthma therapies as lean patients. This leaves health care providers on the hunt for new options.

Successfully treating patients with obesity and asthma requires an understanding of the factors associated with obesity and the state of metabolic dysregulation, as well as the inflammatory phenotype of the airway disease for appropriate medical management, according to Anne E. Dixon, MD, ATSF, a professor at the University of Vermont in Burlington.

"Obesity and associated factors (high fat, low fiber diet, and metabolic syndrome) profoundly alter adaptive and innate immune function, increase susceptibility to respiratory infection, and alter prototypical pathways that cause asthma," said Dr. Dixon. "These changes alter response to standard treatments, and often lead to severe, difficult-to-control disease."

Adult asthma affects the peripheral airway, a zone of the lung not easily measured by conventional lung function testing. It has a unique physiological signature compared with asthma in lean patients, according to Dr. Dixon.

Dr. Dixon will co-chair a panel of physicians and scientists during today's session to examine the pathophysiology of the different phenotypes of obese asthma, and how this affects treatment responses. The panelists will discuss the role of medications, lifestyle interventions, and co-morbidities, including a sharp focus on depression and obstructive sleep apnea. The speakers will preview future therapies in development for this challenging new patient population, as well.


Anne Dixon

In developing a treatment approach, speakers will explore several options, including treatments that address the phenotype of asthma—specifically whether there is evidence of a corticosteroid-sensitive pathway. Additional treatment discussions will take shape over long-term systemic corticosteroids, which Dr. Dixon said actually worsen the disease, and the importance of a proper diet, exercise, and weight loss. In fact, studies suggest that weight loss of between 5 and 10 percent may produce significant improvement in asthma control.

Diet isn't the only thing that contributes to obesity. Tobacco smoke and air pollution lead to obesity and further obstruct airway health, Dr. Dixon said.

"Discuss lifestyle changes with your patients and consider a referral to a weight loss program," Dr. Dixon said. "Evaluate [patients] for co-morbidities that may be contributing to asthma severity. It's important to understand that obesity profoundly alters asthma, and conventional treatments for asthma may have limitations, particularly in patients with little in the way of type 2 inflammation." ●

Treating Asthma in Patients With Obesity: The Need for a New Approach (A10)

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

Room D221/D225/D226 (Level 2), KBHCCD

Research Approach May Change Drug Development

In classical pharmacology, drug-receptor interactions are considered under static conditions. A relatively new concept, mechanopharmacology, differs in that the normal mechanical environment of a tissue is a factor, with potentially significant impacts on function.

Chun Seow

Peter Noble

"It is only recently that we recognized that tissue response to the action of drugs in the moving organs is affected by the movements. For example, airways dilate more in response to bronchodilators in the presence of pressure oscillation due to the action of breathing," said Chun Seow, PhD, ATSF, professor at the University of British Columbia, in Vancouver, BC, Canada.

In organs "living" in a mechanically dynamic environment, drug actions should no longer be considered as simple agonist-receptor-based reactions, said Dr. Seow, co-chair of this afternoon's session on mechanopharmacology. Normal and disease-related changes in the mechanical environment of lung tissue, for example, may have an impact on drug-dose response behavior.

"Our recommendation is that drug-design models be revised to incorporate contemporary knowledge on mechanotransduction that ultimately determine drug efficacy," said Dr. Seow.

Although focused and solid basic research is first required to develop an improved understanding of mechanopharmacology, there are important clinical implications. For example, changes in mechanical properties of lung tissues may contribute to the proportion of patients who do not have a good response to medications that are effective in other patients. The synergistic effects of bronchodilators when administered in the presence of airway pressure oscillation, either due to natural breathing maneuver or artificially imposed pressure wave, have the potential to reduce drug dosage and, therefore, reduce side effects.

"With mechanical intervention, a whole new venue of drug targets will become available, which will lead to improvements in response and quality of life for patients," said Dr. Seow.

"The session is a wonderful demonstration of how focused basic research, both collaborative and competitive, generates knowledge that can be translated to clinical practice," said Peter Noble, PhD, senior lecturer at the University of Western Australia in Perth, also a co-chair of the session. "This knowledge is borne out of pure scientific curiosity, without an initial application in mind. The main message is that drugs act differently in tissues that constantly move."

The presentations in the session will address the mechanical effects on drug action, specifically, the enhanced drug action in the presence of mechanical movements, the molecular pathways perturbed by mechanical actions associated with breathing, and the incorporation of mechanical effects into drug screening.

Relevant for both scientists and clinicians, this session is designed to generate innovative thinking. For example, current laboratory-based technologies could be expanded to include consideration of mechanopharmacology, emerging technologies could be used to assess mechanical changes that may have an impact on treating patients, and mechanical devices could be developed to reduce drug dosage or even achieve therapeutic effects without drugs. ●

Mechanopharmacology of Airway and Airway Smooth Muscle (A86)

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

Ballroom D One (Level 3), KBHCCD

Restoring Joy in Health Care

What does burnout look like and how can we 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, crowd source ways to improve the professional environment, 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.

Promoting Wellness in Health Care Teams: A Practical Approach Workshop (WS4)
Room D171/D173 (Level 1), KBHCCD
Monday, May 20
11:45 a.m.-1:15 p.m.

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.

COPD Is Not a Geriatric Disease

Conventional wisdom suggests that COPD is a disease that typically strikes later in life. The reality is that COPD may start in early childhood. It just doesn't become obvious in most patients until their sixth or seventh decade of life.

"Most clinicians don't know a lot about the actual origins of COPD," said Don D. Sin, MD, director at the Center for Heart Lung Innovation (HLI) and professor of medicine at the University of British Columbia, Vancouver, BC, Canada. "Because so many clinicians see COPD patients in their 60s, 70s, and 80s, the impression is that it is a geriatric disease. You may see the final consequences in the geriatric years, but a lot of this has been imprinted in the lungs by birth or early in childhood."

Dr. Sin is one of three co-chairs for this morning's session. He shares the platform with Fernando Martinez, MD, director of the Asthma/Airway Disease Research Center and professor of pediatrics at the University of Arizona in Tucson, and Francesca Polverino, MD, PhD, assistant professor of medicine and assistant research scientist at the University of Arizona Asthma/Airway Disease Research Center.

Cigarette smoking has long been viewed as the primary driver of COPD, Dr. Sin said. A growing body of evidence, however, indicates that COPD can be rooted in much more than smoking.

"Babies don't smoke, but you can see reduced lung function in babies that presents as COPD decades later," he said. "COPD may be driven by secondhand smoke, air pollution, genomics, abnormal immune response, and dysbiosis of both the lung and the gut microbiomes. Those factors can all have their beginning in the womb."

The lung and gut microbiomes have their origin *in utero*, Dr. Sin said, and develop more fully during the first 6 to 12 months after birth.


