Welcome to ATS 2016

Thank you for joining us at the American Thoracic Society’s 2016 International Conference.

Whether you’re a clinician determined to stay at the forefront of practice, a researcher eager to explore an emerging field of science, or a trainee assessing professional pathways, ATS 2016—where today’s science meets tomorrow’s care—has something for everyone.

As the leading scientific conference in respiratory medicine, results of many major studies in the field have been announced first at the ATS International Conference. More recently, landmark studies testing new drugs to treat idiopathic pulmonary fibrosis, the use of statins to prevent chronic obstructive pulmonary disease exacerbations, and high-flow oxygen therapies for respiratory failure and postoperative cardiac surgery patients have been presented at the International Conference. Recent conferences also have underscored research on Idiopathic Pulmonary Fibrosis: Past, Present, Future (K2) is supported by educational grants from Boehringer Ingelheim Pharmaceuticals, Inc. and Genentech.

By Zea Borok, MD
International Conference Committee Chair

The 2016 ATS International Conference kicks off today in vastly scenic San Francisco, California, the City by the Bay.

OSA, IPF Headline Keynote Series

The ATS Keynote Series showcases a broad range of discoveries in pulmonary, critical care, and sleep medicine in eight state-of-the-art lectures. Member input and ATS committee involvement were key in identifying topics, and several presenters are internationally recognized speakers.

Unopposed by other programming, two lectures will be given concurrently from 8 to 8:45 a.m. Sunday, Monday, Tuesday, and Wednesday.

Be sure to attend the series highlighting major advances, recent discoveries, significant accomplishments, transformative findings, and important best practices.

Personalized Management of Obstructive Sleep Apnea
Moscone Center, Room 134 (North Building, Lower Level)
John R. Stradling, MD, MBBS, emeritus professor of respiratory medicine in the Nuffield Department of Medicine, University of Oxford, and National Health Services Trust consultant respiratory physician with the Oxford Centre for Respiratory Medicine, Churchill Hospital, Oxford Radcliffe Trust, United Kingdom

Idiopathic Pulmonary Fibrosis: Past, Present, Future
Moscone Center, Room 135 (North Building, Lower Level)
Talmadge E. King, MD, dean of the School of Medicine, vice chancellor of medical affairs, and chair of the department of medicine at the University of California, San Francisco

"Idiopathic Pulmonary Fibrosis: Past, Present, Future" (K2) is supported by educational grants from Boehringer Ingelheim Pharmaceuticals, Inc. and Genentech.

Connect With Clinical Trial Recruitment Reps

Visit the Clinical Trials Awareness Area to learn about clinical trial investigator opportunities and provide feedback on products in development. Four exhibitors in that area welcome your insights and expertise about how to improve and advance patient care. Stop by and see them in the Moscone Center Lobby (North Building, Lower Level).

FibroGen, Inc. in Booth 3 is a biotechnology company focused on the development and commercialization of therapeutic agents for serious unmet medical needs. FG3019, an investigational therapeutic antibody that inhibits the activity of connective tissue growth factor, is currently being evaluated in a randomized placebo-controlled Phase 2 trial in idiopathic pulmonary fibrosis. In a previous open-label Phase 2 IPF clinical trial, FG-3019 was found to be safe and well-tolerated, and changes in fibrosis were correlated with changes in pulmonary function.

Genentech, Inc. in Booth 6, which is now a member of the Roche Group, has been delivering on the promise of biotechnology for more than 35 years. Genentech uses human genetic information to discover, develop, manufacture, and commercialize medicines to treat patients with serious or life-threatening medical conditions. Today, they are

See WELCOME page 3

See TRIALS page 14

Accuracy.
Even with low perfusion, dark skin tones and rapid SpO2 changes.

Booth #1004
Join us for a non-CME dinner symposium featuring leading experts in PAH in an interactive and engaging discussion-based format. The faculty will explore developments in PAH, including combination therapy and clinical trial data. The program will also feature an interactive patient scenario and allow for audience participation.

Controversies in PAH: Experts Explore Combination Therapy

Sunday, May 15, 2016
6:30 PM Registration & Buffet Dinner
7:00 - 8:30 PM Interactive Session

SAN FRANCISCO MARRIOTT MARQUIS
Yerba Buena Ballroom 9
780 Mission Street, San Francisco, CA

TERESA DE MARCO, MD
Director of Advanced Heart Failure and Pulmonary Hypertension
Professor, University of California, San Francisco, School of Medicine
San Francisco, CA

NICHOLAS HILL, MD
Chief, Pulmonary, Critical Care and Sleep Division
Professor, Tufts University School of Medicine
Boston, MA

RAJAN SAGGAR, MD
Assistant Clinical Professor of Medicine, Pulmonary & Critical Care
University of California, Los Angeles Medical Center
Los Angeles, CA

An Industry-Organized Symposium at the ATS 2016 International Conference.
A non-CME educational program sponsored by Gilead Sciences, Inc. open to all ATS 2016 International Conference attendees.
Participants will need to wear their ATS badges to the event.
Please be mindful and observe any restrictions mandated by your employer or state related to meals or gifts. In accordance with company policy and the PhRMA Code on Interactions with Health Care Professionals, attendance at this educational program is limited to U.S. health care professionals. Accordingly, attendance by a guest is not appropriate and cannot be accommodated.

To Register For This Program
www.Gilead-dinner.com
ATS Honors 2016 Respiratory Health Award Recipients

Every year at the International Conference, the ATS recognizes individuals whose contributions have helped to improve health worldwide by advancing research, clinical care, and public health in respiratory disease, critical illness, and sleep disorders. This year, the Awards Committee has selected a diverse group of outstanding researchers and clinicians to receive 2016 Respiratory Health Awards. The following individuals will be honored at an awards ceremony from 4:30 to 6:30 p.m. Sunday at the Moscone Center, Gateway Ballroom 102-104 (South Building, Lower Level).

AMBERSON LECTURE
Marlene Rabinovitch, MD, the Dwight and Vera Dunlevie Professor of Pediatric Cardiology at Stanford University School of Medicine, California, will deliver the Amberston Lecture, named in honor of Dr. James Burns Amberston, an international authority on chest disease and tuberculosis. The lecture recognizes a career of major lifetime contributions to clinical or basic pulmonary research or and/or clinical practice.

EDWARD LIVINGSTON TRUDEAU MEDAL
Joe G.N. “Skip” Garcia, MD, senior vice president for health sciences and the Dr. Merlin K. DuVal Professor of Medicine at the University of Arizona, Tucson, will be awarded the Trudeau Medal. One of the Society’s highest recognitions, the Trudeau Medal recognizes lifelong major contributions to the prevention, diagnosis, and treatment of lung disease through leadership in research, education or clinical care.

WORLD LUNG HEALTH AWARD
Charles L. Daley, MD, professor of medicine at National Jewish Health (NJH) and the University of Denver, will receive the World Lung Health Award, which recognizes contributions to improving worldwide lung health in the area of translational or implementation research, delivery of health care, continuing education or care of patients with lung disease, or related political advocacy with a special emphasis on efforts that have the potential to eliminate gender, racial, ethnic, or economic health disparities worldwide. He also is chief of the Division of Mycobacterial and Respiratory Infections and director of the Nontuberculous Mycobacteria Center of Excellence at NJH.

OUTSTANDING EDUCATOR AWARD
Robert Kotloff, MD, chairman of the department of pediatrics at the University of North Carolina, Chapel Hill, and J. Usha Raj, MD, of the University of Illinois, Chicago, will receive Distinguished Achievement Awards, which recognize individuals who have made outstanding contributions to fighting respiratory disease through research, education, patient care, or advocacy. Dr. Doerschuk is professor and director of the Center for Airways Disease at the University of North Carolina, and Dr. Raj is a professor of pediatrics at the University of Illinois, Chicago.

PRESIDENT’S SYMPOSIUM
Making a Case for Applied Physiology

The use of applied physiological methods to optimize treatment will be examined in Monday’s President’s Symposium. Presenters will share how the discipline is paramount in the assessment of respiration mechanics, sleep apnea, the asthmatic airway epithelium, sepsis mechanisms, and regional lung strain, and perfusion. Although some suggest that applied physiology is dead, Monday’s President’s Symposium will present the case that applied physiology is alive and well. Molecular and cellular biology have made major advances, but the importance of function remains critical.

During “Applied Physiology Is Alive and Well,” from 9 to 11 a.m. in Moscone Center, Room 2016/2018 (West Building, Level 2), attendees will gain an understanding of the inflammatory reflex, the concept of driving pressure at the bedside, and the therapeutic importance of loop gain. World-renowned scientists, clinical investigators, and other thought leaders will review areas in which applied physiology has advanced and helped change the lives of patients.

“We have an exciting lineup,” says ATS President Atul Malhotra, MD, the Ken Moser Professor of Medicine and chief of the Division of Pulmonary and Critical Care Medicine at the University of California, San Diego. “Members should feel lucky that so many high-caliber speakers agreed to participate.” His co-moderator is Tatum S. Simonson, PhD, assistant adjunct professor of medicine and a postdoctoral fellow in the Division of Physiology at the University of California, San Francisco, and professor of medical education and mentoring in the fields of pulmonary, critical care, or sleep medicine. This award honors excellence in clinical or research education as it relates to pulmonary disease. This award will be given at the Plenary Session at 11:45 a.m. Tuesday.

JO RAE WRIGHT AWARD FOR OUTSTANDING SERVICE
Megan N. Ballinger, PhD, research assistant professor in the Division of Pulmonary, Allergy, Critical Care, and Sleep in the department of medicine at The Ohio State University, Columbus, will receive the Jo Rae Wright Award for Outstanding Science. The late Dr. Wright was the first PhD scientist to head the ATS, an outstanding researcher, and an extraordinary educator. The award is given in her memory and recognizes a rising generation of individuals who have the potential to be scientific leaders.

