Tuesday, May 17, 2016

San Francisco, California
May 13 - May 18, 2016

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ATS 2016 Draws Big Crowds

Early attendance numbers show ATS 2016 in San Francisco, California, is a popular destination. As of Monday afternoon, there were more than 17,000 registered attendees from 90 countries. Nearly 7,000 scientific abstracts, case reports, and late-breaking abstracts were presented this year. Please join us for ATS 2017, May 19-24, in Washington, D.C. The ATS is seeking input for sessions in all areas of respiratory, critical care, and sleep medicine with a clinical, basic science, and/or translational focus. All proposals must be submitted online by 5 p.m. EDT June 29, 2016. Visit conference.thoracic.org to learn more.

Ebola Fighter Catalyst for Change

Katie Meyler will share the story of her compelling work as one of the “Ebola Fighters,” collectively recognized by TIME magazine as the 2014 Person of the Year, during the Plenary Session on Tuesday. At the onset of the largest Ebola epidemic in history, Ms. Meyler was spurred to turn her school for girls in Liberia into a disaster-response center.

In 2009, Ms. Meyler founded the More Than Me Academy, a tuition-free girls school located in a Liberian slum. She helped girls get off the streets and into school by providing scholarships, free meals and supplies, and an after-school program. The More Than Me Academy opened its doors in 2013. A year later, when Ebola broke out, airlines canceled flights and the U.S. Peace Corps left Liberia. Ms. Meyler was fundraising in the United States, but she returned to Liberia. With the help of a donor, she transformed the school into a disaster-response center. Her team took in Ebola orphans, organized meetings, distributed food, provided home health care, and ran an ambulance service transporting the sick for medical treatment. According to More Than Me, its ambulance service reduced response times from the local service’s four days to 30 minutes, which likely

More Than Me Academy founder, Katie Meyler, started a school and ended up fighting Ebola. Hear her story during Tuesday’s Plenary Session.

Accuracy.

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

Booth #1004

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Gilead is committed
to expanding healthcare options for individuals living with cardiovascular and respiratory diseases through innovative research, access, and education programs.
Q&A: 2016-17 President-Elect David Gozal, MD

Q: What are your top priorities as President this year?
A: My priorities are twofold. Support for travel and attendance at the International Conference is on the decline. In response, we’re exploring alternative conference models that will better serve neighboring North American countries. This brings ATS engagement to our neighbors’ own backyards and should help to diversify revenue.

Implementing new clinical guidelines can be time-consuming and overwhelming. So, we’re working to provide better support to assemblies in creating and updating official statements and position papers. A few ideas to smooth this transition include better resources, such as technology or dedicated staff. Essentially, we would expand the scope of producing guidelines and equip operational facilitators with tools to help them better perform their jobs. If we help strengthen these roles in managing institutional-wide implementation, quality improves across the board.

To achieve these goals, teamwork and shared values are integral to our work as members of the ATS Executive Committee, Board of Directors, and staff. Open communication is needed to receive the most insightful feedback on issues. Ongoing dialogue and close collaboration keep parties informed throughout a project, and it is the not work of one but the work of many that leads to a plants development and success. Moving forward, we have decided to relinquish annual presidential initiatives beginning in 2016. The change should effectively permit the ATS’s long-term strategy and enhance sustainability between leadership successions.

Q: How can the Society work to enhance patient-focused care?
A: In the last two decades, the ATS has diligently worked to put patients in the forefront. At the International Conference, this is evident through the patients involved with the Public Advisory Roundtable, from patients who participate to those who present in our Meet-the-Experts Forum. The PAR is vital to public dialogue on health care, and the program gives a voice to the patient through greater patient-provider engagement.

The ATS Patient Information Series covers a wide range of conditions on the website and in ATS Journals. These are an outstanding means of disseminating resources to the public and sister service groups.

Q: How can the ATS provide more academic capital to its members?
A: The majority of our constituency is clinicians, often with dual role appointments in higher education. Academic currency is essential for career development, and the ATS is a conduit. We welcome abstract submissions, presentations, committee participation, and journal involvement from early career professionals. Also encouraged is participation at the international level, through programs such as the Methods in Epidemiological, Clinical, and Operations Research (MECOR) program, Global Scholars, and International Poster Sessions showcasing the work of young investigators.