Don D. Sin

The immune system also develops in the mother's womb and matures during the first few years of life. Environmental factors, in combination with individual genomics, can give rise to early bronchopulmonary dysplasia, an emerging culprit in the pathogenesis of COPD.

Medical therapy 60 to 70 years later cannot alter those early changes. The only way to prevent these changes that lead to COPD in adulthood are to alter the early risk factors and exposures in childhood.

Reducing the prevalence and the toll of COPD calls for education.

"I remember my dad smoking in the car when I was a kid," Dr. Sin said. "Not because he wanted to hurt me, but because he didn't have enough information about the harmful effects that smoking has on the developing lungs. Kids have the most sensitive lungs. If a child's lung growth is stunted by 20 percent, their risk of COPD is five times higher by age 50. There is a profound amplification of even small deficits in childhood over the decades."

The new Global Initiative for Chronic Obstructive Lung Disease (GOLD) mentions the impact of lung development on COPD, he continued, but not prominently. Lung growth is not a familiar concept for adult COPD physicians.

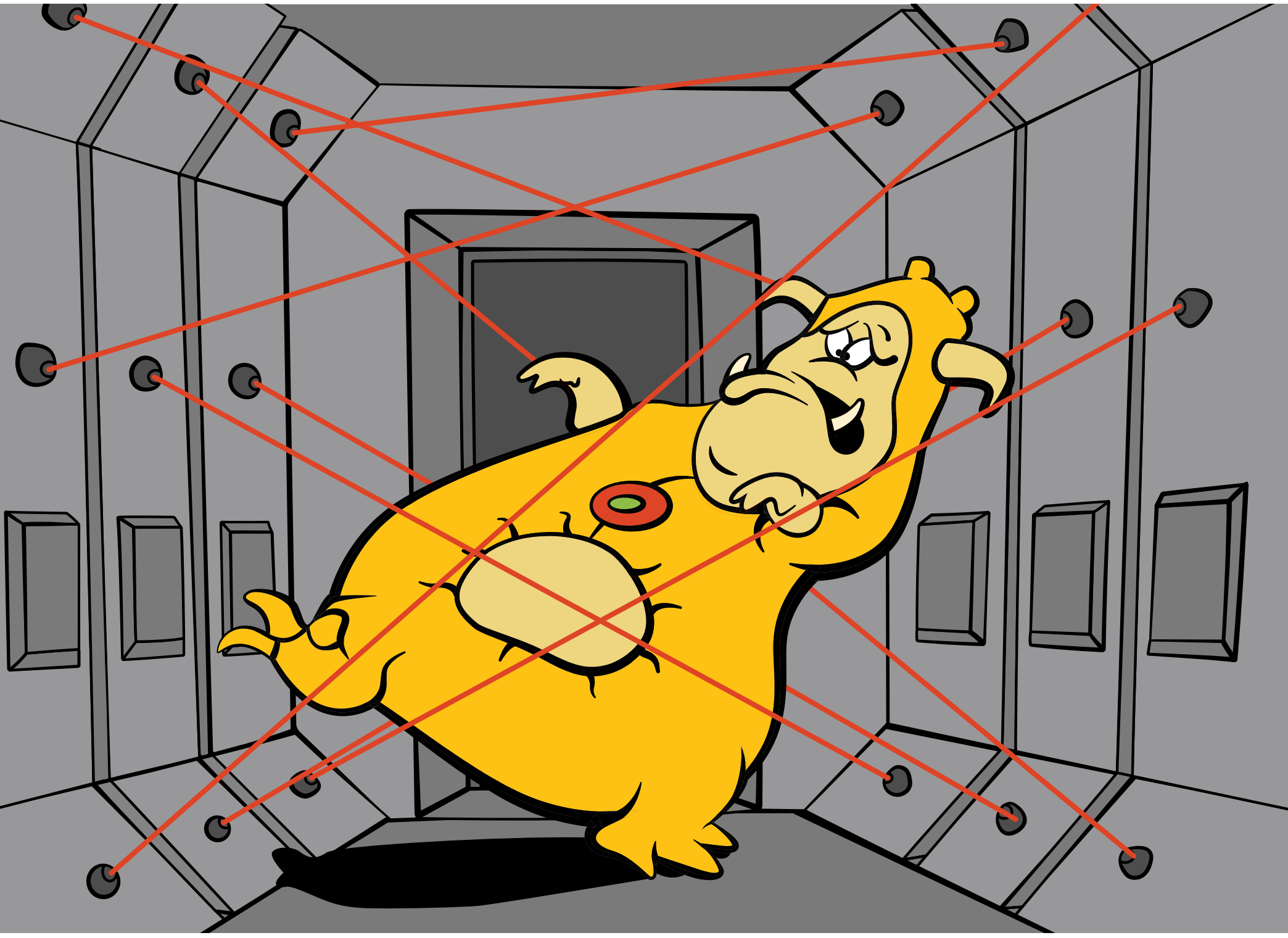
"We are breaking the paradigm of COPD," Dr. Sin said. "This information will profoundly impact not only present COPD but future COPD and the way we practice medicine. We have never thought about targeting kids (and possibly even mothers) for intervention to prevent COPD. The new approach is that in COPD, we can have the biggest impact by targeting kids and their parents. Modifying the factors that drive poor lung growth will have a profound impact on the individual and on society going forward." ●

Breaking the Paradigm: Early Origins of COPD — Tomoko Betsuyaku, MD, Memorial Symposium (A7)

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

Ballroom D One (Level 3), KBHCCD

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.

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Q&A

Trudeau Medalist's Research Creates New Paradigm for ARDS Treatment

Jacob I. Sznajder, MD, is the recipient of the 2019 Edward Livingston Trudeau Medal, which recognizes significant contributions to the prevention, diagnosis, and treatment of lung disease. Dr. Sznajder spoke with the ATS *Daily Bulletin* about his past research regarding a reduction in capillary wedge pressure and mechanical ventilation with smaller tidal volumes for ARDS patients—and what he's up to now in an effort to improve treatments for patients with lung treatments.

Q What has most of your research focused on, and what kind of impact has that had for patients who are suffering from diseases or injuries of the lungs?

A: Most of my research pertains to understanding the mechanisms of lung injury and repair. We focus on preclinical models of lung injury to be translated into clinical studies. Some of our early publications, with my mentor Dr. Larry Wood, defined the physiologic advantage of reducing the capillary wedge pressure while maintaining adequate cardiac output, which resulted in less edema formation and improved gas exchange. This was later confirmed in clinical studies, and it is now the accepted paradigm in the treatment of patients with ARDS.

Our group also demonstrated that in a model of acute lung injury, mechanical ventilation with smaller tidal volumes resulted in less injury than when ventilating with high tidal volumes. These approaches were controversial until studies in patients with ARDS showed that mechanical ventilation with lower tidal volumes resulted in better outcomes.

