ATS DAILY BULLETIN

Where today's science meets tomorrow's care™

Monday, May 16, 2016

San Francisco, California
May 13-May 18, 2016

Revolutionizing Human Longevity

J. Craig Venter, PhD: 'Human longevity is not just about trying to make people live longer.'

Supercomputers can analyze enormous amounts of data, and use algorithms to predict your life span and the development of diseases in their genesis. This heady update on technology and the status of precision medicine was delivered by J. Craig Venter, PhD, the leader in genome research, during Saturday's Opening Ceremony.

"We are looking across the genome and across all diseases," Dr. Venter says of his team's research. "Human longevity is not just about trying to make people live longer; it is about trying to create a healthy life span."

Dr. Venter led the effort to first sequence a genome in 1995, and then the human genome in 2001. Those early efforts were expensive and limited by the power of computers of that era. It cost $100 million to sequence the first genome; today, it costs $2,000 to sequence a human genome. In 1999, a 1.5-teraflop computer that Dr. Venter's team used in its sequencing work cost $50 million; today, a 1-teraflop card for a PC costs $100. (A teraflop is a measure of a computer's speed.)

The newest research vehicle for Dr. Venter is Human Longevity, Inc., a genomics-based, technology-driven company whose groundbreaking work is laying the foundation of precision

see OPENING CEREMONY page 3

New Technologies to Check Out

The ATS Exhibit Hall is *the* venue for getting a first look at the latest technologies available for pulmonary, critical care, and sleep medicine professionals. Several exhibitors will launch new products, including Broncus Medical Inc., Cogentix Medical, Richard Wolf Medical Instruments Corporation, and VIDA Diagnostics Inc.

Broncus Medical Inc. in Booth 834 will feature Kendal Hervert, DO, from the Cancer Treatment Centers of America, Southwestern Regional Medical Center, Tulsa, Oklahoma. Dr. Hervert will present the latest clinical data using the new Archimedes™ System at 1 p.m. PDT on Monday.

The company developed the system to address the challenge of accessing nodules not accessible via the traditional airway tree route. This technique uses a trans-parenchymal approach, which is not dependent on an airway that leads directly to a lesion.

The system uses virtual navigation bronchoscopy guidance to select the optimal point of entry. Then, a coring needle (FlexNeedle™, Broncus Medical) is inserted through the airway wall, after which a specialized Broncus Medical sheath is inserted in the hole. The sheath, with special radiopaque markers, is advanced to create a tunnel within the lung parenchyma directly to the lesion. This is achieved by using a unique software system that fuses the virtual

see NEW TECHNOLOGIES page 8

Cogentix Medical demonstrates its EndoSheath microbial barrier, which eliminates the need for high-level disinfectant between procedures.

KEYNOTE SERIES

Lung Cancer, PAH, and CTEPH

The ATS Keynote Series continues Monday with discussions about lung cancer detection and prevention, and the evolution of pulmonary arterial hypertension (PAH) and chronic thromboembolic pulmonary hypertension (CTEPH). The series showcases major discoveries in pulmonary, critical care, and sleep medicine. The lectures will be given concurrently from 8 to 8:45 a.m.

Lung Cancer Detection and Prevention in the Precision Medicine Era

Avrum Spira, MD, MSc

Moscone Center, Room 134 (North Building, Lower Level)
Avrum Spira, MD, MSc, chief of the Division of Computational Biomedicine, and professor of medicine, pathology, laboratory medicine, and bioinformatis, Boston University School of Medicine; director of the translational bioinformatics program, Clinical and Translational Science Institute, Boston University, Massachusetts

Pulmonary Hypertension: Evolution of PAH and CTEPH

Nick H. Kim, MD

Moscone Center, Room 135 (North Building, Lower Level)
Nick H. Kim, MD, clinical professor of medicine, director of pulmonary vascular medicine, and director of the pulmonary and critical care medicine fellowship at the University of California, San Diego School of Medicine; clinical service chief of Thornton PCCM, La Jolla, California

Lung Cancer Detection and Prevention in the Precision Medicine Era (K3) is supported by an educational grant from AstraZeneca LP.

Pulmonary Hypertension: Evolution of PAH and CTEPH (K4) is supported by educational grants from Actelion Pharmaceuticals US, Inc., Gilead Sciences, Inc., and United Therapeutics Corporation.

Gilead is committed

to expanding healthcare

options for individuals living with

cardiovascular and respiratory diseases

through innovative research, access,

and education programs.

GILEAD

Q&A: ATS President Atul Malhotra, MD

An interview with Atul Malhotra, MD, ATS President

Q: What have you found most gratifying during your term as president?

A: My focus has been on the next generation, and attracting and attaining top talent in the field. In my time on the ATS Executive Committee, this has led to the culmination of programs, including the Global Scholars and International Conference offerings, such as the Fellows Track Symposium, Resident Boot Camp, and Student Scholars.

The growth of these programs is astounding, and like all my work at the national/international level, our success was made possible with the help of a dedicated staff and fellow executive committee members.

Q: What do you hope to accomplish in your upcoming role as immediate past president?

A: My primary objective will be offering support to President-Elect David Gozal, MD. I will continue to be a resource to the ATS Executive Committee. And though my role is shifting, my commitment remains the same. I will be available to help align our common goals and help sustain the Society's long-term progress. Like many past presidents, our work with the ATS remains a lifelong endeavor.

Q: As a leader of the Society and a leader in the field, what do you believe is the biggest challenge to pulmonary, critical care, and sleep medicine?

A: I'm concerned about the vanishing physician-scientist. The ATS has sought to address this issue with bridge grants to early career researchers, such as those awarded by the ATS Foundation. At a broader level, we're also advocating for increased funding from the National Institutes of Health, pushing for a greater investment in scientific research, and placing a higher priority on the development of new treatments and therapies.

Additional areas of concern, such as air pollution, can be found in my May President's Message at **news.thoracic.org**.

> "I'm concerned about the vanishing physician-scientist. The ATS has sought to address this issue with bridge grants to early career researchers, such as those awarded by the ATS Foundation."

Authored Sleep Medicine Resources

ATS President Atul Malhotra, MD, is an expert on sleep at the University of California, San Diego. During his ATS presidency, he authored or co-authored the following articles in the American Journal of Respiratory and Critical Care Medicine, and the Annals of the American Thoracic Society.

What Is the Future of Sleep Medicine in the United States?
Volume 192, Issue 8 (October 15, 2015)

Trazodone Effects on Obstructive Sleep Apnea and Non-REM Arousal Threshold
Volume 12, Issue 5 (May 2015)

High Prevalence of Obstructive Sleep Apnea in Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease
Volume 12, Issue 8 (August 2015)

Clinical Use of Loop Gain Measures to Determine Continuous Positive Airway Pressure Efficacy in Patients With Complex Sleep Apnea. A Pilot Study
Volume 12, Issue 9 (September 2015)

Sleep-Disordered Breathing in Patients With Chronic Obstructive Pulmonary Disease
Volume 12, Issue 9 (September 2015)

Treatment of Obstructive Sleep Apnea. Prospects for Personalized Combined Modality Therapy
Volume 13, Issue 1 (January 2016)

View a collection of sleep articles published in the past year, including original research findings, updates, perspectives, letters, editorials, and focused reviews at **news.thoracic.org**.

ATS Announces BEAR Cage Winners

Jake Brenner, MD, PhD, (second from right) University of Pennsylvania, is the winner of the ATS BEAR (Building Education to Advance Research) Cage competition. Earlier this year, early career investigators submitted research proposals to the ATS BEAR Cage competition, sponsored by the ATS Drug Device Discovery and Development Committee, for a chance to win $5,000 at ATS 2016. Theodore F. Reiss, MD, MBE, (right) chair of the ATS DDDD Committee, presents the awards to Dr. Brenner for "Pulmonary Endothelial-Targeted Liposomes (PELs) for the Treatment of ARDS" and to the runners-up Katherine N. Cahill, MD, Harvard Medical School, for "Targeting Mast Cells in Aspirin-Exacerbated Respiratory Disease (AERD)" and Valentin Prieto-Centurion, MD, University of Illinois at Chicago, for "Promoting Activity After COPD Exacerbations (PACE)." These finalists pitched their highly innovative research proposals to a panel of translational science experts representing academia, industry, and governmental sectors in front of a live audience at the Science & Innovation Center on Sunday.

OPENING CEREMONY

Continued from page 1

medicine that could revolutionize the health and longevity of mankind.

Technology advances enabled by supercomputers are driving machine learning, which explores the construction of algorithms that can make predictions about different diseases based on huge amounts of data. This greater collection of data allows researchers to find variations in the genome, which is where medical problems arise.

"Our view is, if we can do early detection or predictions from the genome, where you can either alter these diseases or prevent them, it can have a huge impact on longevity. It is getting so we can predict your likely age of death or your longevity," Dr. Venter says. "If we can change variants, they would be interesting druggable targets."

Human Longevity is now using what it has learned to detect diseases at early stages in people who are not yet experiencing health problems. Dr. Venter highlighted some of those cases and the research data his company collected.

"The goal is to create this massive database … (to) improve the accuracy of predictions," Dr. Venter says. "We will go from this early stage we are at now to having us be part of accurate 'precision medicine.'"

Presidents' Terms Define Progress

ATS President Atul Malhotra, MD, reviewed accomplishments while President-Elect David Gozal, MD, outlined his goals during the Opening Ceremony.

"The focus of my presidency has been on the next generation, trying to develop young talent to find our replacements," Dr. Malhotra says, citing examples through programs such as the Student Scholars, Resident Boot Camp, and Fellows Track Symposium.

Dr. Malhotra presented the ATS Foundation's first Vision Award to Sonia Buist, MD, for her work as founder of the Methods in Epidemiologic, Clinical, and Operations Research (MECOR) program. He concluded with accomplishments of the Global Scholars Program.