The next generation has a major stake in the future of the ATS. Those interested in getting involved will be acknowledged, and with greater involvement comes greater ownership. I look forward to joining forces with our partners and working together to address the challenges of early career professionals. Recruiting the next generation of trainees into the specialty remains one of the field’s looming challenges.

Q: How does your international background influence your perspective as the ATS president?
A: The ATS is a global society representing a large number of international countries and continents. My globetrotter background has opened doors for me to interact with diverse members from our sister societies. In Spanish- or Portuguese-speaking countries, for example, I’m able to give presentations or take questions in both languages. I recently did this for three presentations at the 2016 SOLANEP (Latin American Society of Pediatric Pulmonology) International Congress in Florianopolis, Brazil. I spoke about sleep studies and personalized pediatric medicine. Knowing a foreign language and understanding another culture enriches—and creates for more effective—communication.

Q: How has the ATS changed since you joined as a fellow?
A: We have the potential to radically improve how we practice medicine, and we have new state-of-the-art opportunities to engage with members. We should view the present as a critical time to raise awareness about the misconception of how the ATS engages--not merely as a place for scientists and researchers that is lacking in its offerings to clinicians, but as a true and all-encompassing home for the breadth of experts in pulmonary, critical care, and sleep medicine.

The ATS has come a long way. I urge members to make it their mission to engage colleagues, whether through the International Conference or in their local chapters. Share the benefits and impact the ATS has had in your life, especially with nonmember clinicians.

Companies Shine Patient Perspective on Lung Diseases

Three exhibitors will share unique ways in which they endeavor to raise awareness about devastating lung diseases. From the storytelling and artistry of patients, to a documentary film memorializing an actor, to a patient who ran in Bay to Breakers 2016 during the conference, the companies will show how these individuals are not defined by their lung disease diagnoses.

Insmed Inc. in Booth 1741 paired patients with artists from around the world to create a disease awareness initiative, A Thousand Words. About NTM (nontuberculous mycobacteria), which they will showcase in its booth. Their stories and words have inspired artists to create one-of-a-kind original artwork. These works of art have helped patients communicate what they’ve often struggled to put into words—the long, difficult journey to an NTM diagnosis.

Insmed is developing novel, targeted therapies to help the critical unmet needs of these patients. This exciting and unique project strives to raise awareness about NTM among physicians and could bring about earlier diagnosis for patients.

nnd Medical Technologies in Booth 2001 is the official pulmonary function testing sponsor working with Julie Nimoy and David Knight to promote COPD. Highly illogical, a documentary film tribute to Leonard Nimoy, who had chronic obstructive pulmonary disease and died in 2015. The film illustrates the struggles Mr. Nimoy endured before, during, and after his lung disease diagnosis.

As a sponsor, nnd strives to assist in carrying out Mr. Nimoy’s vision to spread the word on early diagnosis and management of COPD. Through this documentary, the company hopes to educate patients, caregivers, physicians, and all those touched by the disease.

For more information, visit copdilap.com or follow nnd on Twitter @nndMedical for updates.

Primary Ciliary Dyskinesia (PCD) Foundation in Booth 1030 will feature Mary Rose Klotowski, who runs races around the country to raise awareness about PCD, lung diseases, rare diseases, and oxygen needs.

During Bay to Breakers 2016, she wore her portable oxygen concentrator. Ms. Klotowski currently has a FEV1 of 40 percent and needs supplemental oxygen during strenuous activity. She has a goal of participating in races in all 50 states. She has raced in eight states and plans to add five in 2016. Although she raced in California in 2015, she entered the Bay to Breakers 2016 to continue her efforts to raise awareness about lung-related issues and, in conjunction, bring attention to the ATS International Conference. She and her sister, Rebekah Giannakos, who has PCD and has had a double lung transplant in June 2014, are invited patient speakers for the PCD scientific symposium from 9 to 11 a.m. on Tuesday in the Moscone Center, Room 3007/3009 (West Building, Level 3).

WILL LEWIS, MD, Insmed president and CEO, and his company celebrate the artistry of patients from around the world with A Thousand Words About NTM.
Discoveries Offer Hope for Patients With PCD

Until recently, primary ciliary dyskinesia (PCD) has received little attention or research funding. “As a result, delayed diagnosis is the rule, even though signs and symptoms of the disease are usually present right from birth,” says Sharon Dell, MD.