OUTSTANDING CLINICIAN
Jay M. Shames, MD, of New Orleans, Louisiana, will receive this year’s Outstanding Clinician Award, which recognizes a pulmonary, critical care, or sleep clinician who spends at least 75 percent of his or her time providing direct patient care and is recognized by patients and families as a caring and dedicated health care provider and by his or her peers as having made substantial contributions to the clinical care of patients with respiratory disease. Since 1967, Dr. Shames has served as president of Internal Medicine Specialists Inc., a multi-subspecialty practice in New Orleans serving patients at more than a dozen sites.
Meet and Network With Colleagues

Networking opportunities are a vital component of your ATS International Conference experience. These avenues for knowledge exchange foster connections that can lead to joint research projects, referrals, jobs, grants, and published papers. ATS 2016 offers attendees several areas for networking with colleagues.

**2ND ANNUAL BEAR CAGE**
**Sunday**
11:30 a.m.-1:15 p.m.
MOSCON CENTER, ROOM 105
(SOUTH BUILDING, LOWER LEVEL)

Early career investigators will compete for grants before a live audience and pitch their innovative research proposals to a panel of translational science experts representing academia, industry, and governmental sectors in the second annual Bear (Building Education to Advance Research) Cage competition.

Early career investigators who are ATS members submitted research proposals for the ATS competition, sponsored by the ATS Drug Discovery and Development (DDD) Committee. The top three submissions chosen by the ATS DDDD Committee were invited to pitch their research proposals. Again this year, the panel, with audience participation, will award $5,000 to a grand-prize winner and $2,500 each to two runners-up.

**CENTER FOR CAREER DEVELOPMENT**
7 a.m.-5 p.m.
Sunday-Tuesday
MOSCON CENTER, ALCOVE B
(WEST BUILDING, LEVEL 2)

The Center for Career Development is a networking and career development forum for physicians and other health care and research professionals who are in training or have transitioned in their careers.

**CCD WORKSHOPS**
**Sunday**
Noon-1 p.m.: ATS 101
1-2 p.m.: Clinical Trials
4-5 p.m.: Private Practice

**Monday**
Noon-1 p.m.: Early Career Group: How to Write a Paper
1-2 p.m.: Basic/Translational Career
4-5 p.m.: Negotiating a Private Practice Contract

**Tuesday**
Noon-1 p.m.: Grantsmanship: How to Get a K-Grant
1-2 p.m.: PhD Researcher/Scientist Careers
4-5 p.m.: Clinical Educators

Professional Networking Hour: All medical students, residents, fellows, post-docs, and other allied health care and research professionals are welcome to stop by from 3:30 to 4:30 p.m. each day to enjoy free cocktails and appetizers.

**CLINICIANS CENTER EVENTS**
**Sunday**, 11:30 a.m.-12:30 p.m.: Nurses Meet-and-Greet Reception
**Sunday**, 1:30-2:30 p.m.: Kickoff Reception for the ATS Pulmonary Function Laboratory Registry Membership Drive
**Monday**, 4-5 p.m.: Outstanding Clinician Award Reception for Recipient James P. Lambert, MD
**Sunday-Tuesday**, 8-8:45 a.m.: ATS Keynote Series Live Streaming

**MED-DAY EDUCATIONAL DEMONSTRATIONS**
**Sunday, 12:30-1:30 p.m.:** Medical Ventilation: Case Studies
**Monday, 12:30-1:30 p.m.:** Ultrasound in Pulmonary and Critical Care Emergencies
**Tuesday, 11:15 a.m.-12:15 p.m.:** Endobronchial Ultrasound Trambronchial Needle Aspirations—Improving Your Yield

**NEW! CODING AND BILLING PRACTICES IN PULMONARY, CRITICAL CARE, AND SLEEP MEDICINE**
2:30-4 p.m.
Learn and interact with an ATS member panel of experts in the adjacent Learning Lab while you enjoy a late afternoon snack.
**Monday:** ATS Coding and Billing—The Basics
**Tuesday:** ATS Coding and Billing—Advanced

**MOC POST-TESTS**
Take your MOC post-tests relating to the adult and pediatric core curriculum sessions presented at ATS 2016 in the Clinicians Center, where dedicated computers will be available Sunday through Tuesday.
**Breakfast:** A light complimentary breakfast will be available from 7:30-8:30 a.m. each day.

**INTERNATIONAL PARTICIPANTS CENTER**
10 a.m.-4 p.m.
Sunday-Tuesday
MOSCON CENTER LOBBY
(WEST BUILDING, LEVEL 2)

The International Participants Center is designed to enhance the conference experience for participants from outside North America and provide opportunities for all participants to become more knowledgeable about ATS International activities. The center provides a place to meet with colleagues, network, or just relax during your time at ATS 2016.

A social event from 4:15 to 6:30 p.m. Tuesday will recognize international participants attending ATS 2016 and the International Trainee/Methods in Epidemiology, Clinical, and Operations Research (MECOR) Scholarship awardees. All international participants, current and former International Trainee/MECOR award recipients, and colleagues are invited.

While at the center, visit with the ATS International Activities staff from the Washington office or make use of the center’s amenities, including computer stations; complimentary snacks, coffee, and soda; and space to meet with colleagues, network, or relax.

**SCIENCE AND INNOVATION CENTER**
7 a.m.-2:30 p.m.
Sunday-Tuesday
MOSCON CENTER
(WEST BUILDING, STREET LEVEL)

The Science and Innovation Center returns with networking events and presentations presented by experts eager to discuss a range of topics. Learn about research-related resources and consult informally with distinguished scientists about study design.

The center will feature the SIC 101 series, where you’ll learn about the basic principles underpinning high-profile symposia at the conference. Sunday will bring “CRISPR 101” and “Clock Genes," and Monday will offer “Linear Tracing 101” and “Metabolic Reprogramming in Lung Disease 101.” The talks are from 7:15 to 8 a.m.

**OTHER SPECIAL EVENTS**
**Rising Stars of Research:** Hear presentations by researchers at the assistant professor and early associate professor level, who are making outstanding contributions to the field of lung research, from 1:15 to 3 p.m. Sunday and Monday.

**Early Career Professionals Coffee Corner:** Chat and collaborate with mentors and mentees from 7:15 to 8 a.m. Tuesday.

**National Heart, Lung, and Blood Institute and National Institute of Allergy and Infectious Diseases:** Meet with representatives from the NHLBI and NIAID from 11:15 a.m. to noon Tuesday.

**Science and Innovation Center Abstract Awards:** Celebrate the best scientific abstracts submitted to ATS 2016 by early career professionals from 1:15 to 3 p.m. Tuesday.

Each day, breakfast will be served at 7 a.m., and refreshments will be available at noon.
Q: What challenges do clinicians, educators, and researchers face in pulmonary, critical care, and sleep medicine? How is the Society helping to address these issues?
A: The major challenge facing our field is assuring an adequate supply and distribution of high-quality health care professionals to reduce the burdens of lung disease and conditions globally. The unique contributions of the ATS are to advance the speed of scientific discovery and the translation of these findings into effective and affordable health care services and public health practices. Major ATS initiatives include:

a. Advocating for funding increases in National Institutes of Health research and training;
b. Growing our International Conference;
c. Further strengthening our three journals;
d. Producing, disseminating, and implementing strong clinical guidelines and statements;
e. Working collaboratively with our sister societies worldwide; and
f. Supporting the next generation of professionals in their research, clinical, and education careers.

Q: How has the International Conference evolved in recent years to appeal more to early career professionals?
A: We have substantially expanded our offerings to meet the needs of professionals at every stage of their career development. Each of our early career programs helps to synthesize research and integrate the latest therapies and treatments into everyday practice. The Fellows Track Symposium allows adult and pediatric fellows in pulmonary, critical care, and sleep medicine programs to attend a two-day course covering cutting-edge topics in the field of respiratory medicine. The Resident Boot Camp is a two-day course for third- and fourth-year internal medicine and pediatric residents who have matched into fellowship programs to provide them with knowledge that all incoming first-year fellows should know. The Student Scholars Program provides medical students, graduate students, and nursing students with exposure to the excitement of the scientific, translational, and clinical information presented at the conference.

In addition, the Junior Professionals Faculty Development Series gives young faculty knowledge critical to success in an academic career. The Fellows Case Conference offers opportunities for clinically oriented individuals to share their medical experiences and knowledge. The Society is proud to support early career professionals through scholarships and grants. The Minority Trainee Development Scholarship brings promising young physicians from diverse backgrounds to the conference. The Ziskind Clinical Research Scholar Award recognizes the best and the brightest early career individuals in clinical research and education. Finally, the ATS Foundation Research Program provides funding for junior investigators just starting their research careers.

Q: How is the Society maintaining its presence overseas?
A: The ATS is making greater use of technology to bring ATS programs to people abroad. We are expanding and making more available our educational offerings drawn from our International Conference. We co-sponsor several major international meetings and send ATS leadership to present at these meetings. Building upon a decade of experience, our Methods in Epidemiologic, Clinical, and Operations Research (MECOR) Program, an intensive one-week course for physicians and related health care professionals, has helped strengthen capacity and leadership in epidemiological, clinical, and operations research related to respiratory conditions, critical care, and sleep medicine in middle- and low-income countries. Throughout 2016, MECOR will host coursework in Guangzhou, China; Jaipur, India; Hanoi, Vietnam; Blantyre, Malawi; Jakarta, Indonesia; Kusadasi, Turkey; and in Argentina. We have lowered the cost of membership for a number of countries and created three-year membership opportunities. Free electronic subscriptions to the Annals of the American Thoracic Society are available for nonmembers. And we are reaching out at a grassroots level through Global Scholars and fellowship exchange programs.

The major challenge facing our field is assuring an adequate supply and distribution of high-quality health care professionals to reduce the burdens of lung disease and conditions globally.
The Chaos of ACOS

Asthma and chronic obstructive pulmonary disease are separate diseases, but recent research has uncovered more information about patients who have symptoms of both and suffer from asthma-COPD overlap syndrome (ACOS). A Sunday symposium will examine these findings and discuss diagnosis and treatment.

“Bringing Order to the Chaos of ACOS” will feature six speakers who will discuss how to distinguish ACOS from asthma and COPD, the shared immunity in asthma and COPD, the genetic origins of ACOS, the role of smoking in asthma, and ACOS therapies. The session is from 2:15 to 4:15 p.m. Sunday in Moscone Center, Room 2005/2007 (West Building, Level 2).

