ATS DAILY BULLETIN
Where today's science meets tomorrow's care™
Sunday, May 15, 2016
San Francisco, California
May 13-May 18, 2016

Welcome to ATS 2016

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

By Zea Borok, MD
International Conference Committee Chair

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

Zea Borok, MD

see WELCOME page 3

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.

SUNDAY'S KEYNOTE SERIES

John R. Stradling, MD, MBBS

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

Talmadge E. King, MD

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 TRIALS page 14

Join us for a non-CME dinner symposium

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

Controversies in PAH:
Experts Explore Combination Therapy

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

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.

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.

GILEAD

FACULTY

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

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 LECTURER

Marlene Rabinovitch, MD

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

EDWARD LIVINGSTON TRUDEAU MEDAL

Joe G.N. "Skip" Garcia, MD

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.

DISTINGUISHED ACHIEVEMENT AWARDS

Claire M. Doerschuk, MD

J. Usha Raj, MD

Claire M. Doerschuk, MD, of 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.

WORLD LUNG HEALTH AWARD

Charles L. Daley, MD, professor of medicine at National Jewish Health (NJH) and the University of Colorado, Denver, will receive the World Lung Health Award, which recognizes contributions to improving world 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

Charles L. Daley, MD

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

Robert Kotloff, MD, chairman of the department of pulmonary medicine at the at the Cleveland Clinic, Ohio, will receive the Outstanding Educator Award, which recognizes lifetime contributions in 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.

PUBLIC SERVICE AWARD

John R. Balmes, MD

John R. Balmes, MD, professor of medicine at the University of California, San Francisco, and professor of environmental health sciences in the School of Public Health at the University of California, Berkeley, will receive the Public Service Award, which honors contributions to public health related to improvement of indoor and outdoor air quality, eradication of tobacco usage, prevention of lung disease, improved management of communicable respiratory diseases, or improvement in the ethical delivery, and access to health care in areas related to lung diseases, sleep disorders, or critical care.

OUTSTANDING CLINICIAN

Jay M. Shames, MD

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.

JO RAE WRIGHT AWARD FOR OUTSTANDING SERVICE

Megan N. Ballinger, PhD

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.

WELCOME

Continued from page 1

e-cigarettes, from studies investigating cellular and molecular effects to evaluating efficacy in smoking cessation. A session centered on late-breaking abstracts related to high-impact clinical trials should be particularly exciting.

Cutting-edge sessions on personalized medicine for lung disease and breakthroughs in genome editing will be presented by leaders in the field, enabling ATS 2016 to continue its tradition of disseminating the latest clinical and scientific advances, and serving as a forum to shape the future of medicine.

This year, nearly 7,000 scientific abstracts and case reports will be presented, involving a mix of basic and clinical research programming.

The collaborative environment at the conference crosses nationalities, career stages, and clinical and research interests, affording opportunities for social and scientific networking. For early career researchers, the conference delivers an unparalleled opportunity to connect with worldwide leaders and receive input on their studies.

Working with the dedicated members of the International Conference Committee has been so gratifying. We hope you enjoy the outstanding program we've put together here. We truly believe that this year there really will be something for everyone.

Enjoy your time at ATS 2016.

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.

Atul Malhotra, MD

Tatum S. Simonson, PhD

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 Diego.

Presenters will discuss:

- 9 a.m.: "Respiration Mechanics: Saving Lives for Nearly a Century," Jeffrey Drazen, MD, editor-in-chief of the New England Journal of Medicine, Boston
- 9:10 a.m.: "Applied Physiology in Sleep Apnea and Control of Breathing," Magdy Younes, MD, PhD, professor of medicine at the University of Manitoba, Winnipeg
- 9:35 a.m.: "Unjamming and Cell Shape in the Asthmatic Airway Epithelium," Jeffrey Fredberg, PhD, professor of bioengineering and physiology at the Harvard School of Public Health, Boston
- 10 a.m.: "From Sepsis Mechanisms to the Origin of Bioelectronic Medicines," Kevin Tracey, MD, president and CEO, Feinstein Institute for Medical Research, Manhasset, New York
- 10:25 a.m.: "Assessing Regional Lung Strain and Perfusion at the Bedside: The Future Is Now," Marcelo Amato MD, PhD, professor at the University of São Paulo, Brazil
- 10:50 a.m.: Young Investigators Presentations.

Meet and Network With Colleagues

The ATS 2016 International Conference offers several avenues for attendees to network with colleagues. Refer to the list below for dates, times, and locations.

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.

MOSCONE 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 Device Discovery and Development (DDDD) 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

MOSCONE 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

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

Sunday-Tuesday

MOSCONE CENTER
(WEST BUILDING, LEVEL 1)

Clinicians can meet, relax, learn, and gather information and resources in the Clinicians Center. Take your MOC post-tests relating to the adult and pediatric core curriculum sessions presented at ATS 2016. Peruse resources vital to clinicians, including the Clinical Year in Review, Nursing Year in Review, Pediatric Year in Review, and Highlights for Clinicians.

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. Lamberti, MD
Sunday-Tuesday, 8-8:45 a.m.: ATS Keynote Series Live Streaming

MID-DAY EDUCATIONAL DEMONSTRATIONS

Sunday, 12:30-1:30 p.m.: Mechanical 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 Transbronchial 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

MOSCONE 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 Epidemiologic, 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

MOSCONE 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 "Lineage 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&A: ATS Executive Director Stephen C. Crane, PhD, MPH

An interview with
Stephen C. Crane, PhD, MPH
ATS Executive Director

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 it 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; Bekasi, Indonesia; Kusadasi, Turkey; and in Argentina.

> “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.”

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 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).


Amir A. Zeki, MD

"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 U.C. 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)" (A86) is supported by educational grants from AstraZeneca LP, Genentech, GlaxoSmithKline, Meda Pharmaceuticals, Inc., and Teva Pharmaceuticals.

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)

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" (D1) 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.

Exploiting GPCRS for New and Improved Asthma Medicine
Moscone Center, Room 2002/2004
(West Building, Level 2)
"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)

EXPERT PERSPECTIVES
IDIOPATHIC PULMONARY FIBROSIS

Join Us for a Dinner Symposium

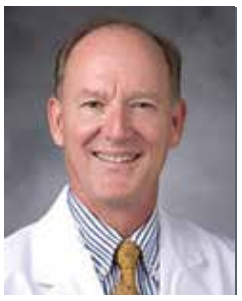
EXPERT PERSPECTIVES: IDIOPATHIC PULMONARY FIBROSIS (IPF)

SUNDAY, MAY 15, 2016, 6:30 PM - 9:30 PM

MARRIOTT MARQUIS, GOLDEN GATE BALLROOM A
780 Mission Street, San Francisco, CA

FDA-approved therapy has advanced the management of IPF while also triggering larger conversations about the role of therapy in clinical practice. In this dinner symposium the traditional podium talk will be transformed into a unique and engaging format where three IPF experts will share their perspectives on the role of therapy in clinical practice.

FEATURED SPEAKERS AND PRESENTATIONS INCLUDE:



TO TREAT OR NOT TO TREAT? WHAT TO DO AFTER THE IPF DIAGNOSIS

Paul Noble, MD
Cedars-Sinai Medical Center
Los Angeles, CA

THE ROLE OF ESBRIET® (PIRFENIDONE) IN THE TREATMENT OF IPF

Steven Nathan, MD
Inova Fairfax Hospital
Fairfax, VA

MANAGING THE IPF PATIENT, AN ESSENTIAL COMPONENT OF THEIR TREATMENT JOURNEY

Robert Sussman, MD
Overlook Medical Center
Summit, NJ

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, gastroesophageal 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 in the Esbriet 2403 mg/day group discontinued treatment due to a gastrointestinal event, as compared to 1.0% in the placebo group. The most common (>2%) gastrointestinal events that led to dosage reduction or interruption were nausea, diarrhea, vomiting, and dyspepsia. Dosage modifications may be necessary in some cases.

Adverse reactions: The most common adverse reactions (≥10%) are nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, gastroesophageal reflux disease, sinusitis, insomnia, weight decreased, and arthralgia.

Drug interactions: Concomitant administration with strong inhibitors of CYP1A2 (eg, 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 at the dosage of 750 mg twice daily cannot be avoided, dosage reductions are recommended. Monitor patients closely when ciprofloxacin is used.

Agents that are moderate or strong inhibitors of both CYP1A2 and CYP isoenzymes 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: Esbriet should be used with caution in patients with mild to moderate (Child Pugh Class A and B) hepatic impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. The safety, efficacy, and pharmacokinetics of Esbriet have not been studied in patients with severe hepatic impairment. Esbriet is not recommended for use in patients with severe (Child Pugh Class C) hepatic impairment.

Esbriet should be used with caution in patients with mild (CL_{cr} 50-80 mL/min), moderate (CL_{cr} 30-50 mL/min), or severe (CL_{cr} less than 30 mL/min) renal impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. The safety, efficacy, and pharmacokinetics of Esbriet have not been studied in patients with end-stage renal disease requiring dialysis. Use of Esbriet in patients with end-stage renal diseases requiring dialysis is not recommended.

Smoking causes decreased exposure to Esbriet, which may alter the efficacy profile of Esbriet. Instruct patients to stop smoking prior to treatment with Esbriet and to avoid smoking when using Esbriet.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

Please see full Prescribing Information for additional important safety information.