An inherited disease, PCD causes impairment of mucociliary clearance. This impairment results in progressive bronchiectasis that may cause end-stage lung disease by adulthood. Dr. Dell is co-chair of a symposium that will highlight new insights into the mechanisms of ciliary assembly defects in PCD, which have come from animal model and human gene discovery studies, and clinical trials that are being conducted around the world.

The symposium, “The Link Between Ciliary Assembly Defects, Neonatal Respiratory Distress, and Bronchiectasis in Adulthood: A Primer on Primary Ciliary Dyskinesia,” will be presented from 9 to 11 a.m. on Tuesday in the Moscone Center, Room 3007/3009 (West Building, Level 3).

“Multicenter, collaborative research over the past decade has resulted in fascinating scientific discovery, diagnostic improvements, and the start of novel clinical trials for this rare disease. These discoveries provide the potential for a paradigm shift in health outcomes in PCD,” says Dr. Dell, staff physician and senior associate scientist at the Hospital for Sick Children, and associate professor of pediatrics, Institute of Health Policy Management and Evaluation, at the University of Toronto, Ontario, Canada.

The symposium will highlight phenotype-genotype relationships in children and adults, emerging genetic testing, new diagnostic tests, airway microbiology, inflammation in PCD, and the impact of disease management strategies on long-term prognosis.

“This scientific symposium comes at an opportune time of scientific discovery,” Dr. Dell says. “There is something for everyone to learn, from the neonatologist to the adult clinician and from the basic scientist to the epidemiologist.”

The program will begin with two young women who will share their experiences about living with PCD and overcoming many of the misunderstandings and devastating health outcomes associated with the disease.

PLENARY

Continued from page 1

First Annual ATS Walking Challenge

Think you walk a lot at an ATS conference? Let’s see how you compare to other attendees.

Step up to the First Annual ATS Walking Challenge.

Every step helps raise money for the ATS Foundation. Walk around the Exhibit Hall, meet new people, move from session to session and engage in friendly competition against other attendees with the ATS Walking Challenge. The top 3 overall steppers win a prize. Watch it all unfold in real-time on leaderboards in the Teva Respiratory booth #419 or at the ATS Walking Challenge booth.

The first 2,000 registrants receive a free ATS wireless activity tracker to use with the ATS Walking Challenge Mobile App (distributed on a ‘first-come, first-served’ basis). The ATS Walking Challenge Mobile App also supports attendees that prefer to use their own FitBit, Jawbone or iPhone/Android smart phone step counters.

The three individuals who log the most steps will win prizes!

- Grand Prize – Microsoft Surface Pro 3
- 2nd prize – Fitbit Surge
- 3rd prize – Zolt Laptop Charger Plus

Learn more and pre-register online at cloud.hekahealth.com/ats2016 or stop by the Walking Challenge Booth in the South building lobby of the Moscone Center, beginning 5/13/16.

Visit the Teva Respiratory booth #419 each day for a step booster. Use the Walking Challenge mobile app to scan the QR code booster each day to earn your bonus steps. The more you visit, the more you receive: First Day Visit - 500 steps Second Day Visit - 750 steps Third Day Visit - 1,000 steps

Walk for a good cause! For every participant who walks 30,000 steps, Teva Respiratory will make a donation of $100 to the ATS Foundation, for a total maximum donation of $50,000. Remember - 100% of all donations to the ATS Foundation fund new research awards. Learn more at Foundation.Thoracic.org.

The ATS Plenary Session will be from 11:45 a.m. to 1:15 p.m. in the Moscone Center, Room 303/305 (South Building, Esplanade Level). It will also feature the introduction of the ATS slate of officers, an in memoriam presentation; remarks from ATS President Atul Malhotra, MD, and ATS President-Elect David Gural, MD; and presentation of the Outstanding Educator Award to Robert Kotloff, MD, chairman of the Department of Pulmonary Medicine at the Cleveland Clinic, Ohio.

Sponsored by:

ATS Plenary Session
11:45 a.m.–1:15 p.m. today
Moscone Center, Room 303/305
(South Building, Esplanade Level)
More than 10 million Americans have diagnosed chronic obstructive pulmonary disease and another 10 million are living with undiagnosed COPD, according to estimates from the Centers for Disease Control and Prevention. In response to this growing number and to help fight the impact of the disease, the ATS has developed recommendations for a COPD National Action Plan.