Dr. Gozal gave a glimpse of his future plans, including a focus on improving technology at ATS International Conferences. Learn more about his vision for the Society at the ATS Plenary Session from 11:45 a.m. to 1:15 p.m. on Tuesday, Moscone Center, Room 303/305 (South Building, Esplanade Level).

He also says that improving document implementation is on his agenda, adding, "We want to streamline the development process so guidelines are developed in a more timely and efficient manner."

ATS PAR Empowers Patients

Patients and families are central to the mission of the American Thoracic Society. With a theme of empowering patients with technology, experts in pulmonary, critical care, and sleep medicine shared their insights with patients and family members during the Public Advisory Roundtable Meet-the-Experts Forum on Saturday.

Discussions focused on using the Internet to find medical answers, improving patient adherence with continuous positive airway pressure, managing lung diseases in rural areas, and using social media as a tool in smoking cessation. Participants also met with disease experts in breakout sessions to discuss the latest in research, clinical trials, and clinical care. These question-and-answer breakouts focused on alpha-1 chronic obstructive pulmonary disease, asthma and allergy, children's interstitial and diffuse lung disease, pulmonary fibrosis, pulmonary hypertension, rare lung diseases, and sarcoidosis.

Chris Higgins, Los Altos, California, who was diagnosed with scleroderma in 2013, says he often looks to the Internet for medical information. "I liked learning about how to find reputable websites because there is so much junk information out there," he says.

Rozzy Hale attended the forum as an advocate for her 6-year-old son, Grant, who is undergoing genetic testing to determine if he has primary ciliary dyskinesia.

"It's difficult to advocate for ourselves when there isn't a lot of information and research available, but here, I can learn about what's happening in research, the tools we need to use, and what we have to look forward to in the future," she says.

Experts share information with patients and their families during the Public Advisory Roundtable Forum on Saturday.

Experts say the forum experience is equally rewarding for them. "I connect with their stories and see what a difference the work we do in research and clinical care makes for individual families," says Robin Deterding, MD, Children's Hospital Colorado, Denver. "It's important that families have interactions with physicians who are leaders in their fields so they can understand what opportunities are here now and coming in the future."

Virginia Steen, MD, a rheumatologist at Georgetown University, Washington, D.C., says she always enjoys talking with patients. "That's part of my passion. This is a great opportunity to be able to reach out to these patients. These are uncommon diseases and uncommon complications, so it's invaluable for them to get insights from people like me who have the experience," Dr. Steen says.

Founded in 2001, the ATS PAR is a partnership with organizations representing persons affected by respiratory diseases, sleep-related conditions, or related critical illnesses. The ATS collaborates with these groups to advance shared educational, research, patient care, and advocacy goals. ■

ATS CENTER

10 Reasons to Visit the ATS Center in the Exhibit Hall in San Francisco

1 Learn about education programs and products including MOC opportunities, Assembly Journal Clubs, chapter educational programs and more.

2 Test your knowledge on pulmonary, critical care, sleep or pediatric medicine when you visit the Take the Challenge kiosk. See how you stack up against others.

3 Receive a FREE gift pack when you join ATS or renew your membership while in San Francisco.

4 Clinicians: Obtain a copy of Highlights for Clinicians for conference sessions most relevant to clinicians; check out our new Guidelines Pocket Cards; and obtain a copy of the Clinical Year in Review or the Pediatric Year in Review (these will also be distributed at sessions on Sunday).

5 Trainees: Get a copy of the Road Map for Early Career Professionals to learn about conference sessions most advantageous for your career. Also pick up a schedule of Assembly Journal Clubs webinars.

6 Rediscover the three ATS scientific journals and the journal apps for iOS and Android.

7 Purchase gift items including a fleece jacket, an International Conference mug with San Francisco images or a pewter lung key chain.

8 Access Patient Education fact sheets at our kiosks; choose from more than 80 titles in English and Spanish. Pick up a schedule for Lung Disease Week at the ATS patient education programs.

9 Learn about grant opportunities with the ATS Foundation Research Program.

10 Travel around the world with us: select an area of the world on our interactive map to learn more about ATS's Global Activities.

Flash drives, webcasts, audio presentations and DVDs of the Postgraduate Courses are available for purchase at the Best of ATS booth located in the Lobby, South Building, Upper Level of the Moscone Center.

Exhibit Hall

Sunday, May 17 8 a.m. to 2:45 p.m
Monday, May 18 8 a.m. to 2:45 p.m
Tuesday, May 19 8 a.m. to 2:45 p.m

The Exhibit Hall is located in Halls A-C, Moscone Center (South Building, Lower Level)

Visit the Membership Booth: Join or Renew Your Membership!

Visit the Membership Booth in the Registration Hall, Moscone Center Lobby (North Building, Street Level) to join the ATS, renew your membership or for answers to your membership questions. ATS members pay reduced registration fees at the International Conference – you must be a member at time of registration to receive the discount.

Receive a **FREE GIFT PACK** when you join or renew while at the conference. The Membership Booth will be open the same hours as conference registration:

Friday, May 13	6:30 a.m. to 5 p.m.
Saturday, May 14	6:30 a.m. to 6 p.m.
Sunday, May 15	7 a.m. to 6 p.m.
Monday, May 16	6:30 a.m. to 4:30 p.m.
Tuesday, May 17	8 a.m. to 4:30 p.m.
Wednesday, May 18	8 a.m. to 2 p.m.

When the Exhibit Hall closes on Tuesday, you can visit the Membership Booth in the Registration Hall for last minute purchases of gift items including fleece jackets, pewter lung key chains, International Conference mugs with San Francisco images and more:

Tuesday	2:45 p.m. to 4:30 p.m.
Wednesday	8 a.m. to 2 p.m.

You can also join ATS or renew your membership at the ATS Center in the Exhibit Hall, booth 937.

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

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Donors Honor Next Generation of Investigators

With an assortment of hors d'oeuvres, music, and dancing the ATS Foundation kicked off its Eighth Annual Research Program Benefit on Saturday evening. More than 650 attendees gathered at the San Francisco Marriott Marquis to recognize Sally E. Wenzel, MD, as the recipient of the 2016 Breathing for Life Award, as well as honor grant awardees, celebrate the ATS Foundation Research Program's successes, and socialize with friends.

The Breathing for Life Award is given by the ATS Foundation to recognize philanthropy and scientific accomplishments. Dr. Wenzel, an internationally recognized expert in severe asthma, gives back to the pulmonary community through her expertise, commitment to patient care, passion and advocacy for women in science, mentoring of young scientists, and her long-standing generosity toward the ATS Foundation Research Program.

Dr. Wenzel is a professor of medicine and director of the University of Pittsburgh Asthma Institute at the University of Pittsburgh Medical Center, Pennsylvania. Her studies of asthma phenotypes have led the field in understanding the complexities of severe asthma. Her laboratory is one of the few that can match cellular and molecular responses to asthma therapies.

Leaders from the ATS Foundation gave remarks, including James F. Donohue, MD, who completes his sixth and final year as the ATS Foundation Board of Trustees chair. Chair-Elect Dean E. Schraufnagel, MD, transitions to the role on Monday, bringing with him four years' experience on the Board of Trustees.

The gala raised more than $577,000 from corporate, medical institution, and individual supporters with proceeds supporting research grants for young investigators.

In 2016, the ATS Foundation will fund more than 20 awards, including unrestricted research awards in pulmonary, critical care, and sleep medicine; research partner awards; and awards for outstanding alumni from the Methods in Epidemiologic, Clinical, and Operations Research (MECOR) program. Since 2004, the ATS Foundation Research Program has provided $15 million in grants to more than 189 investigators, who have gone on to secure $188 million in federal funding.

Applications for the 2016 Research Program are being accepted. Letters of intent are due by June 20, 2016. Visit **foundation.thoracic.org** for details.

James F. Donohue (left), the ATS Foundation Board of Trustees chair, presents the 2015 Breathing for Life Award to Sally E. Wenzel, MD, in recognition of her research into severe asthma, advocacy for women in science, and mentoring of young scientists.

The ATS Foundation thanks Genentech for support at the Sapphire Level; Genentech–Novartis at the Platinum Level; Mylan, Inc., at the Crystal Level; AstraZeneca LP, Boehringer Ingelheim Pharmaceuticals, Inc., Novartis Pharmaceuticals Corporation, and Sanofi Genzyme and Regeneron at the Gold Level; FREEMAN, Gilead Sciences, Inc., Meda Pharmaceuticals, Inc., and Teva Respiratory at the Silver Level; and Boston Scientific Corporation, Inc., Insmed Incorporated, Merck, Sunovion Pharmaceuticals, Inc., and Theravance Biopharma at the Bronze Level.

The ATS Foundation also thanks UPMC & the University of Pittsburgh, Division of Pulmonary, Allergy, and Critical Care Medicine and the many individuals and medical institutions that have stepped forward to support the Research Program and young investigators in pulmonary, critical care, and sleep medicine.

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

Lunchtime Industry Theaters, Mini Theaters Presented in Exhibit Hall

The Industry Theater and Mini Industry Theater discussions continue Monday and Tuesday in the Exhibit Hall. 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 Tuesday issue of the ATS Daily Bulletin for a list of theaters taking place on Tuesday.

MONDAY

Mini Industry Theater

11:30 a.m.-Noon

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

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.

Industry Theater 2

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

kNOw Your Patient Goals: Understanding the Goal-oriented Approach in PAH (WHO Group 1) and CTEPH (WHO Group 4)

Pulmonary arterial hypertension (PAH) and chronic thromboembolic pulmonary hypertension (CTEPH) are characterized by elevated pulmonary artery pressures and increased pulmonary vascular resistance. Impaired synthesis of endogenous nitric oxide contributes to the pathology of both diseases. PH experts will present and discuss cases that demonstrate how targeting the NO-sGC-cGMP pathway can contribute to goal-oriented treatment approaches.