“ACOS is a real entity, but it is not yet defined. The Global Initiative for Asthma 2015 guidelines describe ACOS. In the last two years, there has been an explosion of interest and papers published on the topic. However, we still lack a full understanding of this condition,” says Amir A. Zeki, MD, one of the session chairs.

Although research has opened doors to learning more about ACOS, many questions remain. It is known that 15-55 percent of patients with obstructive lung disease have ACOS. Compared to other patients, they have more symptoms, greater declines in lung function, an increased risk of severe exacerbations, and a possibility of reduced life span.

“I hope that we can come away with a deeper understanding of this condition in order to eventually agree on a definition,” says Dr. Zeki, assistant professor of medicine at the University of California, Davis, School of Medicine, and co-director of the UC Davis Asthma Network Clinic. “This will take some time since much more research is needed. Given that ACOS patients seem to have more symptoms and greater disease severity, yet are younger than those with COPD, we urgently need to develop better and perhaps targeted therapies for those with overlap.”

Speakers will discuss molecular, pathophysiological, and clinical features of ACOS and how this information fits in with the differing British and Dutch hypotheses about the pathogenesis of COPD, which were developed in the 1960s.

“My hope is that the audience will also have a chance to discuss and appreciate the significant heterogeneity and overlap between asthma and COPD, where ACOS serves as an emerging and important clinical phenotype linking both diseases,” Dr. Zeki says.

“Bringing Order to the Chaos of ACOS (Asthma-COPD Overlap Syndrome)” (AB6) is supported by educational grants from AstraZeneca LP, Genentech, GlaxoSmithKline, Meda Pharmaceuticals, Inc., and Teva Pharmaceuticals.

Featured Speakers:

- Amir A. Zeki, MD
- Robert P. Baughman, MD
- James Rosenbaum, MD
- Jinny Tavee, MD
- William Sauer, MD
- Marc A. Judson, MD
- Robert P. Baughman, MD
- William Sauer, MD
- Jinny Tavee, MD
- Amir A. Zeki, MD
- Robert P. Baughman, MD

Related Education Sessions

Several other education sessions focus on the diagnosis and treatment of asthma.

Sunday, 9-11 a.m.
- Joint ATS/ERS/JRS Symposium on Severe Asthma: A Global Perspective
  - Moscone Center, Room 2001/2003 (West Building, Level 2)
- “Joint ATS/ERS/JRS Symposium on Severe Asthma: A Global Perspective” (A6) is supported by educational grants from AstraZeneca LP, Genentech, GlaxoSmithKline, Meda Pharmaceuticals, Inc., and Teva Pharmaceuticals.

Monday, 9-11 a.m.
- New Concepts in Asthma Biology
  - Moscone Center, Room 2005/2007 (West Building, Level 2)
- “New Concepts in Asthma Biology” (B10) is supported by educational grants from AstraZeneca LP, Genentech, GlaxoSmithKline, Meda Pharmaceuticals, Inc., Sanofi US and Regeneron Pharmaceuticals, and Teva Pharmaceuticals.

Tuesday, 2:15-4:15 p.m.
- Emerging Immune Functions of the Pulmonary Epithelium in Infection, Asthma, and Chronic Lung Disease
  - Moscone Center, Room 2005/2007 (West Building, Level 2)
- “Emerging Immune Functions of the Pulmonary Epithelium in Infection, Asthma, and Chronic Lung Disease” is supported by educational grants from AstraZeneca LP, Genentech, GlaxoSmithKline, Meda Pharmaceuticals, Inc., and Teva Pharmaceuticals.

Wednesday, 8-8:45 a.m.
- Biomarkers for Precision Medicine in Asthma
  - Moscone Center, Room 134 (North Building, Lower Level)
- “Biomarkers for Precision Medicine in Asthma” (K7) is supported by educational grants from AstraZeneca LP, Genentech, GlaxoSmithKline, Meda Pharmaceuticals, Inc., Sanofi US and Regeneron Pharmaceuticals, and Teva Pharmaceuticals.

9-11 a.m.
- Clinical Year in Review 4: Asthma
  - Moscone Center, Gateway Ballroom 102-104 (South Building, Lower Level)
- “Clinical Year in Review 4: Asthma” (DJ1) is supported by educational grants from Actelion Pharmaceuticals US, Inc., AstraZeneca LP, Boehringer Ingelheim Pharmaceuticals, Inc., Genentech, GlaxoSmithKline, Meda Pharmaceuticals, Inc., Sanofi US and Regeneron Pharmaceuticals, Teva Pharmaceuticals, and United Therapeutics Corporation.

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Exploiting GPCRs for New and Improved Asthma Medicine

Moscone Center, Room 2002/2004 (West Building, Lower Level)
- “Exploiting GPCRs for New and Improved Asthma Medicine” (D7) is supported by educational grants from AstraZeneca LP, Genentech, GlaxoSmithKline, Meda Pharmaceuticals, Inc., and Teva Pharmaceuticals.

11:45-1:15 p.m.
- Precision Medicine in Asthma: Current Practice, Gaps, Future Directions
  - Moscone Center, Room 302 (South Building, Esplanade Level)
injury that could lead to death or the need for liver transplants in some patients. Conduct liver function tests (ALT, AST, and bilirubin) prior to initiating Esbriet, then monthly for the first 6 months and every 3 months thereafter. Dosage modifications or interruption may be necessary.

Elevated liver enzymes: Increases in ALT and AST >3 × ULN have been reported in patients treated with Esbriet. Rarely these have been associated with concomitant elevations in bilirubin. Patients treated with Esbriet had a higher incidence of elevations in ALT or AST than placebo patients (3.7% vs 0.8%, respectively). No cases of liver transplant or death due to liver failure that were related to Esbriet have been reported. However, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that could lead to death or the need for liver transplants in some patients. Conduct liver function tests (ALT, AST, and bilirubin) prior to initiating Esbriet, then monthly for the first 6 months and every 3 months thereafter. Dosage modifications or interruption may be necessary.

Photosensitivity reaction or rash: Patients treated with Esbriet had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). Patients should avoid or minimize exposure to sunlight (including sunlamps), use a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

Gastrointestinal disorders: Gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastrointestinal reflux disease, and abdominal pain were more frequently reported in patients treated with Esbriet. Dosage reduction or interruption for gastrointestinal events was required in 18.5% of patients in the 2403 mg/day group, as compared to 5.8% of patients in the placebo group; 2.2% of patients treated with Esbriet had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). Patients should avoid or minimize exposure to sunlight (including sunlamps), use a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

Drug interactions: Concomitant administration with strong inhibitors of CYP1A2 (e.g., fluvoxamine) significantly increases systemic exposure of Esbriet and is not recommended. Discontinue prior to administration of Esbriet. If strong CYP1A2 inhibitors cannot be avoided, dosage reductions of Esbriet are recommended. Monitor for adverse reactions and consider discontinuation of Esbriet as needed. Concomitant administration of Esbriet and ciprofloxacin (a moderate inhibitor of CYP1A2) moderately increases exposure to Esbriet. If ciprofloxacin is used, dosage reductions are recommended. Monitor patients closely when ciprofloxacin is used.

Agents that are moderate or strong inhibitors of both CYP1A2 and CYP3A4 enzymes involved in the metabolism of Esbriet should be avoided during treatment. The concomitant use of a CYP1A2 inducer may decrease the exposure of Esbriet, and may lead to loss of efficacy. Concomitant use of strong CYP1A2 inducers should be avoided.

Specific populations: Patients treated with Esbriet had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). Patients should avoid or minimize exposure to sunlight (including sunlamps), use a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

Indication
Esbriet® (pirfenidone) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

Select Important Safety Information
Elevated liver enzymes: Increases in ALT and AST >3 × ULN have been reported in patients treated with Esbriet. Rarely these have been associated with concomitant elevations in bilirubin. Patients treated with Esbriet had a higher incidence of elevations in ALT or AST than placebo patients (3.7% vs 0.8%, respectively). No cases of liver transplant or death due to liver failure that were related to Esbriet have been reported. However, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that could lead to death or the need for liver transplants in some patients. Conduct liver function tests (ALT, AST, and bilirubin) prior to initiating Esbriet, then monthly for the first 6 months and every 3 months thereafter. Dosage modifications or interruption may be necessary.

Photosensitivity reaction or rash: Patients treated with Esbriet had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). Patients should avoid or minimize exposure to sunlight (including sunlamps), use a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

Gastrointestinal disorders: Gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastrointestinal reflux disease, and abdominal pain were more frequently reported in patients treated with Esbriet. Dosage reduction or interruption for gastrointestinal events was required in 18.5% of patients in the 2403 mg/day group, as compared to 5.8% of patients in the placebo group; 2.2% of patients treated with Esbriet had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). Patients should avoid or minimize exposure to sunlight (including sunlamps), use a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

Drug interactions: Concomitant administration with strong inhibitors of CYP1A2 (e.g., fluvoxamine) significantly increases systemic exposure of Esbriet and is not recommended. Discontinue prior to administration of Esbriet. If strong CYP1A2 inhibitors cannot be avoided, dosage reductions of Esbriet are recommended. Monitor for adverse reactions and consider discontinuation of Esbriet as needed. Concomitant administration of Esbriet and ciprofloxacin (a moderate inhibitor of CYP1A2) moderately increases exposure to Esbriet. If ciprofloxacin is used, dosage reductions are recommended. Monitor patients closely when ciprofloxacin is used.

Agents that are moderate or strong inhibitors of both CYP1A2 and CYP3A4 enzymes involved in the metabolism of Esbriet should be avoided during treatment. The concomitant use of a CYP1A2 inducer may decrease the exposure of Esbriet, and may lead to loss of efficacy. Concomitant use of strong CYP1A2 inducers should be avoided.

Specific populations: Patients treated with Esbriet had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). Patients should avoid or minimize exposure to sunlight (including sunlamps), use a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.
Annual Forums to Focus on Diversity and Inclusivity

Two popular forums at ATS 2016 give attendees the opportunity to celebrate diversity and women in the fields of pulmonary, critical care, and sleep medicine. A plated lunch will be served at both forums.