Those recommendations were detailed in a May 6 letter to the National Heart, Lung, and Blood Institute, which is leading a National Institutes of Health effort to develop the Action Plan. In its letter, the ATS outlined four goals, with recommendations for each goal.

1. Preventing COPD: The ATS supports effective regulation of all tobacco products. Regulation should include state and federal excise taxes, FDA regulation of all tobacco products, smoke-free public spaces, prevention of youth access to points-of-sale, bans on candy flavoring and tobacco mechanizing, limits on tobacco advertising, and effective public education campaigns.

2. Increasing COPD Recognition: COPD-related questions should remain part of public health surveillance tools for collecting data to better understand the effects of the disease in the U.S. Additional objective assessments of spirometry as part of primary care procedures should be evaluated and considered, and biannual or triannual federal reports should be issued.

3. Increasing COPD Detection: A national workshop should be presented to explore opportunities for early COPD detection from low-dose spiral CT scans for lung cancer.

4. Improving COPD Care: The ATS itemized these five steps for raising the effectiveness of COPD care.
   - Expand clinical trials on the proper role of pulmonary rehabilitation in the treatment of COPD.
   - Expand education of patients and caregivers to optimize self-management of COPD and develop monitoring tools.
   - Collect better information on the patient experience in ordering, delivery, and use of supplemental oxygen services.
   - Develop quality measures for all aspects of COPD to reduce gaps in treatment.
   - Explore the links between COPD and sleep health.

The plan is expected to be released for public comment in the near future. For updates visit the advocacy pages of the ATS website.

Question of the Day

What Strategies Are You Using to Reduce COPD Readmissions?

“First of all, there is the importance of referring them to smoking cessation clinics. Treatment is focused to reduce exacerbations based on the severity—whether we give a bronchodilator or a bronchodilator with inhaled corticosteroids. We also have them maintain physical activities and have a pneumococcal vaccine.”

Amr Suhail Albabna, DO
Jeddah, Saudi Arabia

“We normally begin with the use of bronchodilators, which have been proven to be effective. We start with that as a recommendation, and then, if needed, we add inhaled corticosteroids.”

Aikaterini Dimakou, PhD
Athens, Greece

“In our hospital, we meet as a group on a regular basis and identify those patients coming in frequently, and we discuss what interventions we might be able to use to reduce readmissions. This is a multidisciplinary group involving social workers, nursing staff, and medical staff. We also are using combination therapies.”

Colin Wong, DrMed
Dunedin, New Zealand

“We emphasize follow-up with the patients, which is important to maintain and then have an improvement of the obstruction. In our facility, we use the combination of LAMA-LABA, and I have had a very nice experience with it. It has reduced readmissions, and patients are quite happy about it.”

Evan Mendoza, MD
Cebu City, Philippines

Established in 2005, the ENTELLIGENCE Young Investigator Program has provided funding to promising young investigators to encourage and promote quality medical care and enhance patients’ lives through research in pulmonary vascular diseases.

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

The next grant cycle opens on September 15, 2016

For more information, please visit our updated website: www.ENTELLIGENCEMD.org
Get More from the ATS Journals

The ATS Journals collectively cover the entire spectrum of adult and pediatric pulmonary, critical care, and sleep medicine—from bench to bedside.

- Researchers appreciate the journals’ emphasis on translating basic science discoveries into clinical advances
- Clinicians turn to the journals for the latest clinical guidelines and important reviews of the literature on the diagnosis and treatment of respiratory disease
- More issues feature CME, ABIM, and ABP MOC opportunities
- Renowned editors include Jadwiga A. Wedzicha, MD, the clinical chair in respiratory medicine at Imperial College London, who is now the new Blue Editor

Join the ATS today!
Member benefits include:

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- Discounts on conferences, educational programs, products, and books
- Participation in assemblies (interest groups)
  - Choose from 14 areas of pulmonary, critical care, and sleep medicine
- Career development support

Members in training receive the first year of membership free!