Q What are you working on now?

A: We are studying the effects of hypercapnia on the lungs. Earlier studies have proposed that hypercapnia is beneficial in patients with lung injury, which led to the current paradigm of tolerating and encouraging "permissive hypercapnia" in patients with ARDS. We and others have recently reported that hypercapnia is associated with increased mortality in patients with ARDS, in patients with alveolobronchial fistulae, and in patients with COPD, in whom hypercapnia was not corrected. We are pursuing studies to shed light on the signaling mechanisms of hypercapnia to inform and effect a shift in paradigm regarding the need to normalize the CO_2 levels in patients with lung diseases.

Another project is focusing on the alveolar epithelial response to influenza A-induced lung injury, focusing on the role of ubiquitination and proteostasis in the lungs and muscle function and how is this affected with age.

Q Why is it important for you to participate in mentoring?

A: I am committed to mentoring the young generation of physician-scientists and PhD-scientists in our field. At Northwestern University we have a NHLBI T32 training grant where I am actively involved in the training of students, residents, postdoctoral fellows, and junior faculty from diverse backgrounds which reflects our society. I believe in collaborations and multidisciplinary approaches, which have inspired me to learn from the research of our trainees/mentees. Our specialty has been energized by novel technologies that have shed new light on genomics, epigenetics, and proteomics, which we have used to foster a community of scholars to attract talented young scientists to our field to understand and alleviate the burden of respiratory diseases. Now more than ever we need team science and trainees — often the glue that brings researchers together.

Q What does it mean to you to receive the Trudeau Medal?

A: I am very honored and humbled in accepting this award from the American Thoracic Society, which has been a home for me as a physician-scientist for more than 30 years. It represents the work of so many of my trainees and colleagues, because I see my work and this award as "we" rather than "me" award. For that, I am very thankful to them.

> "Our specialty has been energized by novel technologies that have shed new light on genomics, epigenetics, and proteomics, which we have used to foster a community of scholars to attract talented young scientists to our field to understand and alleviate the burden of respiratory diseases."
>
> – Jacob I. Sznajder

Speaker Transparency Results in Scientific Integrity

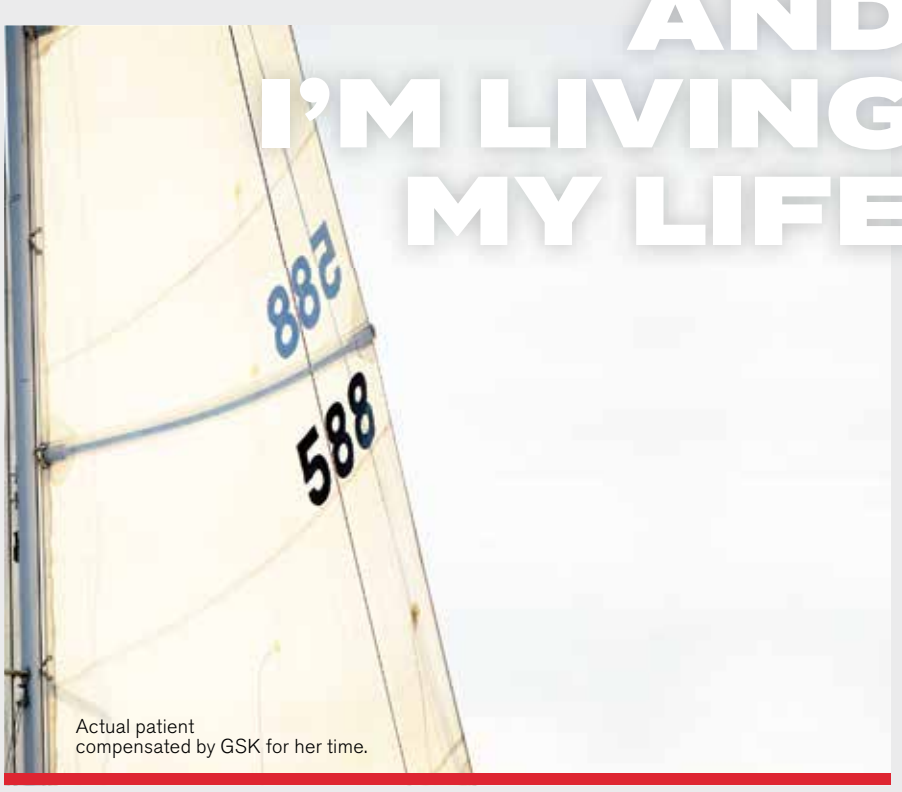
International Conference speakers are required to take several steps to ensure that ATS audiences are aware of any professional or personal relationships they have with companies that are relevant to their presentation content.

The support that pharmaceutical and medical device companies provide for the research, education, and patient care conducted by ATS members and other International Conference speakers is instrumental to finding cures and maintaining quality of life. The ATS and industry take great care to ensure that relevant commercial support received by speakers or relevant personal investments is disclosed and made known to ATS 2019 attendees.

To comply with requirements of the Accreditation Council for Continuing Medical Education, speakers in sessions designated for CME were required to complete extensive questionnaires for review of conflicts of interest ahead of the International Conference. Speakers also re-enter the names of relevant company affiliations when they submit their presentation slides online, so that a disclosure screen automatically appears just before their talk. They are also encouraged to also orally highlight their relevant relationships. In addition, a written summary of disclosures is also posted on the International Conference website and available through the ATS 2019 app.

More information on ATS 2019 requirements for speakers is available at **conference.thoracic.org/speakers/session-speaker-instructions.php**

NUCALA is indicated for the add-on maintenance treatment of patients 12 years and older with severe asthma with an eosinophilic phenotype. NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.



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*Source: IQVIA - NPA™ audit: 12 mo. TRX data ending 11/18 (All rights reserved).

†December 2015 to November 2018 data sourced from IQVIA and GSK. Claims data based on total number of unique patients who had at least one claim for NUCALA in the United States. Not all patients remained on therapy. Individual results may vary.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUCALA should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (eg, anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred with NUCALA. These reactions generally occur within hours of administration but can have a delayed onset (ie, days). If a hypersensitivity reaction occurs, discontinue NUCALA.

Acute Asthma Symptoms or Deteriorating Disease

NUCALA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Opportunistic Infections: Herpes Zoster

In controlled clinical trials, 2 serious adverse reactions of herpes zoster occurred with NUCALA compared to none with placebo. Consider vaccination if medically appropriate.