An Industry-Organized Symposium at the ATS 2016 International Conference.
A non-CME educational program sponsored by Genentech USA, Inc. Due to regulatory restrictions, this program is only available to attendees from the United States.

Minnesota, Vermont, and Federal Entities have restrictions on receiving in-kind benefits (e.g., meals, valet parking) at company-sponsored events. You are accountable for understanding such restrictions and complying with them. If you are licensed in or affiliated with any of these states or federal agencies, Genentech policies may restrict you from consuming any portion of the Genentech-sponsored meal at this program or from receiving any other in-kind benefit from Genentech (e.g., valet parking) in connection with the program.

Genentech
A Member of the Roche Group

EXPERT PERSPECTIVES
IDIOPATHIC PULMONARY FIBROSIS

Esbriet® (pirfenidone) capsules 267 mg

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.

Sonia C. Flores, PhD

Catherine R. Lucey, MD

Irina Petrache, MD

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.

Jeffrey M. Drazen, MD

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.

George T. O'Connor, MD, MS

Both forums will be held in the Moscone Center, Room 2002/2004 (West Building, Level 2).

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.

Derek C. Angus, MD

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 is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity

FOR PULMONARY ARTERIAL HYPERTENSION

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**[1-3]

Early use in FC II and III[1]

Ability to **transition from treprostinil** parenteral therapy[1]*

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 ORENITRAM

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

DRUG INTERACTIONS/SPECIFIC POPULATIONS

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

ADVERSE REACTIONS

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

OREISIhcpJAN16

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

For additional information about Orenitram, visit www.orenitram.com or call 1-877-UNITHER (1-877-864-8437).

References

1. Orenitram [package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2016. **2.** Clapp LH, Gurung R. The mechanistic basis of prostacyclin and its stable analogues in pulmonary arterial hypertension: role of membrane versus nuclear receptors. *Prostaglandins Other Lipid Mediat*. 2015;120:56-71. **3.** McLaughlin VV et al. ACCF/AHA 2009 expert consensus on pulmonary hypertension: developed in collaboration with the ACCP, ATS, and the PHA. *Circulation*. 2009;119(16):2250-2290.

orenitram®
treprostinil
EXTENDED-RELEASE TABLETS
dosing that adapts.

JOIN US AT A MINI INDUSTRY THEATER

SUNDAY
1:30 PM–2:00 PM
OR
MONDAY
11:30 AM–12:00 PM

An Industry Theater Presentation at the ATS 2016 International Conference
This workshop is sponsored by United Therapeutics.
Due to regulatory restrictions, this workshop is only available to attendees from the United States.

Visit Booth #803

United Therapeutics CORPORATION

orenitram®
treprostinil
EXTENDED-RELEASE TABLETS

BRIEF SUMMARY

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Severe hepatic impairment (Child Pugh Class C).

WARNINGS AND PRECAUTIONS

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

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

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

ADVERSE REACTIONS

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

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

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

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

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 fluconazole, rifampin, sildenafil, bosentan, or esomeprazole.

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

USE IN SPECIFIC POPULATIONS

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

Labor and Delivery—The effect of Orenitram on labor and delivery in humans is unknown.

No treprostinil treatment related effects on labor and delivery were seen in animal studies.

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

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

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

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

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

OVERDOSAGE

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

United Therapeutics Corporation, Research Triangle Park, NC 27709
Rx only
January 2016
www.orenitram.com

United Therapeutics CORPORATION

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. Riekert, PhD
San Francisco Marriott Marquis, Yerba Buena Salon 10-13, Lower B2 Level

Pediatrics
Chair: James F. Chmiel, MD, MPH
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 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 Tino, MD
Hilton San Francisco Union Square, Continental Ballroom 6, Ballroom Level

Critical Care
Chair: Carolyn S. Calfee, MD
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 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. Wunderink, MD
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 4-6, Lower B2 Level

Nursing
Chair: DorAnne M. Donesky, PhD, ANP-BC
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 10-12, Lower B2 Level

Pulmonary Circulation
Chair: Troy Stevens, PhD
Hilton San Francisco Union Square, Continental Ballroom 5, Ballroom Level

Pulmonary Rehabilitation
Chair: Carolyn L. Rochester, MD
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 13-15, Lower B2 Level

Respiratory Cell and Molecular Biology
Chair: Naftali Kaminski, MD
San Francisco Marriott Marquis, Golden Gate Ballroom B, B2 Level

Respiratory Structure and Function
Chair: Reynold A. Panettieri, MD
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 9, Lower B2 Level

Sleep and Respiratory Neurobiology
Chair: Susheel P. Patil, MD, PhD
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 7, Lower B2 Level

Thoracic Oncology
Chair: Michael K. Gould, MD, MS
San Francisco Marriott Marquis, Club Room, Second Level

SECTION MEETINGS

SUNDAY

6:30-8:30 p.m.

Section on Terrorism 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. Wurfel, MD, PhD, and Craig P. Hersh, MD, MPH
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 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. Entrance without a ticket will not be permitted. To register for the dinners or receptions, visit the registration desk in the Moscone Center.

ASSEMBLY DINNERS

MONDAY

7-10 p.m.

Pediatrics
San Francisco Marriott Marquis, Atrium, Second Level

ASSEMBLY RECEPTIONS

MONDAY

7-10 p.m.

Allergy, Immunology and Inflammation and Respiratory Cell and Molecular Biology
San Francisco Marriott Marquis, Golden Gate Ballroom C1-C3, B2 Level

Clinical Problems
Hilton San Francisco Union Square Ballroom 7, Ballroom Level

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

> "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."
>
> *Patricia A. Kritek, MD*

Microbiology, Tuberculosis and Pulmonary Infections
San Francisco Marriott Marquis, Yerba Ballroom Salon 1-3, Lower B2 Level

Respiratory Structure and Function
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 9, Lower B2 Level

Sleep and Respiratory Neurobiology
San Francisco Marriott Marquis, Yerba Buena Ballroom Salon 7, Lower B2 Level

Thoracic Oncology
San Francisco Marriott Marquis, Foothill G, Second Level ■

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 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.*

Speakers: **Anne O'Donnell, MD**, *Washington, D.C.;* **James Chalmers, MD**, *Dundee, UK;* **Patrick Flume, MD**, *Charleston, South Carolina. Expert Panelists:* **David Griffith, MD**, *Tyler, Texas;* **Adam Hill, MD**, *Edinburgh, UK;* **Gregory Tino, MD**, *Philadelphia, Pennsylvania;* **Kevin Winthrop, MD**, *Portland, Oregon*

Company: Bayer 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)
Hot topics in COPD: Why focus on exacerbations?—Professor David Price (Singapore)
What are we doing to reduce COPD exacerbations?—Professor Dave Singh (UK)
Shedding further light on COPD exacerbation prevention: New evidence—Professor Claus Vogelmeier (Germany)
Word from the Chair: The implications of new evidence—Professor Roland Buhl (Germany)
Time to talk: Burning questions—Chair facilitated panel discussion
Do we have the answers?—Professor Roland Buhl (Germany)

Company: Novartis Pharma AG

Non-CME Symposia take place on Sunday and Tuesday. See Tuesday's Daily Bulletin for a list of Tuesday sessions.

6:30-9:30 p.m.
SAN FRANCISCO MARRIOTT MARQUIS: YERBA BUENA BALLROOM 7 (LOWER B2 LEVEL)

A Clinical Discussion on Severe Eosinophilic Asthma and Its Management

A review of considerations in the diagnosis and management of severe eosinophilic asthma.

Speakers: **Mario Castro, MD, MPH, FCCP, Alan A.** *and* **Edith L. Wolff** *Professor of Pulmonary and Critical Care Medicine, Professor of Medicine and Pediatrics, Washington University School of Medicine, St. Louis, Missouri*

Company: TEVA Respiratory

6:30-9:30 p.m.
SAN FRANCISCO MARRIOTT MARQUIS: YERBA BUENA BALLROOM 9 (LOWER B2 LEVEL)

Controversies in PAH: Experts Explore Combination Therapy

6:30 p.m. Registration and Buffet Dinner
7-8:30 p.m. Interactive Session

A faculty of PAH experts will explore developments in PAH therapy, including combination therapy and recent clinical trial data. The program will also feature an interactive patient scenario and allow for audience participation.

Speakers: **Theresa De Marco, MD**, *Director of Advanced Heart Failure and Pulmonary Hypertension, Professor, University of California, San Francisco, School of Medicine, San Francisco, California;* **Nicholas Hill, MD**, *Chief, Pulmonary, Critical Care and Sleep Division, Professor, Tufts University School of Medicine, Boston, Massachusetts;* **Rajan Saggar, MD**, *Assistant Clinical Professor of Medicine, Pulmonary & Critical Care, University of California, Los Angeles Medical Center, Los Angeles, California*

Company: Gilead Sciences Inc.

6:30-9:30 p.m.
HILTON UNION SQUARE: CONTINENTAL BALLROOM 6 (BALLROOM LEVEL)

COPD Treatment Options Available Via Ellipta® Inhaler

This interactive dinner program will provide an overview of COPD treatment options available via the Ellipta® inhaler. The presentation will address the rationale for combination therapy in the treatment of COPD and will include clinical trials data, and important safety information as well as a demonstration of the Ellipta® inhaler and examination of the device characteristics and features.