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http://www.thoracic.org/membership/join-the-ats.php

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• Membership/ATS Center Booth, Moscone Center, Lobby (North Building, Upper Level)
Sunday–Tuesday
• Booth #2303 in the Exhibit Hall

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Miss a poster presentation at ATS 2016?
We have you covered with ePosters. Abstract presenters have been invited to prepare an ePoster of their research. Attendees may view available ePosters by logging in to https://cms.psva.com/library/ats_eposter_itinerary/login.

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• Search for exhibiting companies, view the Exhibit Hall layout, and navigate the San Francisco Moscone Center

Supported by Gilead Sciences, Inc.

2016 ATS Assembly Awards

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Follow #ATS2016 for the latest updates during the ATS 2016 International Conference.
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
Early use in FC II and III
Ability to transition from treprostinil parenteral therapy

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

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

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

IMPORTANT SAFETY INFORMATION FOR 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
• 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.
• Concomitant administration of Orenitram with diuretics, antihypertensive agents, or other vasodilators increases the risk of symptomatic hypotension
• Therefore, Orenitram dosage reduction may be necessary in these patients
• Safety and effectiveness in patients under 18 years of age have not been established

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
• In the 30-week placebo-controlled extension study, the most common 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

Visit Booth #803

An Industry Theater Presentation
at the ATS 2016 International Conference
This workshop is sponsored by United Therapeutics.

References:
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—A 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 in patients receiving Orenitram included: headache, diarrhea, nausea and flushing. Table 1 lists the adverse reactions that occurred in patients receiving Orenitram included: headache, diarrhea, nausea and flushing. Approximately 9% of such patients experienced an adverse reaction, but only 4% discontinued therapy for an adverse reaction (compared to 3% receiving placebo). The overall discontinuation rate for any reason was 17% for active and 14% for placebo.

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

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

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

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

Effect of CY2C8 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, sildenafi, 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 μg/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.

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

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

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

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

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

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

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

Recent studies are making many researchers re-evaluate long-standing ideas on the development of chronic obstructive pulmonary disease. An ATS mythbusters symposium on Wednesday will examine the emerging theory that the alteration of lung tissue regeneration, not inflammation, plays a driving role in the pathogenesis of COPD.

Presenters will explain how aberrant airway and alveolar regeneration contribute to the pathogenesis of COPD, and how this could be translated into personalized approaches to prevent, diagnose, and treat the disease.

“The goal of this symposium is to facilitate a better understanding of COPD as a complex disease based on these discoveries, which could lead to novel approaches to prevent and treat this incurable disease,” says Renat Shaykhiev, MD, PhD.

Dr. Shaykhiev is one of the moderators of “ATS Mythbusters: Aberrant Tissue Regeneration Is a Primary Driver of COPD Pathogenesis,” which will be presented from 9 to 11 a.m. in the Moscone Center, Room 2016/2018 (West Building, Level 2).

“A long-standing dogma in the field of COPD research has been that lung tissue derangement in this disease develops as a result of an exaggerated inflammatory response of lung cells to cigarette smoke or other environmental stressors,” says Dr. Shaykhiev, assistant professor of medicine at Weill Cornell Medical College, New York, New York.

However, anti-inflammatory therapies have not been fully effective in treating patients with COPD. This suggests that other mechanisms may be the driving force of COPD pathogenesis, he says. The results of recent studies link several aspects of lung tissue regeneration to the development of COPD, with endogenous stem cells playing a key role in this process and inflammation taking a secondary role.

“This session will provide an interactive forum where researchers who contributed to the innovative concept will discuss their ideas and data with the audience and a panel of internationally recognized speakers,” Dr. Shaykhiev says. “To facilitate a balanced discussion, the list of mythbusters and speakers includes researchers who study various aspects of COPD pathogenesis.”

This scientific symposium continues a series of mythbuster sessions presented at previous ATS conferences. It features five presentations and a discussion with renowned researchers. A related session on the disease is “COPD Exacerbations: Biology and Targets for Novel Treatments” presented from 1:30 to 3:30 p.m. Wednesday in the Moscone Center, Room 134 (North Building, Lower Level).

Six presentations will explain that inflammation is not the only mechanism for COPD exacerbations, the roles of cells and mechanisms in COPD exacerbations, and the role of novel treatments.

“COPD Exacerbations: Biology and Targets for Novel Treatments” (D83) is supported by educational grants from AstraZeneca LP and GlaxoSmithKline.
Non-CME Symposia Wrap Up on Tuesday

The ATS encourages attendees to participate in Non-CME Symposia taking place today at various locations.