Speakers: **Murali Chakinala, MD**, *Associate Professor of Medicine, Director, Pulmonary Hypertension Care Center, Co-Director, HHT Center of Excellence, Washington University School of Medicine;* **Rajeev Saggar, MD**, *Executive Director of Advanced Lung Disease Institute, Medical Director of Critical Care, Associate Clinical Professor of Medicine, University of Arizona*

Company: Bayer

Mini Industry Theater

12:30-1 p.m.

Positive Airway Pressure and the Heart: Benefit or Harm

Discuss sleep-disordered breathing (SDB) that occurs in patients with congestive heart failure (CHF). Compare advanced positive airway pressure modalities in the management of SDB that occurs in patients with CHF. Examine recent research and discuss specific indications and limitations of servo ventilation.

Speaker: **Professor Dr. Winfried Randerath,** *Chief Physician and Medical Director, Hospital Bethanien, Department of Pulmonology and Allergology, Solingen, Germany*

Company: Philips Respironics, Inc.

Learn about product launches and treatment options during Monday's Industry Theaters and Mini Industry Theaters.

Industry Theater 1

1:15-2 p.m.

Exploring the Significance of Early Lung Function Loss in COPD Maintenance Treatment: An Interactive Discussion

A dynamic, expert-led debate which will highlight the considerations that impact initial COPD maintenance treatment decisions.

Speakers: **Gary T. Ferguson, MD**, *Director, Pulmonary Research, Institute of Southeast Michigan, Farmington Hills, Michigan;* **Donald P. Tashkin, MD**, *Emeritus Professor of Medicine, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, California*

Company: Boehringer Ingelheim Pharmaceuticals, Inc.

Industry Theater 2

1:15-2 p.m.

Meet the FLAME Experts: Discussion Session

(open to non-U.S. attendees only)

During this Novartis supported mini industry theater, experts involved in the recently completed FLAME study will discuss key findings from the study, its importance in understanding the effects of indacaterol/glycopyrronium in high-risk patients, and the potential implications for treatment guidelines and clinical practice.

1:30-1:35 p.m. Introduction—Jim Donohue

1:35-1:40 p.m. FLAME study design—Don Banerji

1:40-1:50 p.m. FLAME data and potential implications—Ken Chapman

1:50-2 p.m. Q&A—All

Company: Novartis Pharma AG

Join the Conversation on Twitter: #ATS2016

Sapna Kudchadkar @SapnaKmd Love conferences like #ATS2016 that capitalize on the awesome benefits of #SoMe for engagement!@atscommunity #medicine #research

Brandon Seay MD, MPH @BSeay05 "You learn differently today, so we will invest in those learning styles" ~David Gozal #ATS2016 music to this young physician's ears!

Susheel Patil @spatilmd Susheel Patil Retweeted Sean Barnes, MD, MBA @atscommunity Great topic at #ATS2016. Controversy: does knowing if a patient has #OSA truly improve outcomes?

Heka Health @heka_health Walk to Ferry Bldg = 2200 steps! #ATS2016 #ATS2016Walk http://buff.ly/1O3wV2O @atscommunity #health

Dr. Alison S. Clay @AS_Clay Excited to hear Cystic Fibrosis update by former "co-fellow" - jennifer taylor-cousar. In the Big Leagues #ATS2016

Question of the Day

How Do You Counsel Patients Using E-Cigarettes?

"I counsel patients against using e-cigarettes. The science behind e-cigarettes, in terms of what harm they can do, outweighs what the benefit might be. Every week or so we get more evidence that e-cigarettes carry a lot of harm."

Sahar Halabi, MD
Chicago, Illinois

"I tell them there are potential harms with chemicals that are associated with e-cigarettes. I tell people I can't say whether they are better for you than regular cigarettes, and so the best thing is to stop putting anything in your lungs."

Steven Purtle, MD
Denver, Colorado

"It is a problem in Germany. I tell people it is the same as smoking, and so for cessation it is not the correct way to go. In Germany, we have health insurance programs to help people quit smoking, and that is where I tell them to go to quit smoking."

Bjoern Laudahn, MD
Hamburg, Germany

"I tell patients e-cigarettes harm your lungs. I encourage patients to stop, and I offer my help to do that. We try to establish real objectives where they taper it down and then stop."

Julio Huapaya, MD
Baltimore, Maryland

"I tell them it is like what we knew about regular cigarettes in the 1930s or 1940s, when we didn't have enough information. If people want to use e-cigarettes as a nicotine replacement to quit, they can try it, but I tell them the data likely is not going to support that you are going to be nicotine-free down the road."

Tyson Sjulin, DO
San Antonio, Texas

"The data is not in yet, but we know that, in general, people who try to use e-cigarettes to quit smoking are not successful. I absolutely tell them it is not a way to quit smoking."

Viola Tracy, MD
Woodbury, Minnesota

Changes for Monitoring Patients on Ventilators

Levels of ventilator-assisted pneumonia (VAP) have declined but remain a concern, so the Centers for Disease Control and Prevention has proposed changes to the monitoring of complications from ventilators. The changes focus on ventilator-associated complications (VAC), which may affect VAP.

"The CDC and others have worried that hospitals have manipulated the VAP definition so that VAP data are not reliable any more. However, because the two are not exactly the same, and the problems with the new VAC definition are just being understood, the entire area remains confusing," says Michael S. Niederman, MD.

Dr. Niederman is a chair of "Controversies and Advances in the Management of Ventilator-Associated Pneumonia," which will explore a number of management strategies aimed at improving the management of VAP and avoiding the overuse of antibiotics.

The session, presented from 1:30 to 3:30 p.m. Wednesday in Moscone Center, Room 3016/3018 (West Building, Level 3), will examine evolving management approaches, including the use of anti-inflammatory therapies, rapid diagnostics, biomarker-guided therapies, and antibiotics in development.

Attendees will learn about new research in treatment approaches and whether reporting rates of VAC are tied to a reduction in VAP rates, as well as whether current prevention strategies can reduce the rates of both VAP and VAC.

"We will explore advances in diagnosis, disease monitoring, and therapy, giving attendees the newest information to help them optimize the management of patients at risk for VAP and those who have acquired this infection," says Dr. Niederman, professor of medicine and clinical director of pulmonary and critical care at New York Presbyterian/Weill Cornell Medical Center.

Michael S. Niederman, MD

A discussion period will follow five presentations:

- Can Anti-Inflammatory Therapy Help Improve Outcomes in VAP?
- Are New Antibiotics Going To Help Us Manage VAP in the ICU?
- Can Biomarkers Help With Antibiotic Stewardship in the ICU?
- Do Reporting Rates of VAC Improve Patient Care?
- New Diagnostic Tests for VAP: Faster and Better?

RELATED SESSIONS

Two additional education sessions related to VAP—focusing on fungal pneumonia and community-acquired pneumonia—will be presented.

Emerging scientific principles and clinically relevant advances pertinent to the understanding of invasive fungal infection of the respiratory system will be discussed during "New Insights Into the Predisposition, Pathogenesis, and Management of Fungal Pneumonia." It will be from 2:15 to 4:15 p.m. Monday in Moscone Center, Room 3016/3018 (West Building, Level 3).

Five presentations will look at research on genetic defects and immune factors that predispose patients to develop fungal pneumonia, new information about molecular and cellular mechanisms that drive the pathophysiology of fungal pneumonia, and diagnostic and treatment options for fungal pneumonia.

The second session, "Viral Community-Acquired Pneumonia," will provide epidemiological data on respiratory viruses as the cause of CAP, the utility of procalcitonin and other diagnostic tools to detect viral infection, and how to integrate new information on respiratory viruses into clinical practice. It will be from 2:15 to 4:15 p.m. Tuesday in Moscone Center, Room 3016/3018 (West Building, Level 3).

Five speakers will give an overview on how respiratory viruses contribute to community-acquired pneumonia and acute lung injuries in the ICU, as well as the use of genetic-based diagnostic approaches to detect viruses. ■

Take the ATS Walking Challenge

Neeraj Vij, PhD, Mount Pleasant, Michigan, stops by the ATS Walking Challenge information booth in the Moscone Center Lobby (South Building, Upper Level) to pick up a complimentary fitness tracker to track his Walking Challenge steps. Increase your steps virtually by visiting the ATS Walking Challenge sponsor, TEVA Respiratory in Booth 419, for a daily step booster. 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. 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 landmarks, such as Union Square, which is about 1,200 steps from the Moscone Center.

Four Honored for Scientific Accomplishments

Celebrate the achievements of four expert researchers for their outstanding scientific contributions in basic or clinical research that enhances the understanding, prevention, and treatment of lung disease during the Recognition Awards for Scientific Accomplishments.

The awards will be presented from 2:15 to 4:15 p.m. on Monday in the Moscone Center, Room 3010/3012 (West Building, Level 3).

Andrew J. Halayko, PhD, Winnipeg, Canada, and Thomas W. Ferkol, MD, St. Louis, Missouri, are chairs of the session. Awardees will make 25-minute presentations detailing their research.


Serpil Erzurum, MD


Anuradha Ray, PhD


Edwin K. Silverman, MD, PhD


Victor J. Thannickal, MD

- **2:15 p.m.: Serpil Erzurum, MD**, Cleveland, Ohio, presents "Cellular and Molecular Mechanisms in Pulmonary Hypertension."
- **2:45 p.m.: Anuradha Ray, PhD**, Pittsburgh, Pennsylvania, presents "Asthma and Its Regulation Through the Lens of the Immune System."
- **3:15 p.m.: Edwin K. Silverman, MD, PhD**, Boston, Massachusetts, presents "COPD: From Genetics to Networks."
- **3:45 p.m.: Victor J. Thannickal, MD**, Birmingham, Alabama, presents "Reactive Oxygen, Aging and Fibrotic Lung Disease." ■

NEW TECHNOLOGIES

Continued from page 1

bronchoscopy image with fluoroscopic guidance and 3D target projection. Upon reaching the lesion, diagnostic or therapeutic tools can be used.