Speakers: **Deborah Long, MD, FCCP**, *U.S. Medical Affairs Lead, GSK, Research Triangle Park, North Carolina;* **Neil C. Barnes, MD**, *Medical Head, Global Respiratory Franchise, GSK, Uxbridge, UK*

6:30-9:30 p.m.
SAN FRANCISCO MARRIOTT MARQUIS: GOLDEN GATE BALLROOM B (B2 LEVEL)

Is It Idiopathic Pulmonary Fibrosis? Diagnostic Challenges and Treatment

The process of identifying, diagnosing, and treating idiopathic pulmonary fibrosis (IPF) will be explored by a multidisciplinary panel of expert faculty, including a pulmonologist, radiologist, and a pathologist. The use of OFEV® (nintedanib) for the treatment of patients with IPF will also be reviewed.

Speakers: **Marilyn K. Glassberg, MD**, *Professor of Medicine, Surgery, and Pediatrics, University of Miami Miller School of Medicine;* **Mark Rumbak, MD**, *Professor, College of Medicine, Internal Medicine University of South Florida;* **Sudhakar Pipavath, MD**, *Associate Professor, Radiology, University of Washington; Kirk Jones, Professor, Pathology, UCSF School of Medicine*

Company: Boehringer Ingelheim Pharmaceuticals Inc.

6:30-9:30 p.m.
HILTON UNION SQUARE: CONTINENTAL BALLROOM 4 (BALLROOM LEVEL)

Evolving Science in the Management of COPD

This non-CME dinner symposium will offer novel insights into the latest research in inhaled respiratory medication in COPD.

Speakers: **Bartolome Celli** *(Chair), U.S.;* **Klaus F. Rabe**, *Germany;* **Leonardo M. Fabbri**, *Italy;* **Gary T. Ferguson**, *U.S.;* **Fernando J. Martinez**, *U.S.*

Company: AstraZeneca Pharmaceuticals Inc.

6:30-9:30 p.m.
SAN FRANCISCO MARRIOTT MARQUIS: GOLDEN GATE BALLROOM A (B2 LEVEL)

Expert Perspectives: Idiopathic Pulmonary Fibrosis (IPF) Dinner Symposium

Join three esteemed IPF experts as they share their perspectives on the diagnosis and management of IPF at this dinner symposium. These IPF experts will engage participants in a series of presentations on topics such as making an early diagnosis, the efficacy and safety profile of an FDA-approved therapy, and effectively managing the IPF patient.

Company: Genentech Inc.

6:30-9:30 p.m.
INTERCONTINENTAL SAN FRANCISCO: GRAND BALLROOM (THIRD LEVEL)

Introducing a New Treatment Option for PAH: A Case-based Discussion

The science behind pulmonary arterial hypertension (PAH) continues to evolve. This interactive,

see NON-CME page 14

NON-CME

Continued from page 13

case-based symposium will feature a panel of experts who will introduce a new option for the treatment of patients with PAH.

Dinner will be provided. Dinner will not be provided to physicians and other healthcare professionals licensed in Vermont or other states where gifts and meals are prohibited.

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

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.

Speakers: **William E. Berger, MD, MBA**, *University of California Irvine, Mission Viejo, California;* **Randall W. Brown, MD, MPH**, *AE-C, University of Michigan, Ann Arbor, Michigan;* **Bradley Chipps, 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 Relief, Charlotte, North Carolina*

Company: MEDA Pharmaceuticals Inc.

TRIALS

Continued from page 1

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 mycobacteria (NTM) to the ATS International Conference. Its CONVERT™ INS-212 study is a clinical research study designed to explore an investigational medication—liposomal amikacin for inhalation—in adult patients with NTM lung infections caused by mycobacterium avium complex and who have not experienced success with previous treatments.

Reata Pharmaceuticals in Booth 5 is a clinical-stage biopharmaceutical company located in Irving, Texas. Its focus is to develop drugs that modulate the activity of important regulatory proteins, called transcription factors, to address serious or life-threatening diseases. One of our lead product candidates, bardoxolone methyl, is in Phase 2 clinical development for the treatment of pulmonary arterial hypertension and pulmonary hypertension due to interstitial lung disease.

MORE CLINICAL INFO

To learn about additional clinical trial research, look for large signs in the Clinical Trials Awareness Area listing current clinical trials in progress from both participating exhibitors and the ATS Corporate Members. To obtain more information, scan the QR codes next to each one.

ATS Daily Bulletin
We help the world breathe
PULMONARY • CRITICAL CARE • SLEEP

Judi Huck, Manager, Editor, and Writer
ATS Communications

Photography by R.C. Photographic Productions and Steve Schneider.

25 Broadway, 18th Floor
New York, New York 10004
(212) 315-8600
thoracic.org

Publishing Partner
Ascend Integrated Media LLC
6710 W. 121st St., Suite 100
Overland Park, KS 66209
(913) 469-1110

ATS 2016 International Conference
Practical Workshop

Shake, Rattle and Cough:

Guide to Airway Clearance from Hospital to Home.

Join industry exerts 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

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

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

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

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

TODAY!

May 15, 2016
12:30 pm - 2:00 pm

197363 rev 1 14-APR-2016 ENG – US

Enhancing outcomes for patients and their caregivers.®

Hill-Rom®

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.

Boehringer Ingelheim

AND VISIT BOOTH #1003 TO LEARN MORE ABOUT OFEV

OFEV®
(nintedanib)
capsules 150mg

Support the Conference With #ATS2016

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.

Speak with images. Photos uploaded to Facebook generate five times the interaction and engagement compared to posts without photos. Twitter is the same, with tweeted photos getting twice the interaction.

Stay fit: Social networks are mobile, so view your posts on mobile devices to make sure they appear correctly. Use link shorteners, such as **bit.ly**, to add more information and keywords to your updates.

Test content variations. Do certain pictures perform better than others? Is there an optimal time of day, or day of the week to post? As you adjust what you post and how often, you'll soon go from social media novice to pro. ■

Insights Brought to You by Physician, Patient Bloggers

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-ones 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.


Ann Wu, MD, MPH


Jess Mandel, MD


Jeff Goldstein


Susan Wisliceny


Valerie Chang, JD

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. ■

You are invited to an evening symposium

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

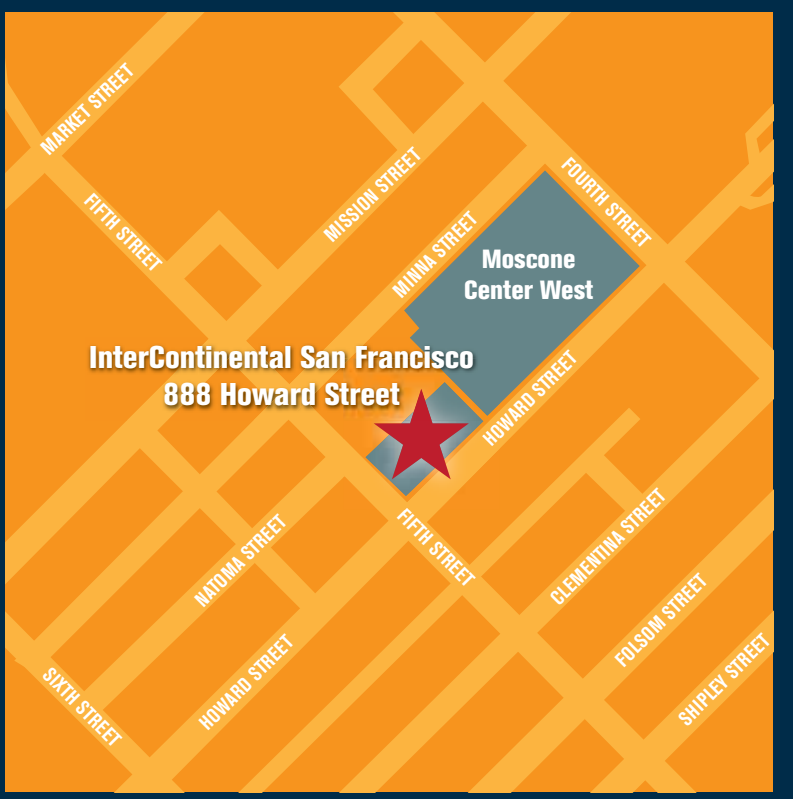
Panel Discussion
All Faculty

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



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

This promotional program is sponsored by Actelion Pharmaceuticals US, Inc.