Reduction of Corticosteroid Dosage

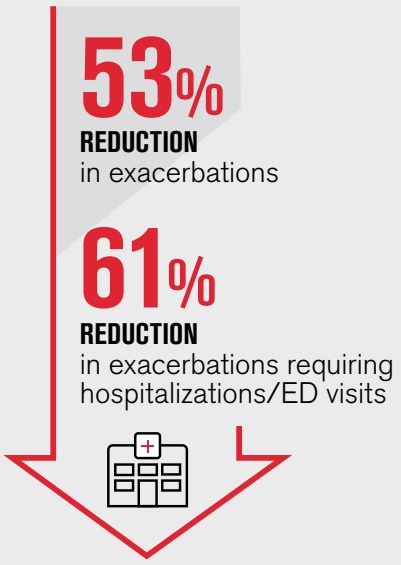
Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with NUCALA. Decreases in corticosteroid doses, if appropriate, should be gradual and under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

Treat patients with pre-existing helminth infections before initiating therapy with NUCALA. If patients become infected while receiving NUCALA and do not respond to anti-helminth treatment, discontinue NUCALA until infection resolves.

Choose NUCALA:

Powerful Protection From Exacerbations[2‡]



Powerful Reduction in OCS Dose[3]

Lasting Evidence[4]

Only anti-interleukin 5 (IL-5) with a

4.5-year

open-label study that evaluated safety and efficacy

MENSA (Trial 2)[2]: 32-week study comparing NUCALA 100 mg to placebo, each added to SOC in 576 patients with severe eosinophilic asthma (SEA). **Primary Endpoint Results:** Frequency of exacerbations. NUCALA: 0.83/year, placebo: 1.74/year; *P*<0.001. **Secondary Endpoint Results:** Frequency of exacerbations requiring hospitalization and/or ED visit; NUCALA: 0.08/year; placebo: 0.20/year; *P*=0.02.

SIRIUS (Trial 3)[3]: 24-week study comparing NUCALA 100 mg to placebo in 135 patients with SEA receiving prednisone 5-35 mg (or equivalent) per day and regular use of high-dose ICS and 1 other controller. **Primary Endpoint Results:** Percent reduction in daily OCS dose (Weeks 20 to 24) while maintaining asthma control vs placebo; *P*=0.008.

COLUMBA[4]: 4.5-year open-label study assessing the safety, immunogenicity, and efficacy of NUCALA 100 mg added to asthma controller therapy in 347 patients with SEA.

‡ Worsening of asthma that required use of oral/systemic corticosteroids and/or hospitalizations and/or emergency department (ED) visits; for patients on maintenance oral/systemic corticosteriods, exacerbations were defined as requiring at least double the existing maintenance dose for at least 3 days.

Standard of care (SOC)=regular treatment with high-dose inhaled corticosteroids (ICS) and at least 1 other controller with or without oral corticosteroids (OCS).

Learn more at **KnowNucalaHCP.com**

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (≥3% and more common than placebo) reported in the first 24 weeks of 2 clinical trials with NUCALA (and placebo) were: headache, 19% (18%); injection site reaction, 8% (3%); back pain, 5% (4%); fatigue, 5% (4%); influenza, 3% (2%); urinary tract infection, 3% (2%); abdominal pain upper, 3% (2%); pruritus, 3% (2%); eczema, 3% (<1%); and muscle spasms, 3% (<1%).

Systemic Reactions, including Hypersensitivity Reactions: In 3 clinical trials, the percentages of subjects who experienced systemic (allergic and nonallergic) reactions were 3% for NUCALA and 5% for placebo. Manifestations included rash, flushing, pruritus, headache, and myalgia. A majority of the systemic reactions were experienced on the day of dosing.

Injection site reactions (eg, pain, erythema, swelling, itching, burning sensation) occurred in subjects treated with NUCALA.

USE IN SPECIFIC POPULATIONS

A pregnancy exposure registry monitors pregnancy outcomes in women exposed to NUCALA during pregnancy. To enroll call 1-877-311-8972 or visit www.mothertobaby.org/asthma.

The data on pregnancy exposures are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as the pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimesters.

References: 1. Data on file, GSK. **2.** Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Engl J Med.* 2014;371:1198-1207. **3.** Bel EH, Wenzel SE, Thompson PJ, et al. Oral glucocorticoid-sparing effect of mepolizumab in eosinophilic asthma. *N Engl J Med.* 2014;371:1189-1197. **4.** Khatri S, Moore W, Gibson PG, et al. Assessment of the long-term safety of mepolizumab and durability of clinical response in patients with severe eosinophilic asthma [published online ahead of print, October 22, 2018]. *J Allergy Clin Immunol.* doi.org/10.1016/j.jaci.2018.09.033.

Please see Brief Summary of Prescribing Information for NUCALA on the following pages.

MPLJRNA190002 March 2019
Produced in USA.

Nucala
(mepolizumab)
for Subcutaneous Injection
100 mg/vial

BRIEF SUMMARY

NUCALA
(mepolizumab) for injection, for subcutaneous use

The following is a brief summary only and is focused on the indication for maintenance treatment of severe asthma with an eosinophilic phenotype. See full prescribing information for complete product information.

1 INDICATIONS AND USAGE

1.1 Maintenance Treatment of Severe Asthma

NUCALA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Limitation of Use

NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.

4 CONTRAINDICATIONS

NUCALA should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred following administration of NUCALA. These reactions generally occur within hours of administration, but in some instances can have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, NUCALA should be discontinued *[see Contraindications (4)]*.

5.2 Acute Asthma Symptoms or Deteriorating Disease

NUCALA should not be used to treat acute asthma symptoms or acute exacerbations. Do not use NUCALA to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with NUCALA.

5.3 Opportunistic Infections: Herpes Zoster

Herpes zoster has occurred in subjects receiving NUCALA 100 mg in controlled clinical trials *[see Adverse Reactions (6.1)]*. Consider vaccination if medically appropriate.

5.4 Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids (ICS) abruptly upon initiation of therapy with NUCALA. Reductions in corticosteroid dosage, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dosage may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

5.5 Parasitic (Helminth) Infection

Eosinophils may be involved in the immunological response to some helminth infections. Patients with known parasitic infections were excluded from participation in clinical trials. It is unknown if NUCALA will influence a patient's response against parasitic infections. Treat patients with pre-existing helminth infections before initiating therapy with NUCALA. If patients become infected while receiving treatment with NUCALA and do not respond to anti-helminth treatment, discontinue treatment with NUCALA until infection resolves.

6 ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:

- Hypersensitivity reactions *[see Warnings and Precautions (5.1)]*
- Opportunistic infections: herpes zoster *[see Warnings and Precautions (5.3)]*

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.