The annual Diversity Forum, from 11:45 a.m. to 1:15 p.m. Sunday, will feature Sonia C. Flores, PhD, professor of medicine, Division of Pulmonary Sciences, University of Colorado Anschutz Medical Campus, Aurora, who will address career and diversity issues, and answer questions from the audience. Minority Trainee Development Scholarships (MTDS) also will be presented. MTDS recipients are selected for the quality of science in their submitted abstracts.

The annual Women’s Forum, from 11:45 a.m. to 1:15 p.m. Monday, will bring guest speaker Catherine R. Lucey, MD, the Faustino and Martha Molina Bernadett Presidential Chair for Medical Education, professor of medicine, and vice dean for education at the University of California, San Francisco, School of Medicine.

The 2016 Elizabeth A. Rich, MD, Award will be presented to Irina Petrache, MD, professor of medicine and chief of pulmonary, critical care, and sleep medicine at National Jewish Health, Denver, Colorado. Men are welcome to attend. Lunch will be served during both forums, which are sponsored by the ATS and hosted by Yolanda Mageto, MD, MPH, ATS Membership Committee chair. Both forums will be at the Marriott Marquis, Yerba Buena Ballroom 7.

Only conference badges are required for admission. Seating is available on a first-come, first-serve basis. If you did not register in advance, you may be able to get a seat by arriving early.

Journal Editors Lead Forums

Editors from the journal of the American Medical Association and the New England Journal of Medicine will share their insights during two Sunday forums.

Jeffrey M. Drazen, MD, NEJM editor-in-chief, and George T. O’Connor, MD, MS, a JAMA associate editor, will moderate “JAMA and the New England Journal of Medicine. Discussion on the Edge: Reports of Recent Pulmonary Research” from 9 to 11 a.m. on Sunday.

Derek C. Angus, MD, MPH, JAMA section editor for caring for the critically ill, and Dr. Drazen will moderate “The New England Journal of Medicine and JAMA. Discussion on the Edge: Reports of Recent Critical Care Research” from 2:15 to 4:15 p.m. on Sunday.

These sessions will provide a forum for attendees to interact with the authors and editors about papers published in JAMA and NEJM. Editors selected papers from recent publications based on their significant importance to the field of pulmonary medicine. Each of the speakers will give a short research presentation, which will be followed by analysis by one of the moderators. Attendees will have the opportunity to ask questions of both the authors and editors. The discussion is intended to provide a unique insight into these papers, the selection process, and how the research will impact pulmonary medicine.

Exhibit Hall Hours

SUNDAY-TUESDAY
8 a.m.-2:45 p.m.
Unopposed Hours: 1:15-2:15 p.m.
ORENITRAM DOSING ADAPTS

Introduce prostacyclin treatment early with Orenitram, which enables you to adjust dose based on tolerability and clinical response.

The only prostacyclin analogue in a tablet:

For PAH, a progressive disease

Early use in FC II and III

Ability to transition from treprostinil parenteral therapy

Orenitram allows you to initiate treatment with 0.125 mg TID (~8 hrs apart) or 0.25 mg BID (~12 hrs apart), then titrate up or down every 3 to 4 days as needed per Full Prescribing Information (PI). In the pivotal trial, dose was titrated based on clinical response and tolerability. If not tolerated, titrate slower or decrease dose by 0.25 mg. Avoid abrupt discontinuation. Orenitram tablets should be taken whole and with food. If a dose is missed, please refer to the PI. Orenitram should not be used in patients with moderate hepatic impairment. Dose adjustments required for mild hepatic impairment.

*In a 24-week, multicenter, open-label study to establish safety and tolerability of transition, WHO Group 1 patients (FC I or II) on stable doses of IV/SC treprostinil as well as a PDE-5i and/or ERA were evaluated.

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 FOR OREINTRAM

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 CYP2C9 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

References


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 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 9% 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.

DRUG INTERACTIONS
Antihypertensive Agents or Other Vasodilator—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 coadministered with either flosemide, rifampin, sildenafíl, 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 mg/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.

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

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Orenitram (N=151)</th>
<th>Placebo (N=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>63%</td>
<td>19%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>30%</td>
<td>16%</td>
</tr>
<tr>
<td>Nausea</td>
<td>30%</td>
<td>18%</td>
</tr>
<tr>
<td>Flushing</td>
<td>15%</td>
<td>6%</td>
</tr>
<tr>
<td>Pain in jaw</td>
<td>11%</td>
<td>4%</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>14%</td>
<td>8%</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>9%</td>
<td>3%</td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>6%</td>
<td>0%</td>
</tr>
</tbody>
</table>

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.

Genetic 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 2016
www.orenitram.com
Assemblies and Sections Meet and Host Events

One of the best ways to get involved in the ATS is through your Assembly and/or Section. “While an Assembly Membership Meeting can seem a little overwhelming, it is the best way to learn about the group’s current projects and future plans,” says Patricia A. Kritek, MD, chair of the Section on Medical Education. “At each meeting, there are opportunities to sign up and help with the group’s activities. This is a great way to meet fellow members and start participating in the Assembly or Section.”

“The Society’s Assemblies and Sections will hold their annual Membership Meetings Sunday and Monday at various San Francisco locations. All attendees are encouraged to attend these meetings. See below for the schedule of Assembly Membership Meetings, Receptions, Section Meetings, and Assembly Dinners.”

**ASSEMBLY MEMBERSHIP MEETINGS**

The Assembly Membership Meetings provide an update on each assembly’s activities via each assembly’s leadership and give assembly members the chance to have input on future directions, information on how to get involved, and networking opportunities. Voting results for the assembly’s future leaders also will be announced.

These meetings will all be held in various locations from 5 to 7 p.m. Monday, with the exception of the Assembly on Behavioral Science and Health Services Research and the Assembly on Pediatrics, which will meet from 6:30 to 8:30 p.m. Sunday.

**SUNDAY**

6:30-8:30 p.m.

**Behavioral Science and Health Services Research**

Chair: Kristin A. Riskert, PhD
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 10-13, Lower B2 Level

**Pediatrics**

Chair: James F. Cherniak, MD, MPH
San Francisco Marriott Marquis, Yerba Buena Ballroom 8, Lower B2 Level

**MONDAY**

5-7 p.m.

**Allergy, Immunology, and Inflammation**

Chair: Mitchell A. Olman, MA, MD
San Francisco Marriott Marquis, Golden Gate Ballroom A, B2 Level

**Clinical Problems**

Chair: Gregory Tine, MD
Hilton San Francisco Union Square, Continental Ballroom 6, Ballroom Level

**Critical Care**

Chair: Carolyn S. Cadée, MD
San Francisco Marriott Marquis, Yerba Buena Ballroom 8, Lower B2 Level

**Environmental, Occupational, and Population Health**

Chair: Jack R. Harkema, DVM, PhD
Hilton San Francisco Union Square, Continental Ballroom 4, Ballroom Level

**Microbiology, Tuberculosis, and Pulmonary Infections**

Chair: Richard G. Vanderklink, MD
San Francisco Marriott Marquis, Yerba Buena Ballroom 4-6, Lower B2 Level

**SECTION MEETINGS**

**SUNDAY**

6:30-8:30 p.m.

**Section on Tobacco and Inhalation Disasters**

Co-Chairs: Eleanor Summerhill, MD, and Sadis Matalon, PhD, ScD (Hon.)
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 1-2, Lower B2 Level

6:30-8:30 p.m.

**Section on Genetics and Genomics**

Co-Chairs: Mark M. Worgel, MD, PhD, and Craig P. Hersh, MD, MPH
San Francisco Marriott Marquis, Yerba Buena Ballroom 4-6, Lower B2 Level

**MONDAY**

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

**Section on Medical Education**

Co-Chairs: Patricia A. Kritek, MD, and Alison S. Clay, MD
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 13-15, Lower B2 Level

**RECEPTIONS**

Eight assemblies will hold dinners or receptions from 7 to 10 p.m. Monday. Assembly members and nonmembers, students, and fellows are invited to join these assemblies for an evening of food, company, camaraderie, and an entertaining program. This is a wonderful opportunity to introduce young members and trainees to assembly leaders, to connect with friends, and to establish new interactions and collaborations. Pre-registration and an additional fee are required to attend the dinners and receptions.

**ASSEMBLY DINNERS**

**MONDAY**

7-10 p.m.

**Dinners**

San Francisco Marriott Marquis, Atrium, Second Level

**ASSEMBLY RECEPTIONS**

**MONDAY**

7-10 p.m.

**Receptions**

San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 1-3, Lower B2 Level

**Sleep and Respiratory Neurobiology**

San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 7, Lower B2 Level

**Critical Care**

San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 8, Lower B2 Level

**Thoracic Oncology**

San Francisco Marriott Marquis, Foothill G, Second Level

**Microbiology, Tuberculosis and Pulmonary Infections**

San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 1, Lower B2 Level

**Respiratory Structure and Function**

San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 9, Lower B2 Level

**Thoracic Oncology**

San Francisco Marriott Marquis, Foothill G, Second Level

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**2nd Annual BEAR Cage**

Sunday, May 15, 2016 11:30 a.m. - 11:15 p.m.

Moscone Center, Room 105 (South Building, Lower Level)

Join us to see the top three finalists of the BEAR Cage competition “pitch” their highly innovative research proposals to a panel of translational science experts.

**Grand Prize**

$5,000

**Finalists**

$2,500

Hosted by the ATS Drug Device Discovery and Development Committee (DDDD).
For more information please contact DDDD@thoracic.org.

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**California Republic**
Learning Opportunities Abound at Non-CME Symposia

The ATS encourages ATS 2016 attendees to participate in any of several Non-CME Symposia Sunday and Tuesday. Please see the Tuesday issue of the ATS Daily Bulletin for a list of Tuesday Non-CME Symposia.