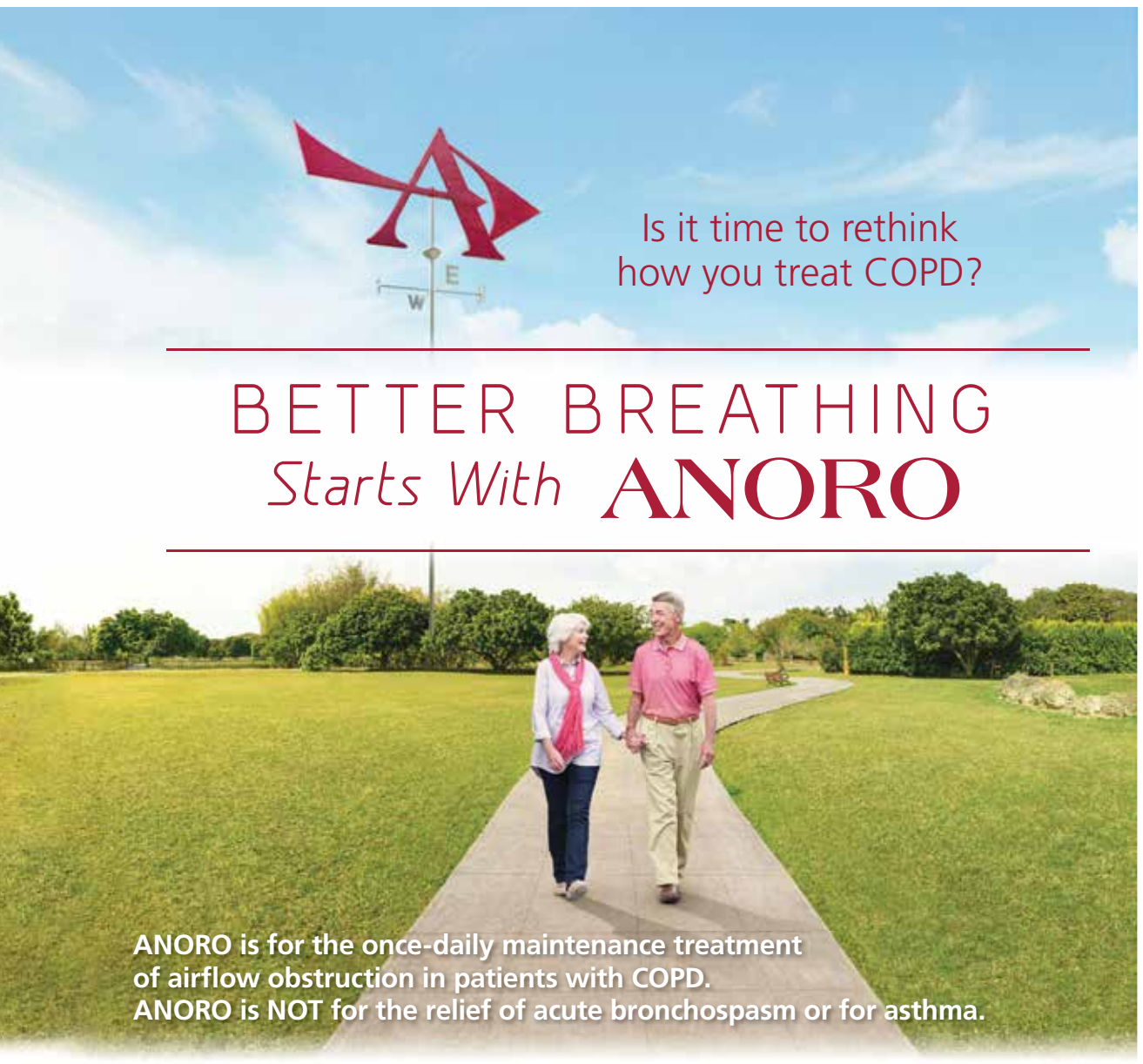
Dinner will not be provided to physicians and other healthcare professionals licensed in Vermont or other states where gifts and meals are prohibited. Dinner provided to physicians will be subject to reporting under Federal law. We regret that spouses and other guests may not be accommodated.

An Industry-Organized Symposium at the ATS 2016 International Conference. A non-CME educational program sponsored by Actelion Pharmaceuticals US, Inc. open to all ATS 2016 International Conference attendees.

ACTELION

In a subset (n=366) of a managed care population with a diagnosis of COPD

81% of patients had moderate or worse COPD at spirometry-confirmed diagnosis[1]



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

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 beta$_2$-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.**

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 beta$_2$-agonist.

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

gsk | Theravance

ANORO for the maintenance treatment of COPD

Description of Lung Function Comparison Studies[2-4]

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 FEV_1 range 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) FEV_1 at Day 169 (defined as the mean of the FEV_1 values obtained 23 and 24 hours after dosing on Day 168).

FEV_1=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.

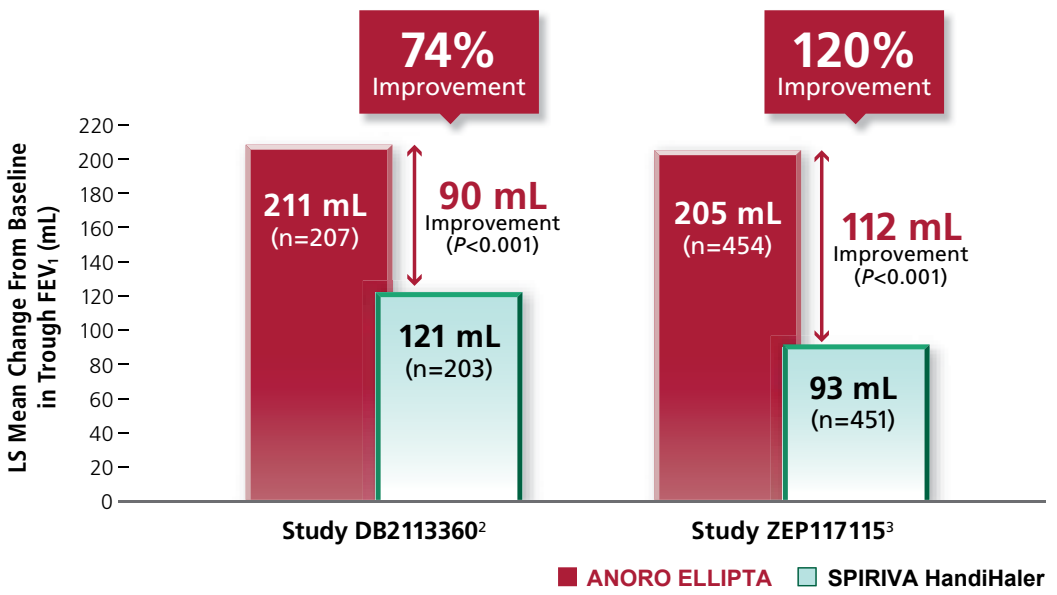
ADVERSE REACTIONS

- 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.

For patients with moderate or worse COPD

Start with ANORO ELLIPTA instead of SPIRIVA HandiHaler for superior improvement in lung function

ANORO ELLIPTA DELIVERED SIGNIFICANT IMPROVEMENT IN TROUGH FEV_1 vs SPIRIVA HandiHaler AT DAY 169 IN 2 STUDIES[2,3]



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.[5]

In a separate study, ANORO ELLIPTA showed a 60-mL difference* compared with SPIRIVA HandiHaler (208 mL and 149 mL, respectively), but due to testing hierarchy, statistical significance cannot be inferred.[2]

LS=least squares.
*Reflects rounding.

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, nelfinavir, saquinavir, telithromycin, troleandomycin, 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

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.

References: 1. Mapel DW, Dalal AA, Blanchette CM, et al. Severity of COPD at initial spirometry-confirmed diagnosis: data from medical charts and administrative claims. *Int J Chron Obstruct Pulmon Dis*. 2011;6:573-581. **2.** Decramer M, Anzueto A, Kerwin E, et al. Efficacy and safety of umeclidinium plus vilanterol versus tiotropium, vilanterol, or umeclidinium monotherapies over 24 weeks in patients with chronic obstructive pulmonary disease: results from two multicentre, blinded, randomised controlled trials. *Lancet Respir Med*. 2014;2(6):472-486. **3.** Maleki-Yazdi MR, Kaelin T, Richard N, et al. Efficacy and safety of umeclidinium/vilanterol 62.5/25 mcg and tiotropium 18 mcg in chronic obstructive pulmonary disease: results of a 24-week, randomized, controlled trial. *Respir Med*. 2014;108(12):1752-1760. **4.** Data on file, GSK. **5.** SPIRIVA HandiHaler [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2014.

ANORO ELLIPTA was developed in collaboration with Theravance

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

BRIEF SUMMARY

ANORO® ELLIPTA®
(umeclidinium and vilanterol inhalation powder)
FOR ORAL INHALATION USE
The following is a brief summary only; see full prescribing information for complete product information.

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US trial that compared the safety of another LABA (salmeterol) with placebo added to usual asthma therapy showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of all LABA, including vilanterol, one of the active ingredients in ANORO ELLIPTA *[see Warnings and Precautions (5.1)]*.

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

1 INDICATIONS AND USAGE
ANORO ELLIPTA is a combination anticholinergic/long-acting beta$_2$-adrenergic agonist (anticholinergic/LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.
Important Limitations of Use: ANORO ELLIPTA is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

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

5 WARNINGS AND PRECAUTIONS
5.1 Asthma-Related Death
- Data from a large placebo-controlled trial in subjects with asthma showed that LABA may increase the risk of asthma-related death. Data are not available to determine whether the rate of death in patients with COPD is increased by LABA.
- A 28-week, placebo-controlled, US trial comparing the safety of another LABA (salmeterol) with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in subjects receiving salmeterol (13/13,176 in subjects treated with salmeterol vs. 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25, 15.34]). The increased risk of asthma-related death is considered a class effect of LABA, including vilanterol, one of the active ingredients in ANORO ELLIPTA.
- No trial adequate to determine whether the rate of asthma-related death is increased in subjects treated with ANORO ELLIPTA has been conducted. The safety and efficacy of ANORO ELLIPTA in patients with asthma have not been established. ANORO ELLIPTA is not indicated for the treatment of asthma.