Cogentix Medical in Booth 2029 was formed through a merger of Vision Sciences and Uroplasty in April 2015. The combined company subsequently launched a new brand, PrimeSight™, for its innovative line of endoscopy systems, which leverage the unique advantages of the EndoSheath® protective barrier. The EndoSheath barrier is a proven microbial barrier that advances the efficiency of bronchoscopy and eliminates the need for high-level disinfectant between procedures.

Richard Wolf Medical Instruments Corporation in Booth 2320 announces a set of instruments that will bring the use of rigid bronchoscopes into the future. In today's operating room, the possibilities in endoscopic instrumentation are finite with a few standard sets. Richard Wolf's TipControl is a new set of articulating forceps created to meet the needs in rigid bronchoscopy. This multifunctional, ambidextrous hand instrument allows users to bend beyond restrictions, making the instrument anything but rigid. A first for bronchoscopy, TipControl will change the approach of complex anatomy and tumor debulking within the tracheal-bronchial space.

VIDA Diagnostics Inc. in Booth 2221 will release and demonstrate VIDA|vision™ Lung Bronchoscopy Planning (LBP) software at ATS 2016. VIDA|vision brings speed, simplicity, and cost savings to physicians planning peripheral nodule biopsy procedures. This is a landmark release for VIDA, as VIDA|vision features an entirely new user interface tailored for everyday clinical use. The software provides path planning, virtual bronchoscope views, and much more. Unlike alternatives, VIDA's LBP is fast, accurate, and cost-effective, providing greater confidence for a quality result.

In addition to Lung Bronchoscopy Planning, VIDA offers an advanced clinical workflow for Lung Volume Reduction Planning (LVR). This is a precision pulmonary imaging solution, providing precise, evidence-based lung measures to aid treatment selection and treatment planning in LVR cases.

VIDA will demonstrate both workflows in its booth. ■


An attendee uses the TipControl, a set of articulating forceps developed by Richard Wolf Medical Instruments for use in rigid bronchoscopy.

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

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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.

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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

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1. Restrepo, et al. Expert Review Respiratory Medicine, 2014.
2. Klein K, et al. Impact of Early Mobilization on Mechanical Ventilation and Cost in Neurological ICU. Neurocrit Care; Oct, 2015.

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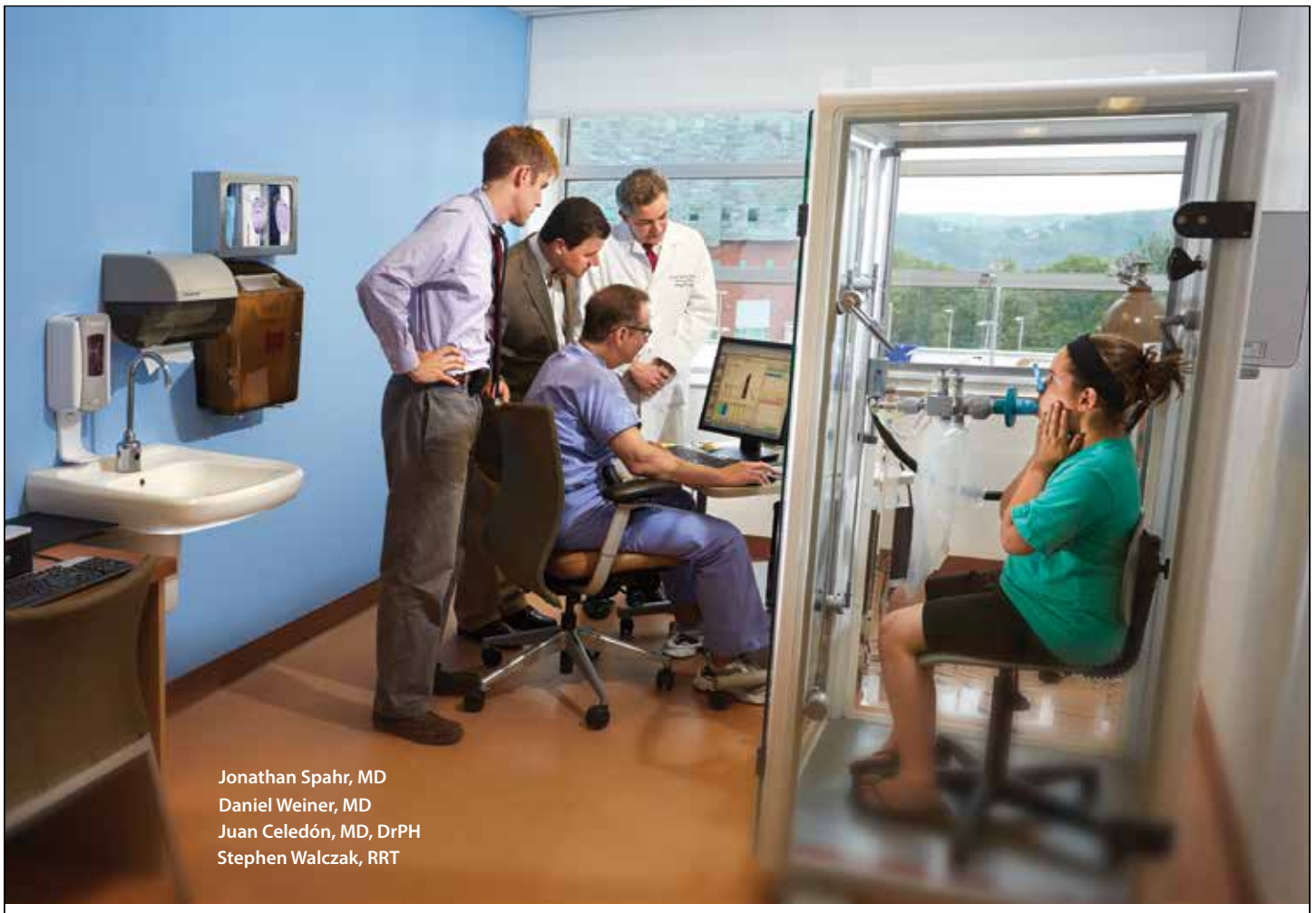

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BREO ELLIPTA 100/25—Improves lung function, and also reduces exacerbations in patients with a history of exacerbations

Indications

- BREO 100/25 is a combination inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist (ICS/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. BREO 100/25 is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. BREO 100/25 is the only strength indicated for COPD.
- BREO is NOT indicated for the relief of acute bronchospasm.

Important Safety Information for BREO 100/25 for COPD

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in BREO, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths. This finding with salmeterol is considered a class effect of all LABA. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids (ICS) or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA.

CONTRAINDICATIONS

- BREO is contraindicated for primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required.
- BREO is contraindicated in patients with severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, vilanterol, or any of the excipients.

WARNINGS AND PRECAUTIONS

- BREO should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD or asthma.
- BREO should not be used for the relief of acute symptoms, i.e., 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 BREO 100/25 throughout this advertisement.

Please see Brief Summary of Prescribing Information, including Boxed Warning, for BREO 100/25 on the pages following this advertisement.

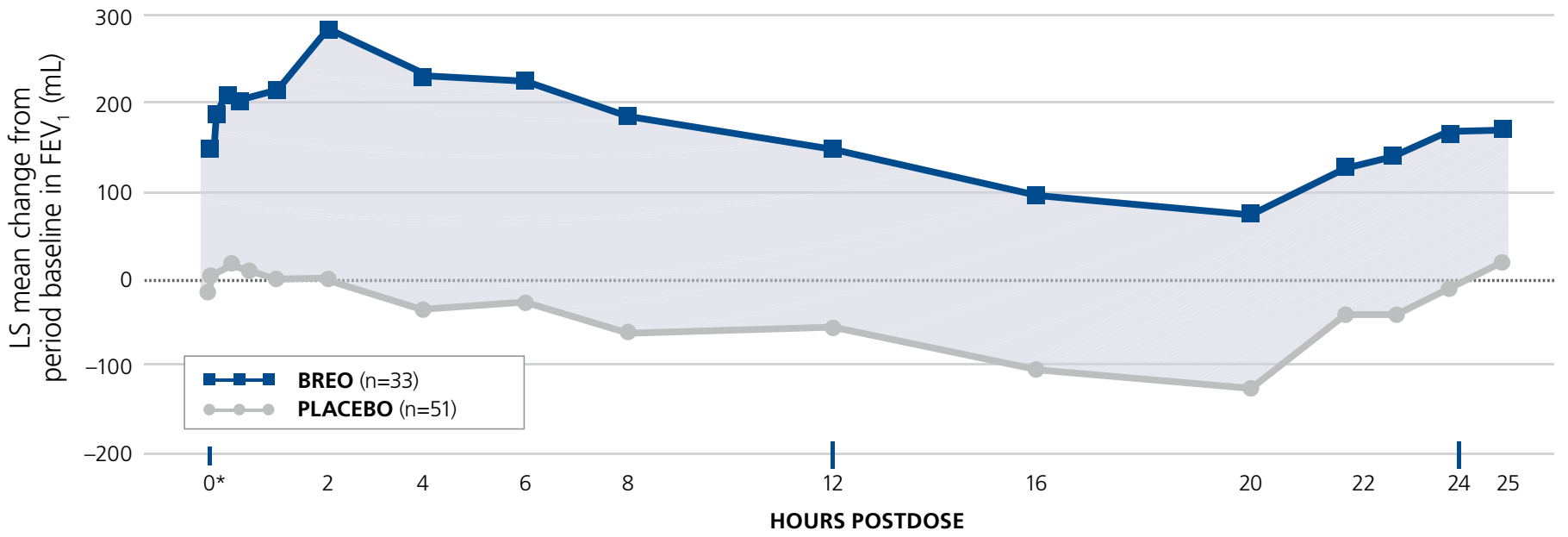
gsk | Theravance

BREO® ELLIPTA®
(fluticasone furoate 100 mcg and vilanterol 25 mcg inhalation powder)

24-hour BREO 100/25 provided sustained improvement in lung function

Primary endpoint: BREO 100/25 provided a 220 mL improvement in weighted mean FEV_1 (0-24 hours) from period baseline vs placebo (P<0.001) at end of the 28-day treatment period[1]

SECONDARY ENDPOINT: SERIAL FEV_1 (0-25 HOURS) ASSESSED OVER 1 FULL DAY AT DAYS 28 AND 29[1,2]



*Zero=dose administration time (between 6 AM and 10 AM).
FEV_1=forced expiratory volume in 1 second; LS=least squares.