6.1 Clinical Trials Experience in Severe Asthma

A total of 1,327 subjects with asthma were evaluated in 3 randomized, placebo-controlled, multicenter trials of 24 to 52 weeks' duration (Trials 1, 2, and 3). Of these, 1,192 had a history of 2 or more exacerbations in the year prior to enrollment despite regular use of high-dose ICS plus additional controller(s) (Trials 1 and 2), and 135 subjects required daily oral corticosteroids (OCS) in addition to regular use of high-dose ICS plus additional controller(s) to maintain asthma control (Trial 3). All subjects had markers of eosinophilic airway inflammation *[see Clinical Studies (14.1) of full prescribing information]*. Of the subjects enrolled, 59% were female, 85% were white, and ages ranged from 12 to 82 years. Mepolizumab was administered subcutaneously or intravenously once every 4 weeks; 263 subjects received NUCALA (mepolizumab 100 mg SC) for at least 24 weeks. Serious adverse events that occurred in more than 1 subject and in a greater percentage of subjects receiving NUCALA 100 mg (n = 263) than placebo (n = 257) included 1 event, herpes zoster (2 subjects vs. 0 subjects, respectively). Approximately 2% of subjects receiving NUCALA 100 mg withdrew from clinical trials due to adverse events compared with 3% of subjects receiving placebo.

The incidence of adverse reactions in the first 24 weeks of treatment in the 2 confirmatory efficacy and safety trials (Trials 2 and 3) with NUCALA 100 mg is shown in Table 1.

Table 1. Adverse Reactions with NUCALA with ≥3% Incidence and More Common than Placebo in Subjects with Asthma (Trials 2 and 3)

Adverse Reaction	NUCALA (Mepolizumab 100 mg Subcutaneous) (n = 263) %	Placebo (n = 257) %
Headache	19	18
Injection site reaction	8	3
Back pain	5	4
Fatigue	5	4
Influenza	3	2
Urinary tract infection	3	2
Abdominal pain upper	3	2
Pruritus	3	2
Eczema	3	<1
Muscle spasms	3	<1

52-Week Trial

Adverse reactions from Trial 1 with 52 weeks of treatment with mepolizumab 75 mg intravenous (IV) (n = 153) or placebo (n = 155) and with ≥3% incidence and more common than placebo and not shown in Table 1 were: abdominal pain, allergic rhinitis, asthenia, bronchitis, cystitis, dizziness, dyspnea, ear infection, gastroenteritis, lower respiratory tract infection, musculoskeletal pain, nasal congestion, nasopharyngitis, nausea, pharyngitis, pyrexia, rash, toothache, viral infection, viral respiratory tract infection, and vomiting. In addition, 3 cases of herpes zoster occurred in subjects receiving mepolizumab 75 mg IV compared with 2 subjects in the placebo group.

Systemic Reactions, including Hypersensitivity Reactions

In Trials 1, 2, and 3 described above, the percentage of subjects who experienced systemic (allergic and non-allergic) reactions was 5% in the placebo group and 3% in the group receiving NUCALA 100 mg. Systemic allergic/hypersensitivity reactions were reported by 2% of subjects in the placebo group and 1% of subjects in the group receiving NUCALA 100 mg. The most commonly reported manifestations of systemic allergic/hypersensitivity reactions reported in the group receiving NUCALA 100 mg included rash, pruritus, headache, and myalgia. Systemic non-allergic reactions were reported by 2% of subjects in the group receiving NUCALA 100 mg and 3% of subjects in the placebo group. The most commonly reported manifestations of systemic non-allergic reactions reported in the group receiving NUCALA 100 mg included rash, flushing, and myalgia. A majority of the systemic reactions in subjects receiving NUCALA 100 mg (5/7) were experienced on the day of dosing.

Injection Site Reactions

Injection site reactions (e.g., pain, erythema, swelling, itching, burning sensation) occurred at a rate of 8% in subjects receiving NUCALA 100 mg compared with 3% in subjects receiving placebo.

Long-term Safety

Nine hundred ninety-eight subjects received NUCALA 100 mg in ongoing open-label extension studies, during which additional cases of herpes zoster were reported. The overall adverse event profile has been similar to the asthma trials described above.

6.3 Immunogenicity

In subjects with asthma receiving NUCALA 100 mg, 15/260 (6%) developed anti-mepolizumab antibodies. Neutralizing antibodies were detected in 1 subject with asthma receiving NUCALA 100 mg. Anti-mepolizumab antibodies slightly increased (approximately 20%) the clearance of mepolizumab. There was no evidence of a correlation between anti-mepolizumab antibody titers and change in eosinophil level. The clinical relevance of the presence of anti-mepolizumab antibodies is not known.

The reported frequency of anti-mepolizumab antibodies may underestimate the actual frequency due to lower assay sensitivity in the presence of high drug concentration. The data reflect the percentage of patients whose test results were positive for antibodies to mepolizumab in specific assays. The observed incidence of antibody positivity in an assay is highly dependent on several factors, including assay sensitivity and specificity, assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease.

6.4 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during postapproval use of NUCALA. 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 NUCALA or a combination of these factors.

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis.

7 DRUG INTERACTIONS

Formal drug interaction trials have not been performed with NUCALA.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women with asthma exposed to NUCALA during pregnancy. Healthcare providers can enroll patients or encourage patients to enroll themselves by calling 1-877-311-8972 or visiting www.mothertobaby.org/asthma.

Risk Summary

The data on pregnancy exposure are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy. In a prenatal and postnatal development study conducted in cynomolgus monkeys, there was no evidence of fetal harm with IV administration of mepolizumab throughout pregnancy at doses that produced exposures up to approximately 9 times the exposure at the maximum recommended human dose (MRHD) of 300 mg SC *(see Data)*.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryofetal Risk: In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of preeclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. The level of asthma control should be closely monitored in pregnant women and treatment adjusted as necessary to maintain optimal control.

Data

Animal Data: In a prenatal and postnatal development study, pregnant cynomolgus monkeys received mepolizumab from gestation Days 20 to 140 at doses that produced exposures up to approximately 9 times that achieved with the MRHD (on an AUC basis with maternal IV doses up to 100 mg/kg once every 4 weeks). Mepolizumab did not elicit adverse effects on fetal or neonatal growth (including immune function) up to 9 months after birth. Examinations for internal or skeletal malformations were not performed. Mepolizumab crossed the placenta in cynomolgus monkeys. Concentrations of mepolizumab were approximately 2.4 times higher in infants than in mothers up to Day 178 postpartum. Levels of mepolizumab in milk were ≤0.5% of maternal serum concentration.

In a fertility, early embryonic, and embryofetal development study, pregnant CD-1 mice received an analogous antibody, which inhibits the activity of murine interleukin-5 (IL-5), at an IV dose of 50 mg/kg once per week throughout gestation. The analogous antibody was not teratogenic in mice. Embryofetal development of IL-5–deficient mice has been reported to be generally unaffected relative to wild-type mice.

8.2 Lactation

Risk Summary

There is no information regarding the presence of mepolizumab in human milk, the effects on the breastfed infant, or the effects on milk production. However, mepolizumab is a humanized monoclonal antibody (IgG1 kappa), and immunoglobulin G (IgG) is present in human milk in small amounts. Mepolizumab was present in the milk of cynomolgus monkeys postpartum following dosing during pregnancy *[see Use in Specific Populations (8.1)]*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NUCALA and any potential adverse effects on the breastfed infant from mepolizumab or from the underlying maternal condition.