5.2 Deterioration of Disease and Acute Episodes
ANORO ELLIPTA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. ANORO ELLIPTA has not been studied in subjects with acutely deteriorating COPD. The initiation of ANORO ELLIPTA in this setting is not appropriate.
ANORO ELLIPTA should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. ANORO ELLIPTA has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist. When beginning treatment with ANORO ELLIPTA, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs and to use them only for symptomatic relief of acute respiratory symptoms. When prescribing ANORO ELLIPTA, the healthcare provider should also prescribe an inhaled, short-acting beta$_2$-agonist and instruct the patient on how it should be used. Increasing inhaled, short-acting beta$_2$-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated.
COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If ANORO ELLIPTA no longer controls symptoms of bronchoconstriction; the patient's inhaled, short-acting beta$_2$-agonist becomes less effective; or the patient needs more short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of ANORO ELLIPTA beyond the recommended dose is not appropriate in this situation.
5.3 Excessive Use of ANORO ELLIPTA and Use With Other Long-Acting Beta$_2$-Agonists
ANORO ELLIPTA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using ANORO ELLIPTA should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.
5.4 Drug Interactions With Strong Cytochrome P450 3A4 Inhibitors
Caution should be exercised when considering the coadministration of ANORO ELLIPTA with long-term ketoconazole and other known strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased cardiovascular adverse effects may occur *[see Drug Interactions (7.1), Clinical Pharmacology (12.3) of full Prescribing Information]*.
5.5 Paradoxical Bronchospasm
As with other inhaled medicines, ANORO ELLIPTA can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs following dosing with ANORO ELLIPTA, it should be treated immediately with an inhaled, short-acting bronchodilator; ANORO ELLIPTA should be discontinued immediately; and alternative therapy should be instituted.
5.6 Hypersensitivity Reactions
Hypersensitivity reactions may occur after administration of ANORO ELLIPTA. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder products containing lactose; therefore, patients with severe milk protein allergy should not use ANORO ELLIPTA *[see Contraindications (4)]*.
5.7 Cardiovascular Effects
Vilanterol, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, or symptoms *[see Clinical Pharmacology (12.2) of full Prescribing Information]*. If such effects occur, ANORO ELLIPTA may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiographic changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown.
Therefore, ANORO ELLIPTA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
5.8 Coexisting Conditions
ANORO ELLIPTA, like all medicines containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis and in those who are unusually responsive to sympathomimetic amines. Doses of the related beta$_2$-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.
5.9 Worsening of Narrow-Angle Glaucoma
ANORO ELLIPTA should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a physician immediately if any of these signs or symptoms develops.
5.10 Worsening of Urinary Retention
ANORO ELLIPTA should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a physician immediately if any of these signs or symptoms develops.
5.11 Hypokalemia and Hyperglycemia
Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Beta-agonist medicines may produce transient hyperglycemia in some patients. In 4 clinical trials of 6-month duration evaluating ANORO ELLIPTA in subjects with COPD, there was no evidence of a treatment effect on serum glucose or potassium.

6 ADVERSE REACTIONS
LABA, such as vilanterol, one of the active ingredients in ANORO ELLIPTA, increase the risk of asthma-related death. ANORO ELLIPTA is not indicated for the treatment of asthma. *[See Boxed Warning and Warnings and Precautions (5.1).]*
The following adverse reactions are described in greater detail in other sections:
- Paradoxical bronchospasm *[see Warnings and Precautions (5.5)]*
- Cardiovascular effects *[see Warnings and Precautions (5.7)]*
- Worsening of narrow-angle glaucoma *[see Warnings and Precautions (5.9)]*
- Worsening of urinary retention *[see Warnings and Precautions (5.10)]*

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.
The clinical program for ANORO ELLIPTA included 8,138 subjects with COPD in four 6-month lung function trials, one 12-month long-term safety study, and 9 other trials of shorter duration. A total of 1,124 subjects have received at least 1 dose of ANORO ELLIPTA (umeclidinium/vilanterol 62.5 mcg/25 mcg), and 1,330 subjects have received a higher dose of umeclidinium/vilanterol (125 mcg/25 mcg). The safety data described below are based on the four 6-month and the one 12-month trials. Adverse reactions observed in the other trials were similar to those observed in the confirmatory trials.
6-Month Trials: The incidence of adverse reactions associated with ANORO ELLIPTA in Table 1 is based on four 6-month trials: 2 placebo-controlled trials (Trials 1 and 2; n = 1,532 and n = 1,489, respectively) and 2 active-controlled trials (Trials 3 and 4; n = 843 and n = 869, respectively). Of the 4,733 subjects, 68% were male and 84% were Caucasian. They had a mean age of 63 years and an average smoking history of 45 pack-years, with 50% identified as current smokers. At screening, the mean post-bronchodilator percent predicted forced expiratory volume in 1 second (FEV_1) was 48% (range: 13% to 76%), the mean post-bronchodilator FEV_1/forced vital capacity (FVC) ratio was 0.47 (range: 0.13 to 0.78), and the mean percent reversibility was 14% (range: -45% to 109%). Subjects received 1 dose once daily of the following: ANORO ELLIPTA, umeclidinium/vilanterol 125 mcg/25 mcg, umeclidinium 62.5 mcg, umeclidinium 125 mcg, vilanterol 25 mcg, active control, or placebo.

Table 1. Adverse Reactions With ANORO ELLIPTA With ≥1% Incidence and More Common Than With 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				
Pharyngitis	<1	2	1	2
Sinusitis	<1	1	<1	1
Lower respiratory tract infection	<1	1	<1	<1
Gastrointestinal disorders				
Constipation	<1	1	<1	<1
Diarrhea	1	2	<1	2
Musculoskeletal and connective tissue disorders				
Pain in extremity	1	2	<1	2
Muscle spasms	<1	1	<1	<1
Neck pain	<1	1	<1	<1
General disorders and administration site conditions				
Chest pain	<1	1	<1	<1

Other adverse reactions with ANORO ELLIPTA observed with an incidence less than 1% but more common than with placebo included the following: productive cough, dry mouth, dyspepsia, abdominal pain, gastroesophageal reflux disease, vomiting, musculoskeletal chest pain, chest discomfort, asthenia, atrial fibrillation, ventricular extrasystoles, supraventricular extrasystoles, myocardial infarction, pruritus, rash, and conjunctivitis.
12-Month Trial: In a long-term safety trial, 335 subjects were treated for up to 12 months with umeclidinium/vilanterol 125 mcg/25 mcg or placebo. The demographic and baseline characteristics of the long-term safety trial were similar to those of the placebo-controlled efficacy trials described above. Adverse reactions that occurred with a frequency of greater than or equal to 1% in the group receiving umeclidinium/vilanterol 125 mcg/25 mcg that exceeded that in placebo in this trial were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

7 DRUG INTERACTIONS
7.1 Inhibitors of Cytochrome P450 3A4
Vilanterol, a component of ANORO ELLIPTA, is a substrate of CYP3A4. Concomitant administration of the strong CYP3A4 inhibitor ketoconazole increases the systemic exposure to vilanterol. Caution should be exercised when

considering the coadministration of ANORO ELLIPTA with ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) *[see Warnings and Precautions (5.4), Clinical Pharmacology (12.3) of full Prescribing Information]*.

7.2 Monoamine Oxidase Inhibitors and Tricyclic Antidepressants

Vilanterol, like other beta$_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias.

7.3 Beta-Adrenergic Receptor Blocking Agents

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

7.4 Non–Potassium-Sparing Diuretics

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

7.5 Anticholinergics

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

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

Vilanterol: There were no teratogenic effects in rats and rabbits at approximately 13,000 and 70 times, respectively, the MRHDID in adults (on a mcg/m^2 basis at maternal inhaled doses up to 33,700 mcg/kg/day in rats and on an AUC basis at maternal inhaled doses up to 591 mcg/kg/day in rabbits). However, fetal skeletal variations were observed in rabbits at approximately 450 times the MRHDID in adults (on an AUC basis at maternal inhaled or subcutaneous doses of 5,740 or 300 mcg/kg/day, respectively). The skeletal variations included decreased or absent ossification in cervical vertebral centrum and metacarpals.

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

Vilanterol: There were no effects on perinatal and postnatal developments in rats at approximately 3,900 times the MRHDID in adults (on a mcg/m^2 basis at maternal oral doses up to 10,000 mcg/kg/day).

8.2 Labor and Delivery

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

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

8.3 Nursing Mothers

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

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

Vilanterol: It is not known whether vilanterol is excreted in human breast milk. However, other beta$_2$-agonists have been detected in human milk.

8.4 Pediatric Use

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

8.5 Geriatric Use

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

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

8.6 Hepatic Impairment

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

8.7 Renal Impairment

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

10 OVERDOSAGE

No case of overdose has been reported with ANORO ELLIPTA.