A multicenter, randomized, double-blind, placebo-controlled, crossover study evaluated the effect of 28 days of treatment with BREO 100/25 on lung function over 24 hours in 54 patients (mean age: 57.9 years) with COPD.† The primary endpoint was weighted mean FEV_1 (0-24 hours) at the end of the 28-day treatment period (period Days 28 and 29). This was calculated from predose FEV_1 (mean of –30- and –5-minute measurements) and postdose FEV_1 after 5, 15, 30, and 60 minutes and 2, 4, 6, 8, 12, 16, 20, 22, 23, and 24 hours. The secondary endpoint was serial FEV_1 (0-25 hours) at period Days 28 and 29.

†At screening, patients had a mean postbronchodilator % predicted FEV_1 of 49.8%, a mean postbronchodilator FEV_1 /forced vital capacity (FVC) ratio of 52.9%, and a mean % reversibility of 8.8%.

In a separate 6-month lung-function study: a multicenter, randomized, double-blind, parallel-group study compared the effect of BREO 100/25 vs fluticasone furoate (FF) 100 mcg and vs placebo (each administered once daily by the ELLIPTA inhaler) on lung function in 1030 patients (mean age: 62.7 years) with COPD.‡ For the co-primary endpoints, BREO significantly improved weighted mean FEV_1 (0-4 hours) postdose on Day 168 by 120 mL vs FF§ and 173 mL vs placebo (P<0.001 for both); and BREO demonstrated a greater difference in LS mean change from baseline in trough FEV_1 at Day 169 of 115 mL vs placebo (95% confidence interval [CI]: 60, 169; P<0.001); the 48 mL difference vs vilanterol (VI) 25 mcg‖ did not achieve statistical significance (95% CI: –6, 102; P=0.082).[2,3]

‡At screening, patients had a mean postbronchodilator % predicted FEV_1 of 48.3%, a mean postbronchodilator FEV_1/FVC ratio of 47.6%, and a mean % reversibility of 15.9%.
§The weighted mean comparison of BREO with FF, the ICS component, was assessed to evaluate the contribution of VI to BREO. ICSs are not approved as monotherapy for COPD.
‖The trough FEV_1 comparison of BREO with VI, the LABA component, was assessed to evaluate the contribution of FF to BREO. Vilanterol is not approved as monotherapy.

Important Safety Information for BREO 100/25 for COPD (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- BREO should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications 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 BREO should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.
- Oropharyngeal candidiasis has occurred in patients treated with BREO. Advise patients to rinse the mouth with water without swallowing following inhalation to help reduce the risk of oropharyngeal candidiasis.
- An increase in the incidence of pneumonia has been observed in subjects with COPD receiving BREO. There was also an increased incidence of pneumonias resulting in hospitalization. In some incidences these pneumonia events were fatal.
  – In replicate 12-month studies of 3255 subjects with COPD who had experienced a COPD exacerbation in the previous year, there was a higher incidence of pneumonia reported in subjects receiving BREO 100/25 (6% [51 of 806 subjects]), fluticasone furoate (FF)/vilanterol (VI) 50/25 mcg (6% [48 of 820 subjects]), and BREO 200/25 (7% [55 of 811 subjects]) than in subjects receiving VI 25 mcg (3% [27 of 818 subjects]). There was no fatal pneumonia in subjects receiving VI or FF/VI 50/25 mcg. There was fatal pneumonia in 1 subject receiving BREO 100/25 and in 7 subjects receiving BREO 200/25 (<1% for each treatment group).
- Physicians should remain vigilant for the possible development of pneumonia in patients with COPD, as the clinical features of such infections overlap with the symptoms of COPD exacerbations.
- Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients. Use caution in patients with the above because of the potential for worsening of these infections.

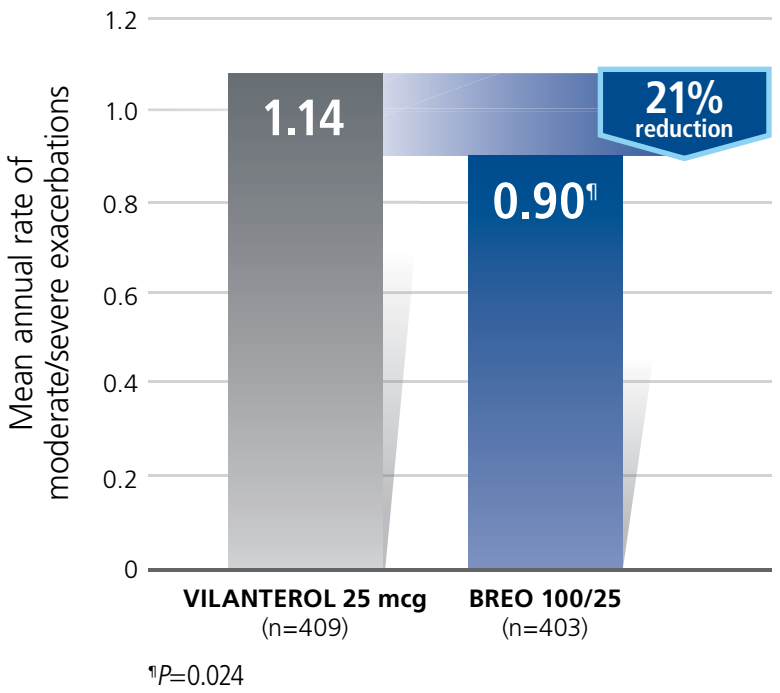
WARNINGS AND PRECAUTIONS (cont'd)

- Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to BREO.
- Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of inhaled corticosteroids in susceptible individuals. If such changes occur, discontinue BREO slowly.
- Caution should be exercised when considering the coadministration of BREO with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and cardiovascular adverse effects may occur.
- If paradoxical bronchospasm occurs, discontinue BREO and institute alternative therapy.
- Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of BREO. Discontinue BREO if such reactions occur.
- Vilanterol can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles. If such effects occur, BREO may need to be discontinued. BREO should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

In patients with a history of exacerbations

BREO 100/25 significantly reduced the annual rate of moderate/severe COPD exacerbations

PRIMARY ENDPOINT: ANNUAL RATE OF MODERATE/SEVERE EXACERBATIONS[2,4]



¶*P*=0.024

Study description

Design: 12-month, multicenter, randomized, double-blind, parallel-group study that evaluated the effect of BREO 100/25, BREO 200/25,# FF/VI 50/25, and VI 25 mcg** (each administered once daily by the ELLIPTA inhaler) on the rate of moderate/severe exacerbations. Patients were randomized to treatment following a 4-week run-in on fluticasone propionate 250 mcg/salmeterol 50 mcg twice daily.

Patients: 1633 patients (mean age: 63.7 years) with COPD and a history of one or more moderate or severe exacerbations in the previous year. At screening, patients had a mean postbronchodilator percent predicted FEV_1 of 45.7% and a mean postbronchodilator FEV_1/FVC ratio of 45.5%.

COPD exacerbation criteria: exacerbations were defined as worsening of 2 or more major symptoms (dyspnea, sputum volume, and sputum purulence) or 1 major symptom together with 1 minor symptom: sore throat, colds (nasal discharge and/or nasal congestion), fever without other cause, and increased cough or wheeze for at least 2 consecutive days.

Exacerbation severity criteria: exacerbations were considered to be of moderate severity if treatment with systemic corticosteroids and/or antibiotics was required, and were considered to be severe if hospitalization was required.

#BREO 100/25 is the only strength approved for COPD.

**Vilanterol is the LABA component of BREO and is not approved as monotherapy.

Important Safety Information for BREO 100/25 for COPD (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care. Since patients with COPD often have multiple risk factors for reduced BMD, assessment of BMD is recommended prior to initiating BREO and periodically thereafter.
- Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with COPD or asthma following the long-term administration of inhaled corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.
- Be alert to hypokalemia and hyperglycemia.

ADVERSE REACTIONS

- In subjects with COPD, the most common adverse reactions (≥3% and more common than placebo) reported in two 6-month clinical trials with BREO 100/25 (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%).
- In addition to the events reported in the 6-month studies, adverse reactions occurring in ≥3% of the subjects treated with BREO 100/25 in two 1-year COPD studies included back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, influenza, pharyngitis, and pyrexia.

DRUG INTERACTIONS

- Caution should be exercised when considering the coadministration of BREO with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and cardiovascular adverse effects may occur.
- BREO 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.
- 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 or asthma.
- 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.

USE IN SPECIFIC POPULATIONS

- Use BREO with caution in patients with moderate or severe hepatic impairment. Fluticasone furoate systemic exposure increased by up to 3-fold in subjects with hepatic impairment. Monitor for corticosteroid-related side effects.