(continued on next page)

(continued from preceding page)

8 USE IN SPECIFIC POPULATIONS (cont'd)

8.4 Pediatric Use
The safety and efficacy in pediatric patients younger than 12 years with asthma have not been established. A total of 28 adolescents aged 12 to 17 years with asthma were enrolled in the Phase 3 asthma studies. Of these, 25 were enrolled in the 32-week exacerbation trial (Trial 2) and had a mean age of 14.8 years. Subjects had a history of 2 or more exacerbations in the previous year despite regular use of high-dose ICS plus additional controller(s) with or without OCS and had blood eosinophils of ≥150 cells/mcL at screening or ≥300 cells/mcL within 12 months prior to enrollment. *[See Clinical Studies (14.1) of full prescribing information.]* Subjects had a reduction in the rate of exacerbations that trended in favor of mepolizumab. Of the 19 adolescents who received mepolizumab, 9 received NUCALA 100 mg and the mean apparent clearance in these subjects was 35% less than that of adults. The adverse event profile in adolescents was generally similar to the overall population in the Phase 3 studies *[see Adverse Reactions (6.1)]*.
The safety and efficacy in pediatric patients other than those with asthma have not been established.

8.5 Geriatric Use
Clinical trials of NUCALA did not include sufficient numbers of subjects aged 65 years and older that received NUCALA (n = 46) to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Based on available data, no adjustment of the dosage of NUCALA in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out.

10 OVERDOSAGE
Single doses of up to 1,500 mg have been administered intravenously to subjects in a clinical trial with eosinophilic disease without evidence of dose-related toxicities.
There is no specific treatment for an overdose with mepolizumab. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential of mepolizumab. Published literature using animal models suggests that IL-5 and eosinophils are part of an early inflammatory reaction at the site of tumorigenesis and can promote tumor rejection. However, other reports indicate that eosinophil infiltration into tumors can promote tumor growth. Therefore, the malignancy risk in humans from an antibody to IL-5 such as mepolizumab is unknown.
Male and female fertility were unaffected based upon no adverse histopathological findings in the reproductive organs from cynomolgus monkeys receiving mepolizumab for 6 months at IV dosages up to 100 mg/kg once every 4 weeks (approximately 20 times the MRHD of 300 mg on an AUC basis). Mating and reproductive performance were unaffected in male and female CD-1 mice receiving an analogous antibody, which inhibits the activity of murine IL-5, at an IV dosage of 50 mg/kg once per week.

17 PATIENT COUNSELING INFORMATION
See FDA-Approved Patient Labeling.

Hypersensitivity Reactions
Inform patients that hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred after administration of NUCALA. Instruct patients to contact their physicians if such reactions occur.

Not for Acute Symptoms or Deteriorating Disease
Inform patients that NUCALA does not treat acute asthma symptoms or acute exacerbations. Inform patients to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with NUCALA.

Opportunistic Infections: Herpes Zoster
Inform patients that herpes zoster infections have occurred in patients receiving NUCALA and where medically appropriate, inform patients that vaccination should be considered.

Reduction of Corticosteroid Dosage
Inform patients to not discontinue systemic or inhaled corticosteroids except under the direct supervision of a physician. Inform patients that reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Pregnancy Exposure Registry
Inform women there is a pregnancy exposure registry that monitors pregnancy outcomes in women with asthma exposed to NUCALA during pregnancy and that they can enroll in the Pregnancy Exposure Registry by calling 1-877-311-8972 or by visiting www.mothertobaby.org/asthma *[see Use in Specific Populations (8.1)]*.

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MPLJRNA190002 March 2019
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Industry Theater 2: Booth 3249
Medium Theater: Booth 4549
Mini Theater: Booth 101

Refine Your Clinical Skills Over Lunch

THEATER 1
11:30 a.m.-12:15 p.m.

Eosinophilic Asthma: Patient Identification and a Targeted Treatment Approach

Eosinophilic asthma is a common type of severe asthma in adult patients. Eosinophils can contribute to exacerbations and lung function decline in patients with allergic or non-allergic severe asthma. This complimentary symposium will highlight the growing body of literature on eosinophils and severe asthma. The presenter will use a case-based approach to help clinicians identify eosinophilic asthma in clinical practice and will discuss a targeted approach to the management of severe eosinophilic asthma. Attendees should leave being able to translate the growing science of eosinophils into real-world applications for severe asthma patients in the clinic.
Speaker: **Reynold Panettieri Jr., MD**, *professor and vice chancellor clinical and translational science, Rutgers University*
Company: AstraZeneca

1:15-2 p.m.

Company: Sanofi Genzyme and Regeneron

THEATER 2
11:30 a.m.-12:15 p.m.

Rethinking the "O" in COPD

This symposium will explore how the physiologic finding of "airflow obstruction" became central to the definition, classification, and treatment of COPD, even though this occurs late in the disease process. Rethinking how we approach disease modification in the future will require that we rethink what comprises early disease, before obstruction is present, and focus on important phenotypes, endotypes, and treatable traits that will guide interventions.
Speakers: **Bart Celli, MD**, *professor of medicine, Harvard Medical School;* **David Mannino, MD**, *U.S. medical expert, GlaxoSmithKline;* **Brad Drummond, MD**, *associate professor of medicine, director, Obstructive Lung Diseases Clinical and Translational Research Center, University of North Carolina;* **MeiLan K. Han, MD**, *professor, division pulmonary and critical care, University of Michigan*
Company: GlaxoSmithKline

1:15-2 p.m.

The First LAMA for Inhalation Using Natural Breathing

Speaker: **Donald A. Mahler, MD**, *emeritus professor of medicine, Geisel School of Medicine at Dartmouth*
Company: Sunovion Pharmaceuticals Inc.

MEDIUM THEATER
12:20-1:05 p.m.

An Oral Treatment for Pulmonary Arterial Hypertension (PAH, WHO Group I): Targeting the Prostacyclin Pathway

The management of pulmonary arterial hypertension (PAH) continues to evolve with targeting multiple pathways through sequential combination therapy now at the forefront of our treatment strategies. This interactive case-based theater will feature a PAH thought leader who will discuss an oral treatment for PAH targeting the prostacyclin pathway. Lunch will be provided. (Lunch will not be provided to physicians and other HCPs licensed in Vermont or other states where gifts and meals are prohibited.) This presentation is sponsored by Actelion Pharmaceuticals US, Inc., a Janssen Pharmaceutical Company of Johnson & Johnson, and is open to all ATS 2019 International Conference attendees. This promotional educational activity is not accredited.
Speaker: **Rajeev Saggar, MD**, *executive director, Lung Institute, director of pulmonary hypertension and fibrosis programs, University of Arizona, COM-Phoenix Banner University Medical Center-Phoenix, Phoenix, Arizona*
Company: Actelion Pharmaceuticals US, Inc., a Janssen Pharmaceutical Company of Johnson & Johnson

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

Going Beyond the Prescription – Consider First the Medication Delivery System

Device delirium. So many choices of inhalers and aerosol delivery systems lead to patient confusion. What needs to be taken into consideration when prescribing medication devices?
Speaker: **James B. Fink, PhD, RRT, FAARC, FCCP**, *chief scientific officer, Aerogen Pharma Corp.*
Company: Philips

12:30-1 p.m.