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

10.1 Umeclidinium

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

10.2 Vilanterol

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

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

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

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

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

In a 2-year carcinogenicity study in rats, vilanterol caused statistically significant increases in mesovarian leiomyomas in females and shortening of the latency of pituitary tumors at inhalation doses greater than or equal to 84.4 mcg/kg/day (greater than or equal to approximately 20 times the MRHDID in adults on an AUC basis). No tumors were seen at an inhalation dose of 10.5 mcg/kg/day (approximately 1 time the MRHDID in adults on an AUC basis).

These tumor findings in rodents are similar to those reported previously for other beta-adrenergic agonist drugs. The relevance of these findings to human use is unknown.

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

No evidence of impairment of fertility was observed in reproductive studies conducted in male and female rats at inhaled vilanterol doses up to 31,500 and 37,100 mcg/kg/day, respectively (approximately 12,000 and 14,500 times, respectively, the MRHDID in adults on a mcg/m^2 basis).

17 PATIENT COUNSELING INFORMATION

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

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

Not for Acute Symptoms: Inform patients that ANORO ELLIPTA is not meant to relieve acute symptoms of COPD and extra doses should not be used for that purpose. Advise them to treat acute symptoms with a rescue inhaler such as albuterol. Provide patients with such medicine and instruct them in how it should be used.

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

- Symptoms get worse
- Need for more inhalations than usual of their rescue inhaler

Patients should not stop therapy with ANORO ELLIPTA without physician/provider guidance since symptoms may recur after discontinuation.

Do Not Use Additional Long-Acting Beta$_2$-Agonists: Instruct patients to not use other medicines containing a LABA. Patients should not use more than the recommended once-daily dose of ANORO ELLIPTA.

Instruct patients who have been taking inhaled, short-acting beta$_2$-agonists on a regular basis to discontinue the regular use of these products and use them only for the symptomatic relief of acute symptoms.

Paradoxical Bronchospasm: As with other inhaled medicines, ANORO ELLIPTA can cause paradoxical bronchospasm. If paradoxical bronchospasm occurs, instruct patients to discontinue ANORO ELLIPTA.

Risks Associated With Beta-Agonist Therapy: Inform patients of adverse effects associated with beta$_2$-agonists, such as palpitations, chest pain, rapid heart rate, tremor, or nervousness. Instruct patients to consult a physician immediately should any of these signs or symptoms develops.

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

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

ANORO ELLIPTA was developed in collaboration with Theravance.

GlaxoSmithKline
Research Triangle Park, NC 27709

Revised 05/2014 ANR:2BRS

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.

Sai Parthasarathy, MD

Jessie P. Bakker, PhD

Nick Antic, MBBS, PhD

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, Cannabimimetics, and Opiates in Sleep and Breathing
Moscone Center, Room 2001/2003
(West Building, Level 2)

FDA-APPROVED ACTHAR

FOR SYMPTOMATIC SARCOIDOSIS

SARCOIDOSIS HAS NUMEROUS CLINICAL MANIFESTATIONS AND RANGES IN SEVERITY[1]

- Lungs are affected in more than 90% of sarcoidosis cases[2]
- Concomitant involvement of extrapulmonary organs can be seen in up to 50% of cases[3]
- Extrapulmonary sarcoidosis adds to the morbidity and mortality of patients with pulmonary sarcoidosis[3]
  - The number of organs impacted by sarcoidosis is likely to increase over time[4]

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, ocular 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.

References: 1. Judson MA. The clinical features of sarcoidosis: a comprehensive review. *Clin Rev Allerg Immunol.* 2015;49:63-78. **2.** Baughman RP, Culver DA, Judson MA. A concise review of pulmonary sarcoidosis. *Am J Respir Crit Care Med.* 2011;183:573-581. **3.** Shigemitsu H, Patel HV, Schreiber MP. Extrapulmonary sarcoidosis. In: Judson MA, ed. *Pulmonary Sarcoidosis: A Guide for the Practicing Clinician.* Vol 17. New York, NY: Springer Science+Business Media; 2014:149-186. **4.** Judson MA, Boan AD, Lackland DT. The clinical course of sarcoidosis: presentation, diagnosis, and treatment in a large white and black cohort in the United States. *Sarcoidosis Vasc Diffuse Lung Dis.* 2012;29:119-127.