References: 1. Boscia JA, Pudi KK, Zvarich MT, Sanford L, Siederer SK, Crim C. Effect of once-daily fluticasone furoate/vilanterol on 24-hour pulmonary function in patients with chronic obstructive pulmonary disease: a randomized, three-way, incomplete block, crossover study. *Clin Ther.* 2012;34(8):1655-1666. **2.** Data on file, GSK. **3.** Kerwin EM, Scott-Wilson C, Sanford L, et al. A randomised trial of fluticasone furoate/vilanterol (50/25 µg; 100/25 µg) on lung function in COPD. *Respir Med.* 2013;107(4):560-569. **4.** Dransfield MT, Bourbeau J, Jones PW, et al. Once-daily inhaled fluticasone furoate and vilanterol versus vilanterol only for prevention of exacerbations of COPD: two replicate double-blind, parallel-group, randomised controlled trials. *Lancet Respir Med.* 2013;1(3):210-223.

Please see additional Important Safety Information for BREO 100/25 throughout this advertisement.

Please see Brief Summary of Prescribing Information, including Boxed Warning, for BREO 100/25 on the pages following this advertisement.

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BREO ELLIPTA was developed in collaboration with Theravance

BREO® ELLIPTA®
(fluticasone furoate 100 mcg and vilanterol 25 mcg inhalation powder)

BRIEF SUMMARY

BREO® ELLIPTA® 100/25 (fluticasone furoate 100 mcg and vilanterol 25 mcg inhalation powder), for oral inhalation

The following is a brief summary only and is focused on the COPD indication. See full prescribing information for complete product information.

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in BREO, increase the risk of asthma-related death. Data from a large placebo-controlled US trial that compared the safety of another LABA (salmeterol) with placebo added to usual asthma therapy showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of LABA. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids (ICS) or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. *[see Warnings and Precautions (5.1) of full prescribing information]*.

1 INDICATIONS AND USAGE

1.1 Maintenance Treatment of Chronic Obstructive Pulmonary Disease BREO 100/25 is a combination inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist (ICS/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. BREO 100/25 is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. BREO 100/25 once daily is the only strength indicated for the treatment of COPD.

Important Limitation of Use

BREO is NOT indicated for the relief of acute bronchospasm

4 CONTRAINDICATIONS

The use of BREO is contraindicated in the following conditions:

- Primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required *[see Warnings and Precautions (5.2)]*.
- Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, vilanterol, or any of the excipients *[see Warnings and Precautions (5.11), Description (11)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Asthma-Related Death

LABA, such as vilanterol, one of the active ingredients in BREO, increase the risk of asthma-related death. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Data are not available to determine whether the rate of death in patients with COPD is increased by LABA.

5.2 Deterioration of Disease and Acute Episodes BREO should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD or asthma. BREO has not been studied in subjects with acutely deteriorating COPD or asthma. The initiation of BREO in this setting is not appropriate.

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If BREO 100/25 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 reevaluation of the patient and the COPD treatment regimen should be undertaken at once. For COPD, increasing the daily dose of BREO 100/25 is not appropriate in this situation.

BREO should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. BREO 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 BREO, 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 BREO, the healthcare provider should also prescribe an inhaled, short-acting beta$_2$-agonist and instruct the patient on how it should be used.

5.3 Excessive Use of BREO and Use with Other Long-Acting Beta$_2$-Agonists BREO 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 BREO should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

5.4 Local Effects of Inhaled Corticosteroids In clinical trials, the development of localized infections of the mouth and pharynx with *Candida albicans* has occurred in subjects treated with BREO. When such an infection develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while treatment with BREO continues, but at times therapy with BREO may need to be interrupted. Advise the patient to rinse his/her mouth with water without swallowing following inhalation to help reduce the risk of oropharyngeal candidiasis.

5.5 Pneumonia An increase in the incidence of pneumonia has been observed in subjects with COPD receiving BREO 100/25 in clinical trials. There was also an increased incidence of pneumonias resulting in hospitalization. In some incidences these pneumonia events were fatal. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations.

In replicate 12-month trials in 3,255 subjects with COPD who had experienced a COPD exacerbation in the previous year, there was a higher incidence of pneumonia reported in subjects receiving fluticasone furoate/vilanterol 50 mcg/25 mcg: 6% (48 of 820 subjects); BREO 100/25: 6% (51 of 806 subjects); or BREO 200/25: 7% (55 of 811 subjects) than in subjects receiving vilanterol 25 mcg: 3% (27 of 818 subjects). There was no fatal pneumonia in subjects receiving vilanterol or fluticasone furoate/vilanterol 50 mcg/25 mcg. There was fatal pneumonia in 1 subject receiving BREO 100/25 and in 7 subjects receiving BREO 200/25 (less than 1% for each treatment group).

5.6 Immunosuppression Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible children or adults using corticosteroids. In such children or adults who have not had these diseases or been properly immunized, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If a patient is exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If a patient is exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract; systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

5.7 Transferring Patients from Systemic Corticosteroid Therapy Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function.

Patients who have been previously maintained on 20 mg or more of prednisone (or its equivalent) may be most susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infection (particularly gastroenteritis) or other conditions associated with severe electrolyte loss. Although BREO may control COPD or asthma symptoms during these episodes, in recommended doses it supplies less than normal physiological amounts of glucocorticoid systemically and does NOT provide the mineralocorticoid activity that is necessary for coping with these emergencies.

During periods of stress, a severe COPD exacerbation, or a severe asthma attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their physicians for further instruction. These patients should also be instructed to carry a warning card indicating that they may need supplementary systemic corticosteroids during periods of stress, a severe COPD exacerbation, or a severe asthma attack.

Patients requiring oral corticosteroids should be weaned slowly from systemic corticosteroid use after transferring to BREO. Prednisone reduction can be accomplished by reducing the daily prednisone dose by 2.5 mg on a weekly basis during therapy with BREO. Lung function (FEV_1 or peak expiratory flow), beta-agonist use, and COPD or asthma symptoms should be carefully monitored during withdrawal of oral corticosteroids. In addition, patients should be observed for signs and symptoms of adrenal insufficiency, such as fatigue, lassitude, weakness, nausea and vomiting, and hypotension.

Transfer of patients from systemic corticosteroid therapy to BREO may unmask allergic conditions previously suppressed by the systemic corticosteroid therapy (e.g., rhinitis, conjunctivitis, eczema, arthritis, eosinophilic conditions).

During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal (e.g., joint and/or muscular pain, lassitude, depression) despite maintenance or even improvement of respiratory function.

5.8 Hypercorticism and Adrenal Suppression Inhaled fluticasone furoate is absorbed into the circulation and can be systemically active. Effects of fluticasone furoate on the HPA axis are not observed with the therapeutic doses of BREO. However, exceeding the recommended dosage or coadministration with a strong cytochrome P450 3A4 (CYP3A4) inhibitor may result in HPA dysfunction *[see Warnings and Precautions (5.9), Drug Interactions (7.1)]*.

Because of the possibility of significant systemic absorption of inhaled corticosteroids in sensitive patients, patients treated with BREO should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response.

It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) may appear in a small number of patients who are sensitive to these effects. If such effects occur, BREO should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids, and other treatments for management of COPD or asthma symptoms should be considered.

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

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

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

5.12 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, and also cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles. If such effects occur, BREO may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiographic changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

In healthy subjects, large doses of inhaled fluticasone furoate/vilanterol (4 times the recommended dose of vilanterol, representing a 12- or 10-fold higher systemic exposure than seen in subjects with COPD or asthma, respectively) have been associated with clinically significant prolongation of the QTc interval, which has the potential for producing ventricular arrhythmias. Therefore, BREO, like other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

5.13 Reduction in Bone Mineral Density Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids. The clinical significance of small changes in BMD with regard to long-term consequences such as fracture is unknown. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care. Since patients with COPD often have multiple risk factors for reduced BMD, assessment of BMD is recommended prior to initiating BREO and periodically thereafter. If significant reductions in BMD are seen and BREO is still considered medically important for that patient's COPD therapy, use of medicine to treat or prevent osteoporosis should be strongly considered.

5.14 Glaucoma and Cataracts Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with COPD or asthma following the long-term administration of inhaled corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

5.15 Coexisting Conditions BREO, 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.

5.16 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 medications may produce transient hyperglycemia in some patients. In clinical trials evaluating BREO in subjects with COPD or asthma, 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 BREO, increase the risk of asthma-related death. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA *[See Warnings and Precautions (5.1) of full prescribing information.]*

Systemic and local corticosteroid use may result in the following:

- *Candida albicans* infection *[see Warnings and Precautions (5.4)]*
- Increased risk of pneumonia in COPD *[see Warnings and Precautions (5.5)]*
- Immunosuppression *[see Warnings and Precautions (5.6)]*
- Hypercorticism and adrenal suppression *[see Warnings and Precautions (5.8)]*
- Reduction in bone mineral density *[see Warnings and Precautions (5.13)]*

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

6.1 Clinical Trials Experience in Chronic Obstructive Pulmonary Disease The clinical program for BREO included 7,700 subjects with COPD in two 6-month lung function trials, two 12-month exacerbation trials, and 6 other trials of shorter duration. A total of 2,034 subjects with COPD received at least 1 dose of BREO 100/25, and 1,087 subjects received a higher strength of fluticasone furoate/vilanterol. The safety data described below are based on the confirmatory 6- and 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 BREO 100/25 in Table 1 is based on 2 placebo-controlled, 6-month clinical trials (Trials 1 and 2; n = 1,224 and n = 1,030, respectively). Of the 2,254 subjects, 70% were male and 84% were white. They had a mean age of 62 years and an average smoking history of 44 pack-years, with 54% identified as current smokers. At screening, the mean postbronchodilator percent predicted FEV_1 was 48% (range: 14% to 87%), the mean postbronchodilator FEV_1/forced vital capacity (FVC) ratio was 47% (range: 17% to 88%), and the mean percent reversibility was 14% (range: -41% to 152%).