Sunday
6:30-9:30 p.m.
Hilton Union Square: Continental Ballroom 5 (Ballroom Level)

Bridging the Evidence: Applying Case-Based Reasoning to Improve Non-Cystic Fibrosis Bronchiectasis Care
The program introduces an exciting learning format that simulates clinical decision making and allows you to compare your clinical impression and management approach to that of the expert faculty.
At the end of this learning activity, participants should be able to:
• Understand the impact of non-cystic fibrosis bronchiectasis (NCFB) on patients’ quality-of-life, disease morbidity, and mortality.
• Consider changes in NCFB management strategy in patients who have chronic infection with respiratory pathogens, including but not limited to P. aeruginosa.
• Recognize the short- and long-term impact of NCFB exacerbations including its consequences on quality-of-life, future exacerbations, hospital admissions, and mortality.
Chairman: Timothy Aksamit, MD Rochester, Minnesota.
Company: Novartis Pharma AG

6:30-9:30 p.m.
PARK CENTRAL SAN FRANCISCO: METROPOLITAN BALLROOM (SECOND LEVEL)

Burning Questions in COPD and Asthma
Open to non-U.S. attendees only.
How have we progressed in COPD exacerbation risk reduction and what are the implications of the new clinical trial evidence? What are the key targets in allergic asthma and how do new treatments align with different phenotypes?
Join world-renowned experts discussing these burning questions during this symposium.
Speakers:
Welcome and Introduction—Professor Roland Buhl (Chair, Germany)
Are burning issues in severe asthma initiated by small sparks?—Professor David Price (Singapore)
Uncovering the hidden elements of the allergic cascade—Professor Dave Singh (UK)
Quick-fire presentations: Role of IgE responses in asthma according to disease endo/phenotypes—Professor Dave Singh (UK) and Professor Chanez (France)
IgE in severe allergic asthma: A strong history and new findings—Professor Pascal Chanez (France)
Word from the Chair: From asthma to COPD—Professor Roland Buhl (Germany)
Company: Novartis Pharma AG

What could be worse than having NTM? Not knowing you have NTM.

References:

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Why is NTM challenging to diagnose?

- Signs and symptoms, such as chronic cough, fatigue, and failed response to antibiotic regimens are common and nonspecific.
- Nontuberculous mycobacteria (NTM) lung infections can be easily masked by other comorbidities, such as bronchiectasis, and may go untreated for months, even years.¹³
- Delaying a diagnosis for NTM can lead to prolonged and inaccurate treatments. This can result in increasing rates of antibiotic resistance and compounding respiratory problems for patients.²
- In some serious cases, a delay in diagnosis can result in irreversible lung damage, such as cavitary lesions, in more than 50% of patients.²⁴

Think NTM? Test for NTM.

Learn more at the updated NTMfacts.com
Continued from page 13

Actelion Pharmaceuticals US Inc.

**Company:**
Cedars-Sinai Medical Center, Los Angeles, California; La Jolla, California; Victor Tapson, MD, Kim, MD, University of California, San Diego, Health System, Ann Arbor, Michigan; Nick Program Chair, University of Michigan, Speakers:

Vallerie McLaughlin, MD, where gifts and meals are prohibited.

provided to physicians and other healthcare treatment of patients with PAH.

case-based symposium will feature a panel of include:

- Introduction to Sarcoidosis, Marc A. Judson, MD
- Cardiac Sarcoidosis, TBD
- Neurosarcoidosis, Jinny Tavee, MD
- Ocular Sarcoidosis, James Rosenbaum, MD
- Pulmonary Sarcoidosis, Robert P. Baughman, MD
- Therapy for Symptomatic Sarcoidosis,

**Company:** Actelion Pharmaceuticals US Inc.

6:30-9:30 p.m. HILTON UNION SQUARE: IMPERIAL BALLROOM (BALLROOM LEVEL)
Sarcoidosis: A Multidisciplinary Approach to Diagnosis and Management
(open to U.S. attendees only)
The current state of sarcoidosis diagnosis and management will be discussed. Topics will include:

- Introduction to Sarcoidosis, Marc A. Judson, MD
- Cardiac Sarcoidosis, TBD
- Neurosarcoidosis, Jinny Tavee, MD
- Ocular Sarcoidosis, James Rosenbaum, MD
- Pulmonary Sarcoidosis, Robert P. Baughman, MD
- Therapy for Symptomatic Sarcoidosis,

Robert P. Baughman, MD
Dinner will be provided.
**Company:** Mallinckrodt Pharmaceuticals

8:30-10:30 p.m. Dessert Symposium
SAN FRANCISCO MARRIOTT MARQUIS: MEZZANINE (SECOND LEVEL)
Joint Presentation on Seasonal Allergic Rhinitis and Maintenance Treatment of Asthma
Meda Pharmaceuticals will host a joint presentation on Seasonal Allergic Rhinitis and maintenance treatment of Asthma. A donation of $75 will be made to The ATS Foundation for each registered ATS attendee attending this Non-CME Symposium.

**Company:** Willoughby, MD, MBA,
University of California Irvine, Mission Viejo, California; Randall W. Brown, MD, MPH, AE-C, University of Michigan, Ann Arbor, Michigan; Bradley Chippis, MD, Capital Allergy & Respiratory Disease Center, Sacramento, California; LeRoy Graham, MD, Bridge Atlanta Medical Group, Atlanta, Georgia; Michael G. Marcus, MD, Maimonides Medical Center, Brooklyn, New York; Kevin R. Murphy, MD, Boys Town National Research Hospital, Omaha, Nebraska; David P. Skoner, MD, Allegheny General Hospital, Pittsburgh, Pennsylvania; Maeve O’Connor, MD, Allergy Asthma & Immunology, Charlotte, North Carolina

**Company:** MEDA Pharmaceuticals Inc.

among the world’s leading biotech companies, with multiple products on the market and a promising development pipeline.

Insmed Incorporated in Booth 1 brings its mission to transform the lives of patients battling serious, rare diseases, such as nontuberculous mycobacterial avium complex and who have not responded to previous treatments.

New ViziShot FLEX 19G EBUS-TBNA Needle

**Achieve More at the Source**

improve sample size for enhanced diagnostic guidance and targeted therapy

- Large, highly flexible EBUS-TBNA needle enables substantial tissue collection, even in highly challenging areas
- Advanced design offers proprietary safety features, including a double-locking mechanism to help avoid accidental needle protrusion
- ViziShot needles are an integral component of the Olympus EBUS Solution, which delivers proven precision in real time

To schedule a demonstration, contact an Olympus EndoTherapy territory manager or call 866-556-8751.
Shake, Rattle and Cough: 
Guide to Airway Clearance from Hospital to Home.

Join industry experts for this hands-on workshop where we will discuss and demonstrate various disease pathologies and the airway clearance therapy modalities that can be implemented in a treatment plan for patients across the continuum of care.

Industry experts

Sherri Katz MDCM, FRCPC, MSc
Associate Professor and
Pediatric Respirologist
University of Ottawa, Canada

Noah Lechtzin, MD, MHS
Assistant Director, Adult
Cystic Fibrosis Program
Associate Professor of Medicine
Johns Hopkins University, MD

John M Coleman, MD
Assistant Professor in Medicine-
Pulmonary and Neurology
Northwestern University, IL

Lisa Wolfe, MD
Associate Professor in Medicine-
Pulmonary and Neurology
Northwestern University, IL

Venessa Holland, MD
Pulmonary Critical Care
Methodist Hospital, Houston, TX

TODAY!
May 15, 2016
12:30 pm - 2:00 pm
JOIN US FOR A NON-CME/CNE INFORMATIONAL PROGRAM
Sponsored by Boehringer Ingelheim Pharmaceuticals, Inc.

Sunday, May 15, 2016
6:30 pm - 9:30 pm
Marriott Marquis, San Francisco
Golden Gate B

ADMISSION IS COMPLIMENTARY AND WILL BE ON A FIRST-COME, FIRST-SERVED BASIS. DINNER WILL BE PROVIDED.

An Industry-Organized Symposium at the ATS 2016 International Conference. All ATS 2016 International Conference attendees are invited to this non-CME/CNE educational program sponsored by Boehringer Ingelheim Pharmaceuticals, Inc.

Attendance is limited to healthcare professionals only. Aspects of this program may be reportable under the physician payments Sunshine Act.

CME, continuing medical education; CNE, continuing nursing education.
AND VISIT BOOTH #1003 TO LEARN MORE ABOUT OFEV
Join the conversation on Instagram and Twitter by tagging your photos and posts with #ATS2016. Follow these simple tips to make the most of all your updates.

**TAKE IMAGES TO THE NEXT LEVEL ON INSTAGRAM**
- Get close to your subject.
- Change your perspective to better frame your photo.
- Switch to portrait orientation for vertical photos.
- Focus on your subject with the tap of your screen.
- Mix things up with off-center photos.
- Enable public setting on your Instagram app.
- Tag your images with #ATS2016.

**USE THE 5Ws**
- **Who:** Include your chapter, committee, assembly, or section in photos of yourself, mentors, and others.
- **What:** Show off your ATS swag (ATS pens, key chains, mugs, and jackets). Share our ATS Walking Challenge steps in a humble brag. (Be sure to register at cloud.hekahealth.com/ats2016.)
- **Where:** Take photos in public spaces of the convention center and hotels, such as lobbies, corridors, and atriums; at receptions, dinners, and anywhere ATS attendees gather; official ATS selfie stations located in the Moscone Center lobbies (South Building, Upper Level, and West Building, Level 1); and out and about at San Francisco landmarks. (Photography is not permitted in the Exhibit Hall.)
- **When:** Avoid the midday sun when natural light is the most harsh. Opt for early morning, late afternoon, and early evening photo opps.
- **Why:** Photos are fun to share, and your colleagues will feel engaged.

**TWITTER ESSENTIALS FOR NEWBIES**
- Go easy on the hashtags. Hashtags are a must-have, but use them in moderation, limiting yourself to about two per tweet. Include the official conference hashtag, #ATS2016, so attendees can see, share, and engage with your tweets.
- Less is more: Stop short of the 140-character limit to allow for easy sharing and reposting (e.g., RT @atscommunity).
- Diversity is key: Follow the 60-30-10 rule with 60 percent re-tweets to promote other posts, 30 percent for conversation and responses, and 10 percent for your updates, announcements, and events. Remember: You are joining the conversation, not taking it over.

**Grow Your Group’s Social Networks**
Active members of ATS chapters, committees, assemblies, or sections can use this primer to build their social media presence.