Mallinckrodt Pharmaceuticals

H.P. Acthar® GEL
(repository corticotropin injection) 80 U/mL

Brief Summary of Prescribing Information. For complete prescribing information (including Medication Guide), consult official package insert. H.P. Acthar Gel (repository corticotropin injection) INJECTION, GEL for INTRAMUSCULAR / SUBCUTANEOUS use. INDICATIONS AND USAGE Infantile spasms: H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. **Multiple Sclerosis:** H.P. Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease. **Rheumatic Disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis. **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis). **Dermatologic Diseases:** Severe erythema multiforme, Stevens-Johnson syndrome. **Allergic States:** Serum sickness. **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation. **Respiratory Diseases:** Symptomatic sarcoidosis. **Edematous State:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. **CONTRAINDICATIONS** H.P. Acthar Gel is contraindicated for intravenous administration. H.P. Acthar Gel is contraindicated where congenital infections are suspected in infants. Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of H.P. Acthar Gel. H.P. Acthar Gel is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular 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. **WARNINGS AND PRECAUTIONS** The adverse effects of H.P. Acthar Gel are related primarily to its steroidogenic effects. Not all of the adverse events described below have been seen after treatment with H.P. Acthar Gel, but might be expected to occur. [*see Adverse Reactions*]. **Infections** H.P. Acthar Gel may increase the risks related to infections with any pathogen, including viral, bacterial fungal, protozoan or helminthic infections. Patients with latent tuberculosis or tuberculin reactivity should be observed closely, and if therapy is prolonged, chemoprophylaxis should be instituted. **Cushing's Syndrome and Adrenal Insufficiency Upon Withdrawal** Treatment with H.P. Acthar Gel can cause hypothalamic-pituitary-axis (HPA) suppression and Cushing's syndrome. These conditions should be monitored especially with chronic use. Suppression of the HPA may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Patients should be monitored for signs of insufficiency such as weakness, hyperpigmentation, weight loss, hypotension and abdominal pain. The symptoms of adrenal insufficiency in infants treated for infantile spasms can be difficult to identify. The symptoms are non-specific and may include anorexia, fatigue, lethargy, weakness, excessive weight loss, hypotension and abdominal pain. It is critical that parents and caregivers be made aware of the possibility of adrenal insufficiency when discontinuing H.P. Acthar Gel and should be instructed to observe for, and be able to recognize, these symptoms. [*see Information for Patients*] The recovery of the adrenal gland may take from days to months so patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids during the period of stress. The adrenal insufficiency may be minimized in adults and infants by tapering of the dose when discontinuing treatment. Signs or symptoms of Cushing's syndrome may occur during therapy but generally resolve after therapy is stopped. Patients should be monitored for these signs and symptoms such as deposition of adipose tissue in characteristics sites (e.g., moon face, truncal obesity), cutaneous striae, easy bruisability, decreased bone mineralization, weight gain, muscle weakness, hyperglycemia, and hypertension. **Elevated Blood Pressure, Salt and Water Retention and Hypokalemia** H.P. Acthar Gel can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium and calcium. Dietary salt restriction and potassium supplementation may be necessary. Caution should be used in the treatment of patients with hypertension, congestive heart failure, or renal insufficiency. **Vaccination** Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of H.P. Acthar Gel. Killed or inactivated vaccines may be administered; however, the response to such vaccines can not be predicted. Other immunization procedures should be undertaken with caution in patients who are receiving H.P. Acthar Gel, especially when high doses are administered, because of the possible hazards of neurological complications and lack of antibody response. **Masking Symptoms of Other Diseases** H.P. Acthar Gel often acts by masking symptoms of other diseases/disorders without altering the course of the other disease/disorder. Patients should be monitored carefully during and for a period following discontinuation of therapy for signs of infection, abnormal cardiac function, hypertension, hyperglycemia, change in body weight and fecal blood loss. **Gastrointestinal Perforation and Bleeding** H.P. Acthar Gel can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Signs of gastrointestinal perforation, such as peritoneal irritation, may be masked by the therapy. Use caution where there is the possibility of impending perforation, abscess or other pyogenic infections, diverticulitis, fresh intestinal anastomoses, and active or latent peptic ulcer. **Behavioral and Mood Disturbances** Use of H.P. Acthar Gel may be associated with central nervous system effects ranging from euphoria, insomnia, irritability (especially in infants), mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated. **Comorbid Diseases** Patients with a comorbid disease may have that disease worsened. Caution should be used when prescribing H.P. Acthar Gel in patients with diabetes and myasthenia gravis. **Ophthalmic Effects** Prolonged use of H.P. Acthar Gel may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves and may enhance the establishment of secondary ocular infections due to fungi and viruses. **Immunogenicity Potential** H.P. Acthar Gel is immunogenic. Limited available data suggest that a patient may develop antibodies to H.P. Acthar Gel after chronic administration and loss of endogenous ACTH and H.P. Acthar Gel activity. Prolonged administration of H.P. Acthar Gel may increase the risk of hypersensitivity reactions. Sensitivity to porcine protein should be considered before starting therapy and during the course of treatment should symptoms arise. **Use in Patients with Hypothyroidism or Liver Cirrhosis** There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver. **Negative Effects on Growth and Physical Development** Long-term use of H.P. Acthar Gel may have negative effects on growth and physical development in children. Changes in appetite are seen with H.P. Acthar Gel therapy, with the effects becoming more frequent as the dose or treatment period increases. These effects are reversible once H.P. Acthar Gel therapy is stopped. Growth and physical development of pediatric patients on prolonged therapy should be carefully monitored. **Decrease in Bone Density** Decrease in bone formation and an increase in bone resorption both through an effect on calcium regulation (i.e. decreasing absorption and increasing excretion) and inhibition of osteoblast function may occur. These, together with a decrease in the protein matrix of the bone (secondary to an increase in protein catabolism) and reduced sex hormone production, may lead to inhibition of bone growth in children and adolescents and to the development of osteoporosis at any age. Special consideration should be given to patients at increased risk of osteoporosis (i.e., postmenopausal women) before initiating therapy, and bone density should be monitored in patients on long term therapy. **Use in Pregnancy** H.P. Acthar Gel has been shown to have an embryocidal effect. Apprise women of potential harm to the fetus. [*see Use in Specific Populations*] **ADVERSE REACTIONS** Please refer to *Adverse Reactions in Infants and Children Under 2 Years of Age* for consideration when treating patients with Infantile Spasms. The adverse reactions presented are primarily provided for consideration in use in adults and in children over 2 years of age, but these adverse reactions should also be considered when treating infants and children under 2 years of age. H.P. Acthar Gel causes the release of endogenous cortisol from the adrenal gland. Therefore all the adverse effects known to occur with elevated cortisol may occur with H.P. Acthar Gel administration as well. Common adverse reactions include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain. **Clinical Studies 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 practice. **Adverse Reactions in Infants and Children Under 2 Years of Age** While the types of adverse reactions seen in infants and children under age 2 treated for infantile spasms are similar to those seen in older patients, their frequency and severity may be different due to the very young age of the infant, the underlying disorder, the duration of therapy and the dosage regimen. Below is a summary of adverse reactions specifically tabulated from source data derived from retrospective chart reviews and clinical trials in children under 2 years of age treated for infantile spasms. The number of patients in controlled trials at the recommended dose was too few to provide meaningful incidence rates or to permit a meaningful comparison to the control groups. **Incidence (%) of Treatment Emergent Adverse Events Occurring in ≥ 2% of H.P. Acthar Gel (repository corticotropin injection) Infants and Children under 2 years of Age with the recommended 75 U/m² bid dose (n=122) vs the 150 U/m² qd dose (n=37)—System Organ Class:** *Cardiac disorders:* cardiac hypertrophy (3, 0); *Endocrine disorders:* Cushingoid (3, 22); *Gastrointestinal disorders:* constipation (0, 5), diarrhea (3, 14), vomiting (3, 5); *General disorders and administration site conditions:* irritability (7, 19), pyrexia (5, 8); *Infections and infestations:* infection[1] (20, 46); *Investigations:* weight gain (1, 3); *Metabolism and nutrition disorders:* increased appetite (0, 5), decreased appetite (3, 3); *Nervous system disorders:* convulsion[2] (12, 3); *Respiratory, thoracic and mediastinal disorders:* nasal congestion (1, 5); *Skin and subcutaneous tissue disorders*: acne (0, 14), rash (0, 8); *Vascular disorders:* hypertension (11, 19). [1]Specific infections that occurred at ≥2% were candidiasis, otitis media, pneumonia and upper respiratory tract infections. [2]In the treatment of Infantile Spasms, other types of seizures/convulsions may occur because some patients with infantile spasms progress to other forms of seizures (for example, Lennox-Gastaut Syndrome). Additionally the spasms sometimes mask other seizures and once the spasms resolve after treatment, the other seizures may become visible. These adverse reactions may also be seen in adults and children over 2 years of age when treated for other purposes and with different doses and regimens. **Postmarketing Experience** The following adverse reactions associated with the use of H.P. Acthar Gel have been identified from postmarketing experience with H.P. Acthar Gel. Only adverse events that are not listed above as adverse events reported from retrospective chart reviews and non-sponsor conducted clinical trials and those not discussed elsewhere in labeling, are listed in this section. Because the adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or establish a causal relationship to use with H.P. Acthar Gel. Events are categorized by system organ class. Unless otherwise noted these adverse events have been reported in infants, children and adults. **Allergic Reactions** Allergic responses have presented as dizziness, nausea and shock (adults only). **Cardiovascular** Necrotizing angitis (adults only) and congestive heart failure. **Dermatologic** Skin thinning (adults only), facial erythema and increased sweating (adults only). **Endocrine** Decreased carbohydrate tolerance (infants only) and hirsutism. **Gastrointestinal** Pancreatitis (adults only), abdominal distention and ulcerative esophagitis. **Metabolic** Hypokalemic alkalosis (infants only). **Musculoskeletal** Muscle weakness and vertebral compression fractures (infants only). **Neurological** Headache (adults only), vertigo (adults only), subdural hematoma, intracranial hemorrhage (adults only), and reversible brain shrinkage (usually secondary to hypertension) (infants only). **Possible Additional Steroidogenic Effects** Based on steroidogenic effects of H.P. Acthar Gel certain adverse events may be expected due to the pharmacological effects of corticosteroids. The adverse events that may occur but have not been reported for H.P. Acthar Gel are: **Dermatologic** Impaired wound healing, abscess, petechiae and ecchymoses, and suppression of skin test reactions. **Endocrine** Menstrual irregularities. **Metabolic** Negative nitrogen balance due to protein catabolism. **Musculoskeletal** Loss of muscle mass and aseptic necrosis of femoral and humeral heads. **Neurological** Increased intracranial pressure with papilledema, (pseudo-tumor cerebri) usually after treatment, and subdural effusion. **Ophthalmic** Exophthalmos. **DRUG INTERACTIONS** Formal drug-drug interaction studies have not been performed. H.P. Acthar Gel may accentuate the electrolyte loss associated with diuretic therapy. **USE IN SPECIFIC POPULATIONS Pregnancy** Pregnancy Class C: H.P. Acthar Gel has been shown to have an embryocidal effect. There are no adequate and well-controlled studies in pregnant women. H.P. Acthar Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from H.P. Acthar Gel, when treating a nursing mother, a decision should be made whether to discontinue nursing or to discontinue the drug, considering the risk and benefit to the mother. **Pediatric Use** H.P. Acthar Gel is indicated as monotherapy for the treatment of infantile spasms in infants and children less than 2 years of age. Both serious and other adverse reactions in this population are discussed in Warnings and Adverse Reactions in Infants and Children Under 2 Years of Age. The efficacy of H.P. Acthar Gel for the treatment of infantile spasms in infants and children less than 2 years of age was evaluated in a randomized, single blinded (video EEG interpreter blinded) clinical trial and an additional active control supportive trial. A responding patient was defined as having both complete cessation of spasms and elimination of hypsarrhythmia. Safety in the pediatric population for infantile spasms was evaluated by retrospective chart reviews and data from non-sponsor conducted clinical trials [*see Adverse Reactions*]. While the types of adverse reactions seen in infants and children under 2 years of age treated for infantile spasms are similar to those seen in older patients, their frequency and severity may be different due to the very young age of the infant, the underlying disorder, the duration of therapy and the dosage regimen. Effects on growth are of particular concern [*see Warnings and Precautions*]. Serious adverse reactions observed in adults may also occur in children [*see Warnings and Precautions*]. **OVERDOSAGE** While chronic exposure to H.P. Acthar Gel at high doses can be associated with a variety of potential serious adverse effects, it is not expected that a single high dose, or even several large doses, has the potential for serious adverse effects compared to a standard dose. There have been no reports of death or acute overdose symptoms from H.P. Acthar Gel in clinical studies or in the published literature. The intramuscular route of administration makes it unlikely that an inadvertent acute overdose will occur. The typical daily dose of H.P. Acthar Gel to treat an infant that has a BSA of 0.4 m^2 would be 60 U/day. Using the 1-cc syringe supplied with H.P. Acthar Gel, the maximum amount that can be injected is 80 U/injection, which is a well-tolerated single dose. **HOW SUPPLIED / STORAGE AND HANDLING** H.P. Acthar Gel (repository corticotropin injection) is supplied as 5 mL multi-dose vial (63004-8710-1) containing 80 USP Units per mL. H.P. Acthar Gel (repository corticotropin injection) should be warmed to room temperature before using. Do not over pressurize the vial prior to withdrawing the product. Store H.P. Acthar Gel (repository corticotropin injection) under refrigeration between 2°-8°C (36°-46°F). Product is stable for the period indicated on the label when stored under the conditions described. **PATIENT COUNSELING INFORMATION** Caretakers of patients with infantile spasms should be informed of the availability of a Medication Guide, and they should be instructed to read the Medication Guide prior to administering H.P. Acthar Gel. Patients should be instructed to take H.P. Acthar Gel only as prescribed. They should not stop treatment suddenly unless instructed by their physician to do so. Patients, their caregivers and families should be advised as to the importance of the need for careful monitoring while on and during titration from H.P. Acthar Gel treatment and the importance of not missing any scheduled doctor's appointments. Patients, their caregivers and families should be advised that if the patient develops an infection or fever they should contact their physician. They should be educated that a fever may not necessarily be present during infection. The patient should also try to limit contact with other people with infections to minimize the risk of infection while taking H.P. Acthar Gel. [*see Warnings and Precautions and Adverse Reactions*]. Patients, their caregivers and families should be advised that if the patient experiences an increase in blood pressure they should contact their physician. [*see Warnings and Precautions and Adverse Reactions*]. Patients, their caregivers and families should be advised that if the patient or the caregiver notices blood or a change in color of the patient's stool they should contact their physician. [*see Warnings and Precautions*]. Caregivers and families of infants and children treated with H.P. Acthar Gel should be informed that the patient may show signs of irritability and sleep disturbances. These effects are reversible once H.P. Acthar Gel therapy is stopped. [*see Warnings and Precautions and Adverse Reactions*]. Patients, their caregivers and families should be advised that changes in appetite, most often leading to weight gain, are seen with H.P. Acthar Gel therapy, becoming more frequent as the dose or treatment period increases. These effects are reversible once H.P. Acthar Gel therapy is stopped. [*see Warnings and Precautions and Adverse Reactions*]. Patients, their caregivers and families should be advised that the patient may be monitored for signs of adrenal insufficiency such as weakness, fatigue, lethargy, anorexia, weight loss, hypotension, abdominal pain or hyperpigmentation (adults only) after treatment has stopped. Since the recovery of the adrenal gland varies from days to months, patients may need to be protected from the stress of trauma or surgery by the use of corticosteroids during the period of stress. [*see Warnings and Precautions*]. Patients should be advised not to be vaccinated with live or live attenuated vaccines during treatment with H.P. Acthar Gel. Additionally, other immunization procedures in patients or in family members who will be in contact with the patient should be undertaken with caution while the patient is taking H.P. Acthar Gel. [*see Warnings and Precautions*]. Patients, their caregivers and families should be advised that prolonged use of H.P. Acthar Gel in children may result in Cushing's syndrome and associated adverse reactions, may inhibit skeletal growth, and may cause osteoporosis and decreased bone density. If prolonged use is necessary, H.P. Acthar Gel should be given intermittently along with careful observation. [*see Warnings and Precautions, and Adverse Reactions*]. Patients, their caregivers and families should be informed that H.P. Acthar Gel may mask symptoms of other diseases/disorders without altering the course of the other disease/disorder. The patient will need to be monitored carefully during and for a period following discontinuation of therapy for signs of infection, abnormal cardiac function, hypertension, hyperglycemia, change in body weight, and fecal blood loss. [*see Warnings and Precautions*]. In the treatment of Infantile Spasms, other types of seizures may occur because some patients with infantile spasms progress to other forms of seizures (for example, Lennox-Gastaut Syndrome). Additionally the spasms sometimes mask other seizures and once the spasms resolve after treatment with H.P. Acthar Gel, the other seizures may become visible. Parents and caregivers should inform their physician of any new onset of seizures so that appropriate management can then be instituted. [*see Adverse Reactions*].