Subjects received 1 inhalation once daily of the following: BREO 100/25, BREO 200/25, fluticasone furoate/vilanterol 50 mcg/25 mcg, fluticasone furoate 100 mcg, fluticasone furoate 200 mcg, vilanterol 25 mcg, or placebo.

Table 1. Adverse Reactions with BREO 100/25 with ≥3% Incidence and More Common than Placebo in Subjects with Chronic Obstructive Pulmonary Disease

Adverse Reaction	BREO 100/25 (n = 410) %	Vilanterol 25 mcg (n = 408) %	Fluticasone Furoate 100 mcg (n = 410) %	Placebo (n = 412) %
Infections and infestations				
Nasopharyngitis	9	10	8	8
Upper respiratory tract infection	7	5	4	3
Oropharyngeal candidiasis[a]	5	2	3	2
Nervous system disorders				
Headache	7	9	7	5

[a]Includes oral candidiasis, oropharyngeal candidiasis, candidiasis, and fungal oropharyngitis.

12-Month Trials

Long-term safety data is based on two 12-month trials (Trials 3 and 4; n = 1,633 and n = 1,622, respectively). Trials 3 and 4 included 3,255 subjects, of which 57% were male and 85% were white. They had a mean age of 64 years and an average smoking history of 46 pack-years, with 44% identified as current smokers. At screening, the mean postbronchodilator percent predicted FEV_1 was 45% (range: 12% to 91%), and the mean postbronchodilator FEV_1/FVC ratio was 46% (range: 17% to 81%), indicating that the subject population had moderate to very severely impaired airflow obstruction. Subjects received 1 inhalation once daily of the following: BREO 100/25, BREO 200/25, fluticasone furoate/vilanterol 50 mcg/25 mcg, or vilanterol 25 mcg. In addition to the reactions shown in Table 1, adverse reactions occurring in greater than or equal to 3% of the subjects treated with BREO 100/25 (n = 806) for 12 months included back pain, pneumonia *[see Warnings and Precautions (5.5)]*, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, influenza, pharyngitis, and pyrexia.

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

Cardiac Disorders Palpitations, tachycardia.

Immune System Disorders Hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria.

Musculoskeletal and Connective Tissue Disorders Muscle spasms.

Nervous System Disorders Tremor.

Psychiatric Disorders Nervousness.

7 DRUG INTERACTIONS

7.1 Inhibitors of Cytochrome P450 3A4 Fluticasone furoate and vilanterol, the individual components of BREO, are both substrates of CYP3A4. Concomitant administration of the strong CYP3A4 inhibitor ketoconazole increases the systemic exposure to fluticasone furoate and vilanterol. Caution should be exercised when considering the coadministration of BREO with long-term 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 (5.9), 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 BREO, but may also produce severe bronchospasm in patients with COPD or asthma. Therefore, patients with COPD or asthma 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, 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 beta-agonists with non–potassium-sparing diuretics.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects

Pregnancy Category C. There are no adequate and well-controlled trials with BREO in pregnant women. Corticosteroids and $beta_2$-agonists have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Because animal reproduction studies are not always predictive of human response, BREO 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 BREO.

Fluticasone Furoate and Vilanterol: There was no evidence of teratogenic interactions between fluticasone furoate and vilanterol in rats at approximately 5 and 40 times, respectively, the maximum recommended human daily inhalation dose (MRHDID) in adults (on a mcg/m^2 basis at maternal inhaled doses of fluticasone furoate and vilanterol, alone or in combination, up to approximately 95 mcg/kg/day).

Fluticasone Furoate: There were no teratogenic effects in rats and rabbits at approximately 4 and 1 times, respectively, the MRHDID in adults (on a mcg/m^2 basis at maternal inhaled doses up to 91 and 8 mcg/kg/day in rats and rabbits, respectively). There were no effects on perinatal and postnatal development in rats at approximately 1 time the MRHDID in adults (on a mcg/m^2 basis at maternal doses up to 27 mcg/kg/day).

Vilanterol: There were no teratogenic effects in rats and rabbits at approximately 13,000 and 160 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 1,000 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. There were no effects on perinatal and postnatal development 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).

Nonteratogenic Effects

Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy. Such infants should be carefully monitored.

8.2 Labor and Delivery There are no adequate and well-controlled human trials that have investigated the effects of BREO during labor and delivery.

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

8.3 Nursing Mothers It is not known whether fluticasone furoate or vilanterol are excreted in human breast milk. However, other corticosteroids and $beta_2$-agonists have been detected in human milk. Since there are no data from controlled trials on the use of BREO by nursing mothers, caution should be exercised when it is administered to a nursing woman.

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

Clinical trials of BREO for COPD included 2,508 subjects aged 65 and older and 564 subjects 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 Fluticasone furoate systemic exposure increased by up to 3-fold in subjects with hepatic impairment compared with healthy subjects. Hepatic impairment had no effect on vilanterol systemic exposure. Use BREO with caution in patients with moderate or severe hepatic impairment. Monitor patients for corticosteroid-related side effects *[see Clinical Pharmacology (12.3) of full prescribing information]*.

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

10 OVERDOSAGE

No human overdosage data has been reported for BREO.

BREO contains both fluticasone furoate and vilanterol; therefore, the risks associated with overdosage for the individual components described below apply to BREO. Treatment of overdosage consists of discontinuation of BREO 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 Fluticasone Furoate Because of low systemic bioavailability (15.2%) and an absence of acute drug-related systemic findings in clinical trials, overdosage of fluticasone furoate is unlikely to require any treatment other than observation. If used at excessive doses for prolonged periods, systemic effects such as hypercorticism may occur *[see Warnings and Precautions (5.8)]*.

Single- and repeat-dose trials of fluticasone furoate at doses of 50 to 4,000 mcg have been studied in human subjects. Decreases in mean serum cortisol were observed at dosages of 500 mcg or higher given once daily for 14 days.

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., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, 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.

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 with asthma that LABA, such as vilanterol, one of the active ingredients in BREO, increase the risk of asthma-related death.

Not for Acute Symptoms

Inform patients that BREO is not meant to relieve acute symptoms of COPD or asthma and extra doses should not be used for that purpose. Advise patients to treat acute symptoms with an inhaled, short-acting $beta_2$-agonist such as albuterol. Provide patients with such medication and instruct them in how it should be used.

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

- Decreasing effectiveness of inhaled, short-acting $beta_2$-agonists
- Need for more inhalations than usual of inhaled, short-acting $beta_2$-agonists
- Significant decrease in lung function as outlined by the physician

Tell patients they should not stop therapy with BREO without physician/provider guidance since symptoms may recur after discontinuation.

Do Not Use Additional Long-Acting $Beta_2$-Agonists

Instruct patients not to use other LABA for COPD and asthma.

Local Effects

Inform patients that localized infections with *Candida albicans* occurred in the mouth and pharynx in some patients. If oropharyngeal candidiasis develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while still continuing therapy with BREO, but at times therapy with BREO may need to be temporarily interrupted under close medical supervision. Advise patients to rinse the mouth with water without swallowing after inhalation to help reduce the risk of thrush.

Pneumonia

Patients with COPD have a higher risk of pneumonia; instruct them to contact their healthcare providers if they develop symptoms of pneumonia.

Immunosuppression

Warn patients who are on immunosuppressant doses of corticosteroids to avoid exposure to chickenpox or measles and, if exposed, to consult their physicians without delay. Inform patients of potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

Hypercorticism and Adrenal Suppression

Advise patients that BREO may cause systemic corticosteroid effects of hypercorticism and adrenal suppression. Additionally, inform patients that deaths due to adrenal insufficiency have occurred during and after transfer from systemic corticosteroids. Patients should taper slowly from systemic corticosteroids if transferring to BREO.

Reduction in Bone Mineral Density

Advise patients who are at an increased risk for decreased BMD that the use of corticosteroids may pose an additional risk.

Ocular Effects

Inform patients that long-term use of inhaled corticosteroids may increase the risk of some eye problems (cataracts or glaucoma); consider regular eye examinations.

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.

Hypersensitivity Reactions, Including Anaphylaxis

Advise patients that hypersensitivity reactions (e.g., anaphylaxis, angioedema, rash, urticaria) may occur after administration of BREO. Instruct patients to discontinue BREO if such reactions occur. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder medications containing lactose; therefore, patients with severe milk protein allergy should not use BREO.

BREO ELLIPTA was developed in collaboration with Theravance.

GlaxoSmithKline
Research Triangle Park, NC 27709

Revised 09/2015 BRE:6BRS

Programs Bolster Early Career Professionals

The ATS Fellows Track Symposium, Resident Boot Camp, and Student Scholars Program have become so popular with early career professionals that attendance has increased each year.

ATS President Atul Malhotra, MD, says the Society endeavors to attract the best and brightest to pulmonary, critical care, and sleep medicine.

"People define their careers early on. In 1990, when I walked into an intensive care unit for the first time, it felt like home," Dr. Malhotra says. "There was an excitement and passion that never went away. My hope is that people who come to the International Conference see how exciting it is. Then in 10, 15, 20 years, we'll have new leaders emerging from these programs."

Friday and Saturday's Resident Boot Camp with 120 faculty members drew 152 residents. Boot Camp Chair Brendan Clark, MD, University of Colorado, Denver, has been involved throughout the program's three years.

"The lectures allow us to attract leaders in pulmonary and critical care medicine," Dr. Clark says. "The breakout sessions are important because they provide an opportunity for faculty and fellows to sit down with each other and ask questions they might feel apprehensive about asking at their home institutions. The hands-on portion is the highlight, and it combines clinical context and procedures."

Barb Chini, MD, Cincinnati Children's Hospital, Ohio, pediatric course chair, noted that the ATS doubled the capacity for the pediatric track to 24 due to interest.

"We're grateful to the ATS for supporting this project. It has been fantastic, the residents are excited, and this is why we went into academic medicine," Dr. Chini says.