- **Have a heartbeat:** Don’t overwhelm your followers. A basic guideline for social media frequency is about one Facebook post per day, or five to seven posts per week. For Twitter, a general rule is three to five tweets per day.
- **Feed your soul:** Inspiration for posts takes time and effort. Get into the habit of regularly searching, sourcing, and posting compelling content.

**Product and Services Showcase**

**Clinical Hands-on Training and Assessment**

Booth #620

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**ATS 2016 AT YOUR FINGERTIPS**

DOWNLOAD THE CONFERENCE APP

The ATS 2016 app can be installed on iPhones and iPads iOS 8+ and Android devices OS 4.3+.
Six physicians and patient advocates attending the ATS International Conference will share their experiences via the ATS Community on Facebook (facebook.com/americanthoracic).

SHOWCASING TODAY'S SCIENCE
An asthma researcher and physician, Ann Wu, MD, MPH, began her blog, Asth.ma (http://asth.ma) for several reasons. She is a pediatrician who treats asthma and the parent of a child with asthma.

“Blogging provides the means to share the latest information in asthma research with patients, to gain a better understanding of what patients think with respect to treating and managing their asthma, and to learn something new that could trigger my next asthma study or new way of providing patient care,” says Dr. Wu, who conducts her research at Harvard Medical School and treats patients at Children’s Hospital of Boston, Massachusetts.

She brings a unique perspective to blog readers, and her goal is to provide a snapshot of ATS 2016. “I hope to provide physicians and patients an idea of the most cutting-edge research,” Dr. Wu says.

Another physician who will blog on the ATS Community Facebook page is Nitin Seam, MD, podcast editor of the American Journal of Respiratory and Critical Care Medicine, assistant professor of medicine at George Washington School of Medicine and Health Sciences, and fellowship associate program director in the critical care medicine department, office of clinical research training and medical education, National Institute’s of Health Clinical Center, Washington, D.C.

Jess Mandel, MD, 2015-17 chair appointee of the ATS International Conference Committee, returns to the blog squad this year after first serving as a guest blogger at ATS 2015. “I chose to help share updates because the conference is enormous, and I hope my blogging will lend a human scale and perspective,” says Dr. Mandel, associate dean for undergraduate medical education and professor of medicine at the University of California, San Diego, School of Medicine.

CHANGING TOMORROW’S CARE
Among three patient advocates blogging about Saturday’s ATS (PAR) Advisory Roundtable Meet-the-Experts Forum is Jeff Goldstein, a lung transplant recipient and former patient with idiopathic pulmonary fibrosis. He is president and founding member of the Lung Transplant Foundation, a PAR organization.

“Meet the Experts is a completely unique experience and opportunity for patients to gather and meet each another, hear experts in their fields share unique and timely information, and interact one-on-one with those experts,” Mr. Goldstein says. “I feel this is of primary importance, and I choose to participate to let as many of our constituents know about it and share it with their networks.”

His hope is that attendees will gain insight into the topics affecting their health care and will feel empowered. “This knowledge has been proven to help patients manage their care and relieve their anxiety of living with a chronic disease,” he says. “By blogging and sharing PAR takeaways through social media, patients can access the information, learn, appreciate, and share in the experiences.”

Susan Wisliceny, director of operations for NTM Info & Research Inc, a PAR member PAR, is equally excited about the forum.

“The Meet-the-Experts program provides an amazing opportunity for patients, friends, and families living with serious lung illnesses to learn from experts and each other,” says Ms. Wisliceny, adding that she looks forward to one-on-one sessions with physicians, which take place during afternoon breakout sessions.

Valerie Chang, JD, has chronic obstructive pulmonary disease and is executive director of the Hawaii COPD Coalition. She says she considers it an honor and privilege to attend and meet top researchers, health care providers, and other patients, and to be able to discuss current issues, research, technology, and exhibits.

“I like to share this information that so many patients and practitioners are unable to get, since so many cannot attend these wonderful events,” Ms. Chang says.

Our experts are challenging conventional treatments for inflammatory conditions of the lungs.

UPMC’s Acute Lung Injury Center of Excellence is dedicated to investigating life-threatening complications of inflammatory disorders, including pneumonia. Our recent focus involves the use of cutting-edge initiatives to reverse lung injury associated with pneumonia, based on fundamentally new discoveries of mechanisms of the disease in critically ill patients. Our researchers are actively pursuing multiple strategies, including identification of biomarkers for at-risk patients with pneumonia, use of stem cell replacement strategies, and the development of novel immunomodulatory drug therapies. To learn more about our breakthroughs in treating inflammatory conditions of the lungs, visit UPMCPHysicianResources.com/Pulmonology.
Introducing a New Treatment Option for PAH:
A Case-based Discussion

Agenda and Faculty

Welcome and Introductions
Vallerie McLaughlin, MD, Program Chair
University of Michigan Health System
Ann Arbor, Michigan

Overview of Pulmonary Arterial Hypertension (PAH)
Vallerie McLaughlin, MD, Program Chair

A New Treatment Option for PAH
Nick Kim, MD
University of California, San Diego
La Jolla, California

Case Studies
Victor Tapson, MD
Cedars-Sinai Medical Center
Los Angeles, California

Panel Discussion
All Faculty

Concluding Remarks
Vallerie McLaughlin, MD, Program Chair

Sunday, May 15, 2016
6:30 – 7:00 PM Registration and Dinner
7:00 – 8:30 PM Symposium

InterContinental San Francisco
Grand Ballroom, 3rd Floor
888 Howard Street
San Francisco, California

You are invited to an evening symposium

Register on-site or online at: www.PAHsymposium.com

This promotional program is sponsored by Actelion Pharmaceuticals US, Inc.
Dinner will not be provided to physicians and other healthcare professionals licensed in Vermont or other states where gifts and meals are prohibited. Dinner provided to physicians will be subject to reporting under Federal law. We regret that spouses and other guests may not be accommodated.


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CONTRAINDICATIONS
• The use of ANORO ELLIPTA is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to umeclidinium, vilanterol, or any of the excipients.

WARNINGS AND PRECAUTIONS
• ANORO ELLIPTA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD.
• ANORO ELLIPTA should not be used for the relief of acute symptoms, ie, as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting beta2-agonist.

In the study referenced above, COPD severity was based on GOLD classification at time of study: 50% moderate, 26% severe, 5% very severe.
COPD=chronic obstructive pulmonary disease; GOLD=Global Initiative for Chronic Obstructive Lung Disease.

Important Safety Information

WARNING: ASTHMA-RELATED DEATH
• Long-acting beta2-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in ANORO ELLIPTA, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of all LABA, including vilanterol.
• The safety and efficacy of ANORO ELLIPTA in patients with asthma have not been established. ANORO ELLIPTA is not indicated for the treatment of asthma.
ANORO for the maintenance treatment of COPD

Description of Lung Function Comparison Studies

The efficacy and safety of a once-daily dose of ANORO ELLIPTA and SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder) were evaluated in 24-week, multicenter, randomized, blinded, active-controlled, double-dummy, parallel-group studies in patients (mean age range: 62 to 65 years) with COPD. At screening, patients had a mean postbronchodilator FEV₁ of 46.4% to 47.7% predicted (ranges for each study were within GOLD classification 2, 3, or 4). The studies were not powered to compare the safety profile of ANORO ELLIPTA with that of SPIRIVA HandiHaler.

Primary endpoint: Trough (predose) FEV₁, at Day 169 (defined as the mean of the FEV₁ values obtained 23 and 24 hours after dosing on Day 168).

FEV₁=forced expiratory volume in 1 second.

SPIRIVA and HandiHaler are registered trademarks owned by Boehringer Ingelheim.

Important Safety Information (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

- ANORO ELLIPTA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using ANORO ELLIPTA should not use another medicine containing a LABA (eg, salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.
- Caution should be exercised when considering the coadministration of ANORO ELLIPTA with long-term ketoconazole and other known strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased cardiovascular adverse effects may occur.
- If paradoxical bronchospasm occurs, discontinue ANORO ELLIPTA and institute alternative therapy.
- Vilanterol can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, or symptoms. If such effects occur, ANORO ELLIPTA may need to be discontinued. ANORO ELLIPTA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

WARNINGS AND PRECAUTIONS (cont’d)

- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.
- Use with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately if signs or symptoms of acute narrow-angle glaucoma develop.
- Use with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to contact a physician immediately if signs or symptoms of urinary retention develop.
- Be alert to hypokalemia and hyperglycemia.

ADVERSE REACTIONS

The most common adverse reactions (≥1% and more common than placebo) reported in four 6-month clinical trials with ANORO ELLIPTA (and placebo) were: pharyngitis, 2% (<1%); sinusitis, 1% (<1%); lower respiratory tract infection, 1% (<1%); constipation, 1% (<1%); diarrhea, 2% (1%); pain in extremity, 2% (1%); muscle spasms, 1% (<1%); neck pain, 1% (<1%); and chest pain, 1% (<1%).

In addition to the 6-month efficacy trials with ANORO ELLIPTA, a 12-month trial evaluated the safety of umeclidinium/vilanterol 125 mcg/25 mcg in subjects with COPD. Adverse reactions (incidence ≥1% and more common than placebo) in subjects receiving umeclidinium/vilanterol 125 mcg/25 mcg were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.
**Important Safety Information (cont’d)**

**DRUG INTERACTIONS**

- Caution should be exercised when considering the coadministration of ANORO ELLIPTA with ketoconazole and other known strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nefcinavir, saquinavir, telithromycin, treoleandomycin, voriconazole) because increased systemic exposure to vilanterol and cardiovascular adverse effects may occur.

- ANORO ELLIPTA should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval, or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists, such as vilanterol, on the cardiovascular system may be potentiated by these agents.

**DRUG INTERACTIONS (cont’d)**

- Use beta-blockers with caution as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.

- Use with caution in patients taking non–potassium-sparing diuretics, as electrocardiographic changes and/or hypokalemia associated with non–potassium-sparing diuretics may worsen with concomitant beta-agonists.

- Avoid coadministration of ANORO ELLIPTA with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects.

**Learn more at StartWithANORO.com**

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**ANORO ELLIPTA** is a combination anticholinergic/LABA for the maintenance treatment of airflow obstruction in patients with COPD.