What You Didn't Know About Budesonide

A retrospective review of the budesonide molecule and its history. Challenge your assumptions, revisit data, and learn new information as this session takes you into a deep dive of budesonide's mechanism, unique characteristics, and other considerations.
Speaker: **Donald Tashkin, MD**, *professor emeritus of medicine, David Geffen School of Medicine at UCLA*
Company: AstraZeneca

1:30-2 p.m.

Interstitial Lung Disease in Systemic Sclerosis: A Case-Based Discussion

This presentation will enlist an expert pulmonologist and rheumatologist who will present patient case studies providing insight into the interactions required to recognize and diagnose systemic sclerosis-associated interstitial lung disease (SSc-ILD). The presentation of these case studies will underscore the importance of the interactions that occur between these specialties to diagnose SSc-ILD and monitor disease progression. An overview of the current knowledge regarding SSc examining the pulmonary manifestations of the disease will also be reviewed.
Speakers: **S. Samuel Weigt, MD, MS**, *director, UCLA Interstitial Lung Disease Center, associate professor of medicine, David Geffen School of Medicine at UCLA;* **Elizabeth Volkmann, MD, MS**, *founder, co-director, UCLA Connective Tissue Disease-Related Interstitial Lung Disease Program, assistant professor of medicine, David Geffen School of Medicine at UCLA*
Company: Boehringer Ingelheim Pharmaceuticals, Inc. ●

MYATS

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Dean Sheppard, MD
Professor of Medicine, Chief of Pulmonary, Critical Care, Allergy and Sleep
University of California San Francisco

MYATS

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Nirav G. Shah, MD
Associate Professor of Medicine
University of Maryland School of Medicine

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Learning how to promote gender equity in the workplace.
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Here is the largest fear of graduating away from home institution to another. How to fight self-doubt as the environment changes and ways to "prove" oneself to peers and learners. #ATS2019

@fjaffer88

Spending a rainy day with a group of amazing physicians, nurses, and pharmacists, and scientists creating the ATS guidelines on treatment of tobacco dependence.
Great PICO questions that will be impactful for all those who care for people who smoke.
#ATS2019 #tobacco

@panagis21

True difficult airway dominated by the disposable bronchoscope!
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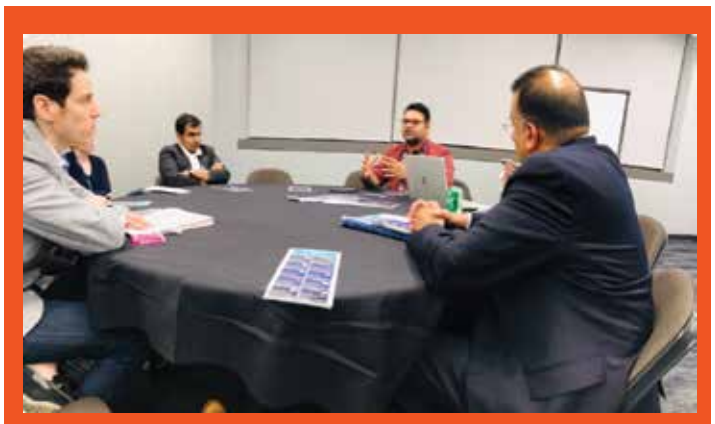

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KEYNOTE SERIES

Continued from page 3

AIDS. He is a staff writer for the New Yorker and has written for the New York Times, the Wall Street Journal, the Washington Post, and the New Republic. He is also the author of several books, including How Doctors Think.

Dr. Hartzband is a noted endocrinologist and educator specializing in disorders of the thyroid, adrenal, and pituitary glands and in women's health. She is the author of articles in the New England Journal of Medicine and the ACP Internist

Keynote Series Lineup

Monday: Data Sharing in the Context of Clinical Trials (K3)

Unraveling the Mystery of Breathlessness in COPD (K4)

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)

on the impact of electronic records, uniform practice guidelines, monetary incentives, and the effect of the Internet on the culture of clinical care.

Implementation Science: How Can It Support Health Research? (K2)

Ballroom C Three-Four (Level 2), KBHCCD

Anne Sales, PhD, RN, MSN, professor and associate chair for educational programs and health system innovation at the University of Michigan Medical School, and research scientist at the Center of Clinical Management Research for the VA Ann Arbor Healthcare System, will describe current definitions of implementation science and how implementation science principles and tools can increase the overall impact of health research.

Dr. Sales' work involves theory-based design of implementation interventions, including understanding how feedback reports affect provider behavior and impacts patient outcomes. She also is researching the role of social networks in uptake of evidence-based practices and implementation interventions. Dr. Sales is co-editor-in-chief of Implementation Science. ●

BIG DATA

Continued from page 1

completely unused," Dr. Liu said.

Matthew Semler, MD, pulmonary critical care physician at Vanderbilt University Medical Center in Nashville, and session co-chair, explained the challenges of extrapolating existing and new EHR data and feeding it into an algorithm to improve hospital operations and determine which treatments are better for which patients. That challenge can be overcome, though, by a combination of medical informatics and IT support in conjunction with hospital leaders, physicians, and medical researchers.

"The challenge the LHS faces is identifying common interventions where there is variation between providers," Dr. Semler said. "This information, combined with patient outcomes, could provide new evidence that can be applied for better patient care."

Patient privacy is always a concern. "We often talk about the limits of patient protection, HIPPA, and how we navigate those," Dr. Semler said, noting that there are encryption tools that can be applied to keep records anonymous.

"This all depends on us making strategic tweaks to the care we deliver every day and analyzing what those results are," Dr. Liu continued. "The flip side is to never learn from the data derived from the care we deliver patients." ●

Want More?

Don't miss these sessions that also explore how learning may be shaped by data and artificial intelligence, both taking place in Ballroom C One-Two (Level 2), KBHCCD.

Monday
8-8:45 a.m.
Data Sharing in the Context of Clinical Trials (K3)

Wednesday
8-8:45 a.m.
What Should Pulmonologists Know About Artificial Intelligence and Machine Learning? (K7)

MYATS

"The ATS responds to and supports its members' diverse and evolving interests, and the creation of the Section on Medical Education is one such example."