H.P. Acthar® Gel (repository corticotropin injection)

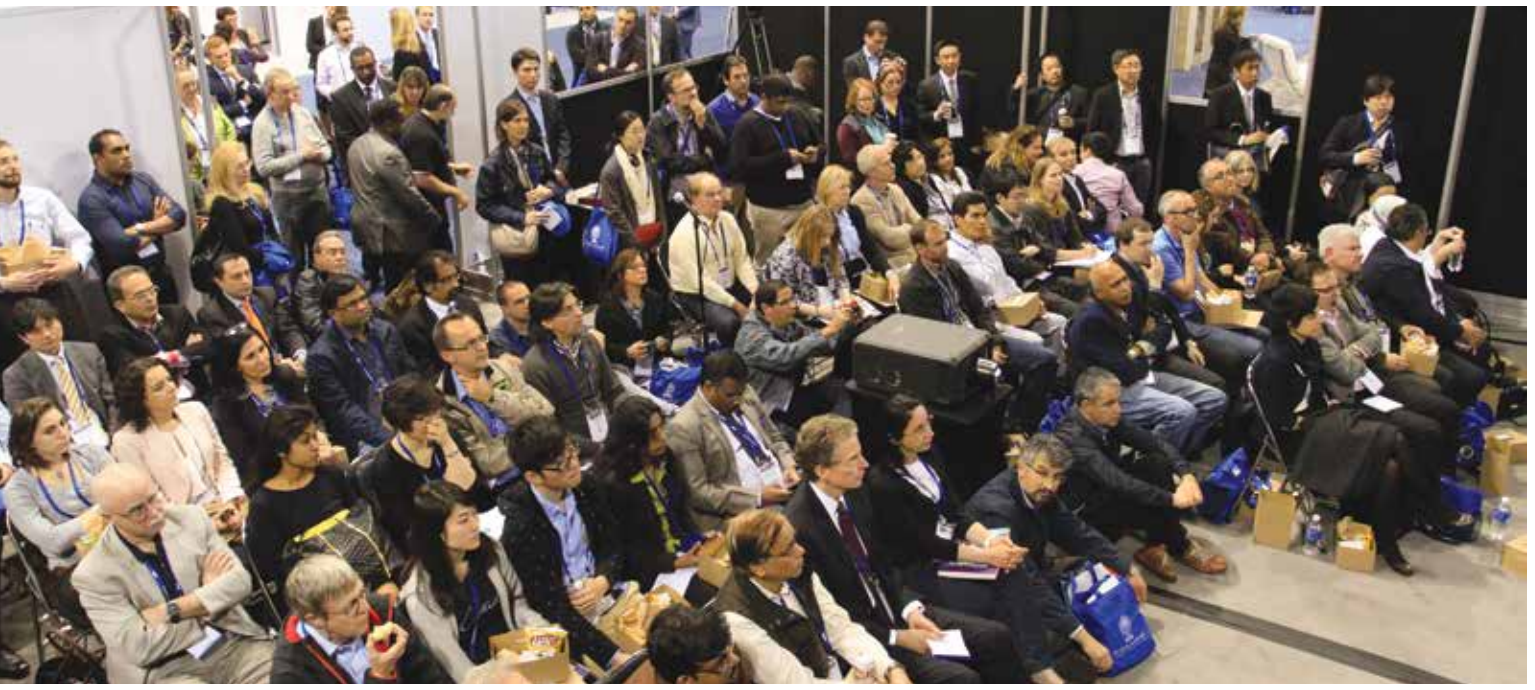
Manufactured for:
Mallinckrodt ARD, Inc.

Hazelwood, MO 63042 USA

Rev 01/2015

Mallinckrodt Pharmaceuticals™

Lunch and Learn at Industry Theaters, Mini Theaters



Learn about product launches and treatment options at the Industry Theaters and Mini Industry Theaters. See the Tuesday and Wednesday Daily Bulletin for future theaters.

ATS 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 Robbins, 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

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

1:15-2 p.m.

Targeting Exacerbations in Moderate to Severe Persistent Allergic Asthma

This program features a presentation on Targeting Exacerbations in Moderate to Severe Persistent Allergic Asthma. Complimentary lunch is provided.

Objectives:

- Discuss current challenges in identifying patients with uncontrolled allergic asthma
- Review case studies and clinical data
- Treatment of moderate to severe persistent allergic asthma
- Review efficacy and safety data for a treatment option for appropriate patients with uncontrolled allergic asthma

Companies: Genentech USA Inc. and Novartis Pharmaceuticals Corporation

MINI INDUSTRY THEATER

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 parenteral patients.

Company: United Therapeutics Corporation ■

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-disordered 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 says. ■

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. ■

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: Zolt 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 virtual steps to prominent places. You'll learn how many 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.

ANNOUNCING . . .

Gilead Sciences Research Scholars Programs

Gilead Sciences Research Scholars Program

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

SCIENTIFIC REVIEW COMMITTEE

Christopher H. Goss, MD, MSc
Committee Chair
University of Washington
Seattle, WA

J. P. Clancy, MD
Cincinnati Children's Hospital Medical Center
Cincinnati, OH

Scott H. Donaldson, MD
University of North Carolina Chapel Hill
Chapel Hill, NC

Jerry A. Nick, MD
National Jewish Health
Denver, CO

Pamela L. Zeitlin, MD, PhD
Johns Hopkins University
Baltimore, MD

Pulmonary Arterial Hypertension

Application Deadline: Friday, August 5, 2016

SCIENTIFIC REVIEW COMMITTEE

Nicholas S. Hill, MD
Committee Chair
Tufts University School of Medicine
Boston, MA

Todd M. Bull, MD
University of Colorado
Denver, CO

Karen A. Fagan, MD
University of South Alabama College of Medicine
Mobile, AL

Paul M. Hassoun, MD
Johns Hopkins University
Baltimore, MD

Bruce R. Pitt, PhD
University of Pittsburgh
Pittsburgh, PA

Ioana R. Preston, MD
Tufts University School of Medicine
Boston, MA

GILEAD
Advancing Therapeutics.
Improving Lives.

Nucala®
(mepolizumab)
for Subcutaneous Injection
100 mg/vial

Visit NUCALAinfo.com
for additional information,
including full Prescribing Information.

To learn more, visit our GSK Booth #1216

www.GSKSource.com