**SPIRIVA HandiHaler** is an anticholinergic for the maintenance treatment of bronchospasm associated with COPD, and for reducing COPD exacerbations.

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Please see additional Important Safety Information for ANORO ELLIPTA on preceding pages. Please see Brief Summary of Prescribing Information, including Boxed Warning, for ANORO ELLIPTA on the following pages.

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References:


4. Data on file, GSK.


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ANORO ELLIPTA (umeclidinium 62.5 mcg and vilanterol 25 mcg inhalation powder) was developed in collaboration with Theravance.
8.7 Renal Impairment

There were no significant increases in either umeclidinium or vilanterol exposure in subjects with severe renal impairment (CrCl<30 mL/min) compared with healthy subjects. No dosage adjustment is required in patients with renal impairment.

8.6 Hepatic Impairment

There were no significant changes in pharmacokinetic parameters of umeclidinium or vilanterol when comparing healthy volunteers to subjects with mild (Child-Pugh A), moderate (Child-Pugh B), and severe (Child-Pugh C) hepatic impairment. No dosage adjustment is required in patients with hepatic impairment.

8.5 CYP3A4 Inhibitors

10.1 Umeclidinium

Table 1. Adverse Reactions With ANORO ELLIPTA With 31% Incidence and More Common Than Placebo in Subjects With Chronic Obstructive Pulmonary Disease

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

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

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

7.2 Interactions

Vilanterol, a component of ANORO ELLIPTA, is a substrate of CYP3A4. Concomitant administration of the strong CYP3A4 inhibitor ketoconazole increases the systemic exposure to vilanterol. Caution should be exercised when
considering the coadministration of ANORO ELLIPTA with ketorolac and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, neflurafur, saquinavir, telithromycin, trovafloxacin, voriconazole) [see Warnings and Precautions (5.4). Clinical Pharmacology (12.9) of full Prescribing Information.

7.2 Monoamine Oxidase Inhibitors and Tricyclic Antidepressants

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

Hear both sides of three much-discussed subjects debated during “Controversies in Sleep Medicine: Davids, Goliaths, and Some Blood on the Floor.” Three pairs of debaters will address the role of sleep-disordered breathing in heart failure, alternatives to continuous positive airway pressure in specific patient populations, and the relationship between obstructive sleep apnea and cancer.

The session is from 9 to 11 a.m. Sunday in Moscone Center, Room 3003/3005 (West Building, Level 3).

“These pro-con debates deal with thorny issues that confront the sleep pillar of the ATS and global health at large. Attendees will benefit significantly from this event, which will tackle these important issues head-on, and be able to synthesize and digest information that could influence their practices, research, and education,” says Sai Parthasarathy, MD, professor of medicine and director of the Center for Sleep Disorders at the University of Arizona College of Medicine, Tucson.

### SLEEP-DISORDERED BREATHING IN HEART FAILURE

The first debate will focus on the results of the Adaptive Servo-Ventilation for Central Sleep Apnea in Systolic Heart Failure (SERVE-HF) trial, which was published in September 2015. Researchers reported that treatment of central sleep apnea in patients with heart failure with reduced ejection fraction (HFREF) leads to an increased risk for all-cause and cardiovascular mortality.

“This study has had a huge and unprecedented impact on the way patients with HFREF and predominant central sleep apnea are treated and has led to safety alerts against adaptive servo-ventilation these patients,” says Dr. Parthasarathy, a session chair.

Jessie P. Bakker, PhD, another session chair and instructor in medicine at Harvard Medical School, Boston, Massachusetts, noted that this session provides the first opportunity for the implications of the trial results to be discussed in a regular conference program.

“I expect that this debate will address topics such as whether alternative adaptive servo-ventilation devices than those used in the trial are likely to lead to similar findings or whether the SERVE-HF results were specific to that particular device.”

### SLEEP-DISORDERED BREATHING AND CANCER

The second debate will address reports in the American Journal of Respiratory and Critical Care Medicine on the association between cancer and OSA, and how cancer-related mortality may be worsened by comorbid OSA.

“There are huge ramifications with regard to cancer surveillance when it comes to detecting and screening for a condition that could potentially increase the risk for cancer or cancer-related mortality,” Dr. Parthasarathy says. “This debate will flesh out this important cause for death and suffering as it relates to OSA.”

see SLEEP page 29

### RELATED SESSIONS

Also look for these sleep-focused education sessions:

**Sunday**
- 2:15-4:15 p.m. 
  Hot Topics in Disparities in Pulmonary, Critical Care, and Sleep Medicine
  Moscone Center, Room 2001/2003 (West Building, Level 2)

**Monday**
- 9-11 a.m. 
  Sleep and Sleep Disorders in Athletes
  Moscone Center, Room 2001/2003 (West Building, Level 2)

- 2:15-4:15 p.m. 
  Lungs Can Tell Time: Clock Genes, Inflammation, Immunology, and Sleep
  Moscone Center, Room 2009/2011 (West Building, Level 2)

**Tuesday**
- 9-11 a.m. 
  Clinical Year in Review 3: Sleep
  Moscone Center, Gateway Ballroom 102-104 (South Building, Lower Level)

**Wednesday**
- 9-11 a.m. 
  Cannabis, Cannabinimimetics, and Opiates in Sleep and Breathing
  Moscone Center, Room 2001/2003 (West Building, Level 2)

Get Involved! For more information, contact the PFF Patient Communication Center: 844.TalkPFF (844.825.5733) | pcc@pulmonaryfibrosis.org or visit pulmonaryfibrosis.org

TOGETHER WE IMAGINE A WORLD WITHOUT PULMONARY FIBROSIS

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**The Pulmonary Fibrosis Foundation**

once again is proud to be a part of the American Thoracic Society International Conference

The PFF offers the following comprehensive resources to our medical colleagues, people living with PF, and their caregivers:

- PFF Patient Registry
- PFF Patient Communication Center
- PFF Care Center Network
- PFF Research Awards
- PFF Disease Education Webinar Series
- PFF Support Group Leader Network
- PFF Ambassadors
- Team PFF
- Daughters of PF
- Breathe Bulletin
- Monthly PFF eNewsletter
- PFF Summit
- Global Pulmonary Fibrosis Awareness Month
FDA-APPROVED ACTHAR

FOR SYMPTOMATIC SARCOIDOSIS

SARCOIDOSIS HAS NUMEROUS CLINICAL MANIFESTATIONS AND RANGES IN SEVERITY¹

- Lungs are affected in more than 90% of sarcoidosis cases²
- Concomitant involvement of extrapulmonary organs can be seen in up to 50% of cases³
- Extrapulmonary sarcoidosis adds to the morbidity and mortality of patients with pulmonary sarcoidosis³
  - The number of organs impacted by sarcoidosis is likely to increase over time⁴

To learn more, visit us at Mallinckrodt Booth #603 in the ATS 2016 Exhibit Hall

INDICATION

H.P. Acthar® Gel (repository corticotropin injection) is indicated for symptomatic sarcoidosis.

IMPORTANT SAFETY INFORMATION

- Acthar should never be administered intravenously.
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar.
- Acthar is contraindicated where congenital infections are suspected in infants.
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, oculer herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origin.
- The following may be associated with Acthar: increased susceptibility to infections, hypothalamic-pituitary-axis suppression and adrenal insufficiency, Cushing's syndrome, elevated blood pressure, salt and water retention, hypokalemia, masking of symptoms of other disorders, gastrointestinal perforation and bleeding, behavioral and mood disturbances, worsening of comorbid diseases, ophthalmic effects, immunogenicity potential, negative effects on growth and physical development, decrease in bone density and embryocidal effects. Patients may need to be monitored for signs and symptoms.
- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain.
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash, and cardiac hypertrophy.

Other adverse events reported are included in the full Prescribing Information.

Please see adjacent page for Brief Summary of Acthar full Prescribing Information for additional Important Safety Information.

Cushingoid (3, 22); constipation (0, 5), diarrhea (3, 14), vomiting (3, 5).

Rheumatic (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under age 2 treated for infantile spasms are similar to those seen in older patients, their specific populations

Specific Populations

H.P. Acthar Gel is immunogenic. Limited available data suggest that a

Vaccination


euphoria, insomnia, irritability (especially in infants), mood swings, personality changes, and severe depression, Disturbances

Disturbances in the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primarily arteriosclerotic hypertension or as maintenance therapy in selected cases of systemic lupus erythematous, systemic dermatomyositis (polymyositis).

Dermatologic Disease: Severe erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis. Severe acute and chronic inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis, and retinitis pigmentosa.

Symptomatic pseudotumor cerebri.

Edema: State to induce a diuresis or a reduction of protein in the systemic circulation. CorticoAdrenocortical.

Cushing's Syndrome: Inconclusive evidence exists that care is advisable. Cushing's syndrome. These conditions should be monitored especially with chronic use. Suppression of the HPA may occur following prolonged therapy or adrenal insufficiency after withdrawal of the medication. Patients should be monitored for signs of insufficiency such as weakness, hypoglycemia, weight loss, and adrenocortical disease (e.g. edema). The onset of signs of hypoadrenalism may be delayed for several weeks or months following the discontinuation of therapy. The possibility of adrenal insufficiency when discontinuing H.P. Acthar Gel should be considered to be present, if and where these symptoms do occur.

Symptoms in other newborns. In some cases, the symptoms may not be recognized until several weeks or months after the first dose of H.P. Acthar Gel. The symptoms may be due to a variety of factors, including adrenocortical insufficiency, adrenal suppression, or a combination of factors. The symptoms may be related to the adrenal gland, and may produce a decrease in the number of circulating hormones that can be measured. The symptoms may include an increase in protein catabolism and a reduction in sex hormone production, which may lead to inhibition of bone growth and development. These symptoms may also be present in infants with congenital adrenal insufficiency, and may not be a result of H.P. Acthar Gel treatment. The symptoms may include an increase in protein catabolism and a reduction in sex hormone production, which may lead to inhibition of bone growth and development. These symptoms may also be present in infants with congenital adrenal insufficiency, and may not be a result of H.P. Acthar Gel treatment.