Jeremy B. Richards, MD, MA, ATSF

Assistant Professor of Medicine
Beth Israel Deaconess Medical Center and Harvard Medical School

Early Career Professionals Tap Resources

Career advice, small-group learning, hands-on training, and networking comprised key elements of the ATS programming for Early Career Professionals on Friday and Saturday.

Added to the lineup of the Student Scholars Program, Resident Boot Camp, and Fellows Track Symposium this year is the Fellow-to-Faculty Boot Camp.

Thirty attendees (15 clinical fellows and 15 post-doctoral PhD fellows) tapped the boot camp to address specific topics and challenges related to the field and to their independent transitions into their careers.

"The fellow-to-faculty transition is something that you haven't done until you do it," said Avraham Cooper, MD, of Columbus. "It seems like, historically, a lot of the advice people get is ad hoc. It happens after they've already gone through the transition. Part of the point of the boot camp is to give us that advice now, while we still have time to look at habits and incorporate that advice into this transition period."

The Student Scholars Program gave 70 medical, graduate, and undergraduate students the opportunity to attend the ATS 2019 International Conference for free in addition to receiving access to special educational sessions in mentorships.

Lorene Cudjoe, BA, a second-year medical student from Indianapolis, came in for the Student Scholars Program. "I'm not sure what I'm interested in, so I felt like if I'm able to get sort of a mentor, and also do some hands-on learning and networking, that will give me a better idea of how to navigate—if I'm interested in pulmonary care—what that looks like and what I can do."

Internal medicine and pediatric fellows who have already matched into a fellowship program for July 2019 participated in the Resident Boot Camp. There, more than 140 faculty teachers participated in presentations, small-group breakouts, and hands-on workshops.

Attendee Cameron McGuire, MD, MPH, Denver, said he is excited but terrified to be a fellow next year. "I'm hoping that all of this hands-on training and the larger lectures and smaller group work with experts helps me to feel more confident and comfortable."

The two-day Fellows Track Symposium allowed adult and pediatric fellows in pulmonary, critical care, and sleep medicine programs to arrive early to get oriented for the ATS 2019 International Conference. FTS participants learned about topics that correspond to specific sessions and poster presentations at ATS 2019 as well as interacted with world-renowned leaders in the field. ●

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OPENING CEREMONY

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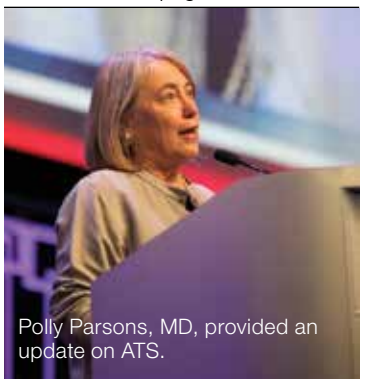


Polly Parsons, MD, provided an update on ATS.

have to refocus within schools, flip the classrooms so time is spent on teamwork."

To that point, Dr. Parsons spoke about the ATS's own efforts of improving education.

"Members now expect enhanced access to information, and they thrive with novel learning strategies that rely heavily on technology," Dr. Parsons said. "And in the even more competitive field of academic medicine, they need additional resources to advance the field of medicine and opportunities to earn academic capital to advance their careers."

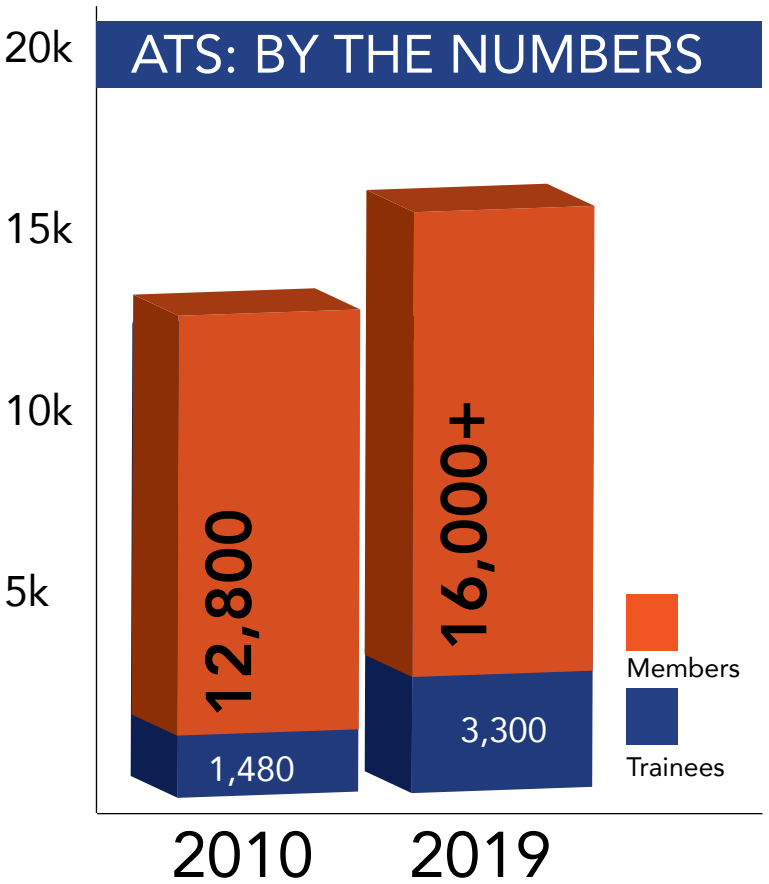
Dr. Parsons addressed the decline in specialists focusing on pediatric pulmonary care and the constant struggles for the scientist all along the pipeline. The ATS is working to address these needs with expanded early career educational opportunities such as The Resident Bootcamp, improved technology and association infrastructure, and the adoption of clear policies covering the areas of diversity, inclusion, and professional conduct.

"While we did have policies in place for some time, these new policies set higher standards and reflect a membership that prizes the extraordinary, not merely the acceptable," she said.

Moving forward, Dr. Parson encouraged continuing to cultivate the next generation of researchers.

"Ten years ago, we awarded four unrestricted research grants. This past year, we awarded 14. Including MECOR and partner grants, in the 2018 grant cycle, the Foundation awarded 30 research grants totaling more than $1.6 million. For this coming year, ATS has contributed additional dollars to the foundation to increase the number of unrestricted grants from 14 to 17, and we earmarked significant funds to ensure the program's future." ●

ATS: BY THE NUMBERS



AT ATS, WE HAVE

14 Assemblies

27 Committees

3 Sections

14 Interest Groups

Dr. Parson pointed to the growth of ATS as an association in the last 10 years, including members, trainees, assemblies, committees and more.

ATS 2019 Ramps Up

Early career education, hands-on learning, and networking were all key components to the kick-off of this year's International Conference.

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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