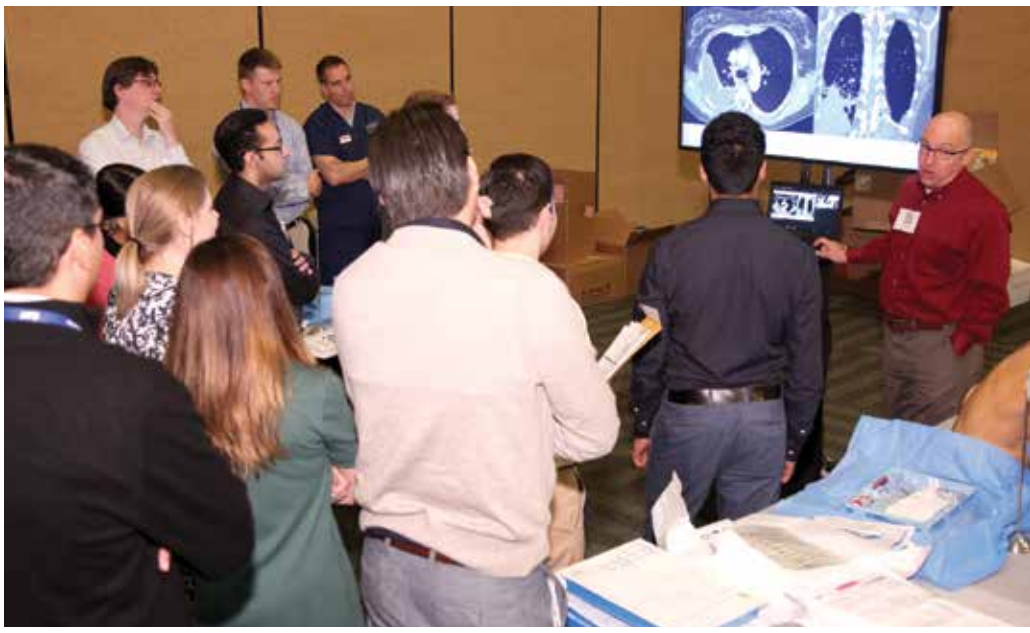
Shalini Dixit, a fourth-year medical student at the University of California, San Francisco, was among the 67 students attending the Students Scholars Program, which gave her an opportunity to take part in the Boot Camp and FTS.

"As someone who is going to be a resident, I think it will be helpful to have some of these experiences," Ms. Dixit says.

This year, 225 fellows took part in the FTS, which attracted attendees from around the world, says FTS Course Director Deborah Shure, MD, of Miami, Florida.

Beyond the geographic reach of the FTS, Sleep Pillar Co-Chair Barbara Phillips, MD, University of Kentucky, Lexington, says she appreciated how fellows and residents mingled on Friday and Saturday, and that the sleep specialty was gaining greater attention.

"The ATS has walked the walk that we are about pulmonary, critical care, and sleep medicine. I am seeing that pulmonary fellows understand that sleep will be part of their practices," Dr. Phillips says.



Residents practice hands-on skills at the Resident Boot Camp, attracting 152 incoming pulmonary and critical care fellows.

The FTS is supported by educational grants from Actelion Pharmaceuticals US, Inc., AstraZeneca LP, Boehringer Ingelheim Pharmaceuticals, Inc., Genentech, GlaxoSmithKline, and Sunovion Pharmaceuticals, Inc. The FTS also received in-kind support from FUJIFILM Sonosite, Inc.

The Resident Boot Camp is supported by educational grants from Olympus Corporation of the Americas. The Resident Boot Camp also received in-kind support from Ambu, BD, ERBE USA, Inc., FUJIFILM Sonosite, Inc., Getinge Group, Hill-Rom, nSpire Health, Inc., Medtronics, Micro Direct, Inc., Monaghan Medical Corporation, Olympus Corporation of the Americas, Philips Respironics, Smiths Medical, Teleflex, and Verathon.

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)

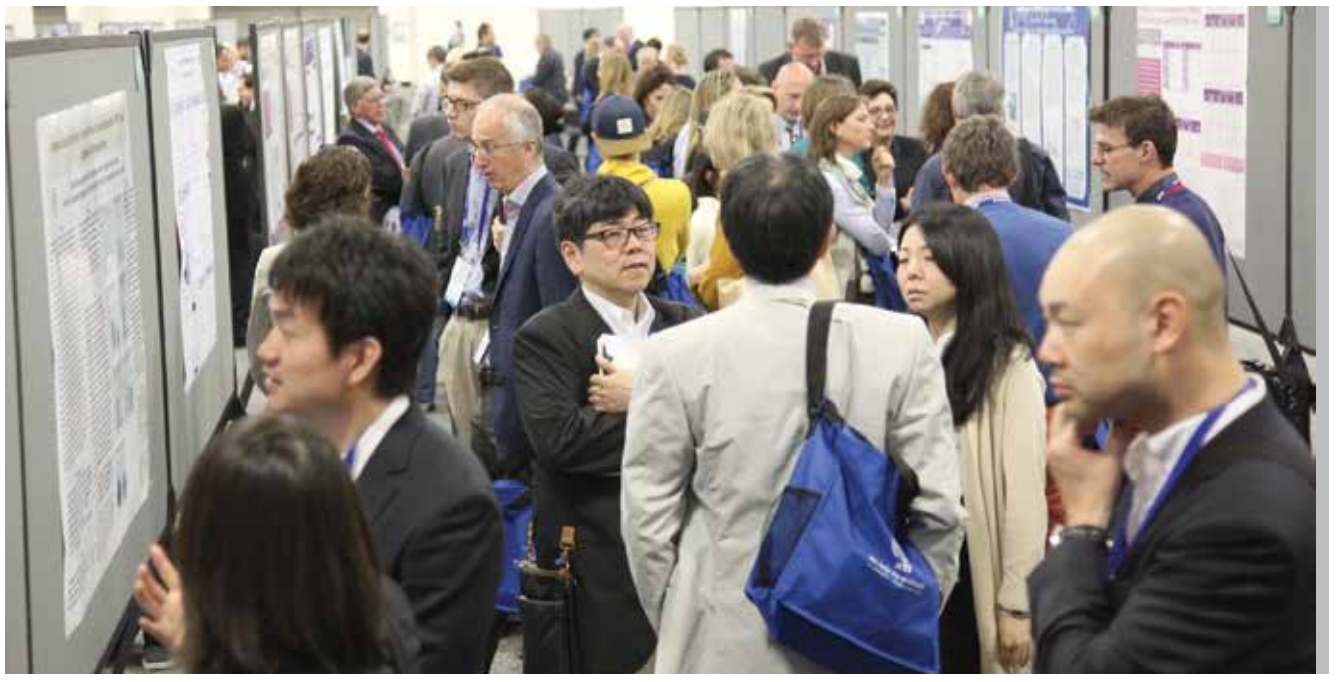
Manufactured for:
Mallinckrodt ARD, Inc.

Hazelwood, MO 63042 USA

Rev 01/2015

Mallinckrodt Pharmaceuticals™

ATS 2016 in Action



Visit the ATS Center

Erica Beatman, MS, (left) and Lydia Kim, MD, visit the ATS Center, where they interact with a large touchscreen digital word map, which illustrates the ATS's presence and activities around the globe. In response to feedback from members, the ATS Center has been transformed so you can easily explore all that the Society has to offer. This year's ATS Center theme is "ATS: Providing a World of Opportunity to Improve Global Lung Health." Obtain patient education materials, learn about ATS educational programming, peruse the three ATS journals, pick up copies of the handy, new guidelines pocket cards, learn about the value of ATS membership, and pick up information on the ATS Foundation Research Program.

Practice Essentials for Non-IPF ILD

Non-IPF ILD: How Do I Make the Diagnosis?
9 to 11 a.m. today
Moscone Center, Room 134 (North Building, Lower Level)

The broad category of interstitial lung disease (ILD) comprises idiopathic and non-idiopathic pulmonary fibrosis (IPF), with the latter making up most of the cases. Yet, determining which form of non-IPF a patient has is challenging for physicians because there are more than 200 non-IPF ILDs.

"Non-IPF varies a great deal by risk factors, presentation, CT appearance, pathology findings, prognosis, and therapy. It is therefore both very important and very difficult to keep them straight," says Maryl Kreider, MD, associate professor of clinical medicine, director of the ILD program at the Harron Lung Center, associate chief for education, and fellowship director of the Division of Pulmonary and Critical Care Medicine at the University of Pennsylvania's Perelman School of Medicine, Philadelphia.

Monday's "Non-IPF ILD: How Do I Make the Diagnosis?" will review the evidence clinicians can use to differentiate non-IPF ILDs. Dr. Kreider will co-chair the symposium, which will take place from 9 to 11 a.m. in the Moscone Center, Room 134 (North Building, Lower Level).

Presenters will share clinical features from a patient's history, radiographic features from a patient's highly conformal radiotherapy, and pathologic features from a patient's biopsy to illustrate best practices. For each, they will highlight the five most important features they rely upon when distinguishing non-IPF ILDs.

"For instance, they could describe a particular symptom, distribution of disease on CT, or types of inflammatory cells they have seen — whatever they think is most important for telling them apart," Dr. Kreider says.

After a review of these characteristics, three ILD clinicians will discuss real-life cases, which were provided to them without a diagnosis, to demonstrate how to best work through challenging cases.

"Our hope with this session is to provide some of the highest yield features so we can help clinicians apply these findings to their own patients and feel more comfortable when faced with a rather overwhelming task," Dr. Kreider says.

"Non-IPF ILD: How Do I Make the Diagnosis" (B3) is supported by educational grants from Boehringer Ingelheim Pharmaceuticals, Inc., and Genentech.

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
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Cystic Fibrosis

Application Deadline: Friday, July 22, 2016

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Pulmonary Arterial Hypertension

Application Deadline: Friday, August 5, 2016

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