Specifically, in infants, including those with congenital adrenal insufficiency, the symptoms may include an increase in protein catabolism and a reduction in sex hormone production, which may lead to inhibition of bone growth and development. These symptoms may also be present in infants with congenital adrenal insufficiency, and may not be a result of H.P. Acthar Gel treatment. The symptoms may include an increase in protein catabolism and a reduction in sex hormone production, which may lead to inhibition of bone growth and development. These symptoms may also be present in infants with congenital adrenal insufficiency, and may not be a result of H.P. Acthar Gel treatment.

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ATOMS 2016 will deliver several Industry Theater and Mini Industry Theater discussions in the Exhibit Hall Sunday through Tuesday. Have lunch while learning about new product launches and treatment options. Complimentary boxed lunch will be provided by the ATS while supplies last. Please see the Monday and Tuesday issues of the ATS Daily Bulletin for a list of theaters taking place those days.

SUNDAY MINI INDUSTRY THEATER
11:30 a.m.-Noon
Is It a Clot? The Progression From PE to CTEPH
Chronic thromboembolic pulmonary hypertension (CTEPH) is the only potentially curable (via pulmonary thromboendarterectomy, PTE) form of pulmonary hypertension (PH). Because it is potentially curable, it’s vitally important that CTEPH not be mistaken for other forms of PH or for a “chronic” pulmonary embolism (PE) or “unresolved clot.” A leading CTEPH expert will discuss
 • How an acute PE can lead to CTEPH
 • The signs and symptoms that should lead one to suspect CTEPH in a patient who has had an acute PE
 • Preferred screening tests and steps for confirming a CTEPH diagnosis
 • The importance of engaging an experienced CTEPH team to assess patients as candidates for PTE surgery
Attendees will better understand CTEPH and its relation to acute PE, and they will appreciate the importance of reasonable suspicion, accurate diagnosis, and timely referral to an experienced center.
Speaker: Ivan Bobbitt, MD, Professor of Medicine, Director, Adult Pulmonary Vascular Center, Vanderbilt University Medical Center
Company: Bayer

INDUSTRY THEATER 1
11:30 a.m.-12:15 p.m.
Multidisciplinary Views on the Diagnosis of Idiopathic Pulmonary Fibrosis (IPF) Learning Theater
Join an expert pulmonologist and radiologist for a multidisciplinary presentation about the diagnosis and management of IPF. Attendees will gain an increased understanding of IPF and its clinical presentation while taking a deeper dive into the challenges associated with making the IPF diagnosis.
Company: Genentech Inc.

MINI INDUSTRY THEATER
12:30-1 p.m.
Parenteral Prostacyclin: Who, When, and How?
In light of various therapy options, who is appropriate for parenteral prostacyclin treatment? Join us for a live presentation where we will discuss variables you can use to identify appropriate patients, at the appropriate point in treatment, and how to optimize the conversation. This presentation is open to all ATS 2016 International Conference attendees.
Company: United Therapeutics Corporation

INDUSTRY THEATER 1
1:15-2 p.m.
Can We Personalise and Simplify COPD Management?
As more treatments for COPD become available for patients, ensuring the right patient receives the right medicine for their disease will be key to optimizing their care. The focus of this Industry Theater will be to discuss treatment options to prevent short term deterioration and the issues of personalising treatment for COPD patients.
1:15 p.m. Welcome and introductions—Neil Barnes, London, UK
1:20 p.m. The importance of preventing short term deterioration, optimizing bronchodilatation—Ian Naya, London, UK
1:30 p.m. Towards a more tailored approach to COPD management—Paul Jones, London, UK
1:50 p.m. Questions and answers—Neil Barnes, London, UK
Company: GlaxoSmithKline Ltd.

INDUSTRY THEATER 2
1:30-2 p.m.
Role and Clinical Application of an Oral Prostacyclin Class Therapy in the Early Treatment of Pulmonary Arterial Hypertension
With prostacyclin class therapy being recommended for treatment of PAH for more than a decade, this session will focus on the use of an oral prostacyclin class therapy in the early treatment of PAH. Discussion will review the clinical data and practical applications for initiating an oral prostacyclin class therapy in prostacyclin naïve or stable parentral patients.
Company: United Therapeutics Corporation

Conflict of Interest Disclosure Reminder
The ATS requires that all faculty members speaking at CME-accredited International Conference sessions prepare and show conflict of interest disclosure slides at the beginning of their presentations. (This is in addition to completing a preconference disclosure questionnaire.) COI slides ensure that the ATS complies with Accreditation Council for Continuing Medical Education requirements for disclosure to learners. Instructions and PowerPoint disclosure slide templates can be downloaded at conference.thoracic.org/speakers. Moderators and presenters can retrieve their 2016 conference disclosures by logging into thoracic.coi-smart.com/login.php.
Session chairs/moderators are reminded to look for the COI documentation form on the podium at their sessions. They must complete the form by the end of each session they moderate in order for the ATS to meet ACCME requirements for written attestation that disclosure slides were shown and of any other disclosures made orally.

SLEEP
Continued from page 26
Drs. Parthasarathy and Bakker pointed to recent studies suggesting an association between sleep apnea and cancer.
“Whether this association is causal has not been established, but we will hear about potential causal mechanisms from Ramon Farre and Chris O’Donnell, whose research focuses primarily on animal models of sleep disorders breathing.” Dr. Bakker says. “Beyond the issue of causality, there is some evidence that the presence of sleep apnea may adversely impact the progression of cancer, supporting the need for more rigorous early screening and treatment programs.”

ALTERNATIVES TO CPAP FOR OSA
CPAP is recognized as the gold standard of treatment for OSA, but patient adherence often is poor and emerging treatments have been developed. However, head-to-head studies of these new treatments against CPAP have not been conducted.
“The big questions are whether an alternative treatment that is perhaps less efficacious, but is used more often, is overall more effective than CPAP, and whether we can accurately identify the underlying cause or causes of an individual’s sleep apnea, and target these mechanisms,” Dr. Bakker says.
Nick Antic, MBBS, PhD, the third session chair and clinical director Adelaide Sleep Health at Repatriation General Hospital, Adelaide, Australia, says the three debates promise to be informative and entertaining.
“This will be a highlight of the program with world leaders in the sleep field discussing in a pro-con format the latest hot topics and controversies,” says Dr. Antic.
Take the ATS Walking Challenge

Stay active during the International Conference with the ATS Walking Challenge. The steps you take will help raise funds for the ATS Foundation Research Program and give you a chance to win prizes.

Stop by the ATS Walking Challenge information booth in the Moscone Center Lobby (South Building, Upper Level) to pick up your complimentary fitness tracker, or to register your own device.

The first 2,000 registrants will receive a free ATS wireless activity tracker to use with the ATS Walking Challenge Mobile App (distributed on a first-come, first-serve basis). Be one of the top three overall walkers and win a prize from ATS.

**Grand prize:** Microsoft Surface Pro 3

**Second prize:** Fitbit Surge

**Third prize:** Zoli Laptop Charger Plus

Increase your steps virtually by visiting the ATS Walking Challenge sponsor, TEVA Respiratory in Booth 419, for a daily step booster. Use the ATS Walking Challenge mobile app to scan the QR code booster each day and earn 500 steps on the first day you visit the booth, 750 steps on the second day you visit the booth, and 1,000 steps on the third day you visit the booth. Watch the results unfold live on leaderboards in the TEVA Respiratory booth and at the ATS Walking Challenge booth.

For every participant who walks 30,000 steps, TEVA Respiratory will donate $100 to the ATS Foundation Research Program, for a total maximum donation of $50,000.

Learn more and register by visiting the ATS Walking Challenge information booth or going online to cloud.hekahealth.com/ats2016. The ATS Walking Challenge mobile app supports attendees who prefer to use their own Fitbit, Jawbone, or iPhone/Android smartphone step counters.

As you take on this challenge, watch for colorful “street” signs reflecting the number of steps it will take you to reach such landmarks as the Embarcadero or the Golden Gate Bridge.

Explore San Francisco on foot and increase your ATS Walking Challenge steps. The sights listed above mark distances from the Moscone Center, whether you seek to take a short walk or more of a hike in this beautiful city.

**FISHBERMAN’S WHARF**
4,300 STEPS

**FISHERMAN’S WHARF**
3,600 STEPS

**THE FERRY BUILDING**
2,200 STEPS

**AT&T PARK**
1,900 STEPS

**UNION SQUARE**
1,200 STEPS

**GOLDEN GATE BRIDGE**
10,000 STEPS

**FISHERMAN’S WHARF**
4,300 STEPS

**LOMBARD STREET**
3,600 STEPS

**THE FERRY BUILDING**
2,200 STEPS

**AT&T PARK**
1,900 STEPS

**UNION SQUARE**
1,200 STEPS

You are invited to a Lunch Industry Theater Presentation at the ATS 2016 International Conference

**THROMBOSIS: DVT/PE**

**AN EXPLORATION IN RISK REDUCTION**

**TUESDAY, MAY 17, 2016**
11:30 AM – 12:15 PM

**Moscone Center**
Industry Theater #1
San Francisco, California

**Joseph K. Choo, MD, FACC**
Staff Cardiologist
Christ Hospital Physicians
Ohio Heart and Vascular
Cincinnati, Ohio

**PROGRAM DESCRIPTION**

This lecture will discuss treatment options for patients with deep vein thrombosis and pulmonary embolism and how they can reduce the risk of recurrent thrombotic events.

In adherence with PhRMA guidelines, spouses or other guests are not permitted to attend company-sponsored programs.

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 are an employee or contractor of any organization or governmental entity, that limits or prohibits meals from pharmaceutical companies, please identify yourself so that you (and we) are able to comply with such requirements.

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Each program provides financial support to three junior faculty researchers for a 2-year period, with each award funded up to $130,000, to be paid in annual installments of up to $65,000. Awards are subject to separate terms and conditions.

For further information on both programs, please visit the website: http://researchscholars.gilead.com
Click on the desired program logo.

Cystic Fibrosis
Application Deadline: Friday, July 22, 2016

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Pulmonary Arterial Hypertension
Application Deadline: Friday, August 5, 2016

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