6:30-9:30 p.m. SAN FRANCISCO MARRIOTT MARQUIS: GOLDEN GATE BALLROOM A (B2 LEVEL)
Do You Know Your Asthma Patients’ Phenotypes?
(joint to non-U.S. attendees only)
Chaired by Professor Eric D. Bateman, an internationally renowned faculty will discuss the impact of asthma pathophysiology on approaches to management, barriers to improving control of symptomatic asthma, and the evidence for using anticholinergic bronchodilator therapy for asthma. Attendance at this symposium is for non-U.S. health care professionals only.

Speakers:
• Professor Eric D. Bateman (South Africa) [Chair]
• Professor Christian Taube (the Netherlands)
• Professor Hauk Kerstjens (the Netherlands)
• Professor William Busse (United States)
Company: Boehringer Ingelheim Pharmaceuticals GmbH & Co. KG

6:30-9:30 p.m. SAN FRANCISCO MARRIOTT MARQUIS: GOLDEN GATE BALLROOM B (B2 LEVEL)
Holding Court in PAH
Experience the drama and excitement of Holding Court in PAH, as some of the most challenging treatment issues are argued by leading experts in pulmonary hypertension. With the honorable judge Lewis Rubin, MD presiding, you the jury will deliberate the evidence, then cast your vote for a winner. Register at www.pah.tv.

Speakers: (Chair) Lewis J. Rubin, MD, APMC, Professor of Medicine, Pulmonary and Critical Care Division, Director, PAH Program UC San Diego School of Medicine, San Diego, California. Faculty: Richard Channick, MD, Director, Pulmonary Hypertension and Thromboendarterectomy Program, Massachusetts General Hospital, Boston, Massachusetts; Martha Kingman Liberty, FNP-C, DNP, Nurse Practitioner, Pulmonary Services, Heart & Lung Center, UT Southwestern Medical Center, Dallas, Texas; Richard A. Krasuski, MD, FACC, FAHA, FESC, Professor of Medicine and Pediatrics, Director of the Adult Congenital Heart Disease Center, Director of Hemodynamic Research, Duke University Medical Center, Durham, North Carolina; Vallerie McLaughlin, MD, Kim A. Eagle, MD. Endowed Professor of Cardiovascular Medicine, Dept. of Internal Medicine/ Cardiovascular Medicine, University of Michigan, Ann Arbor, Michigan; Ioana Preston, MD, Associate Professor of Medicine, Pulmonary Function Lab Director,

6:30-9:30 p.m. SAN FRANCISCO MARRIOTT MARQUIS: YERBA BUENA BALLROOM 7 (LOWER B2 LEVEL)
Evolving Perspectives in Asthma Heterogeneity: The Role of Eosinophils
This non-CME dinner symposium will explore current and emerging scientific concepts in asthma heterogeneity and the role of eosinophils in uncontrolled asthma.

Speakers:
Bartolome Celli, U.S. (Chair)
Unmet Need in Uncontrolled Asthma and Barriers to Improved Outcomes (~30 mins) Mark FitzGerald (Canada)
Cellular and Molecular Endotypes and Phenotypes in Uncontrolled Asthma (~30 mins) Parameswaran Nair (Canada)
The Biology and Role of Eosinophils in Uncontrolled Asthma (~30 mins) Andrew Menzies-Gow (UK)
Understanding Disease Heterogeneity and the Importance of Biomarkers (~30 mins) Rey Pancheri (U.S.)
Company: AstraZeneca Pharmaceuticals Inc.

6:30-9:30 p.m. SAN FRANCISCO MARRIOTT MARQUIS: YERBA BUENA BALLROOM 9 (LOWER B2 LEVEL)
Fixed Dose LAMA/LABA Inhalers in COPD: What are the Trials Tell Us
Evidence increasingly supports a prominent role for fixed-dose combinations of long-acting muscarinic antagonists and long-acting ß2-agonists (LAMA/LABA) in the management of patients with COPD. This interactive symposium will present the latest efficacy and safety data of new and emerging fixed-dose LAMA/LABA combinations, including application to specific patient case scenarios.

Speaker: Chair: Richard H. Casaburi, MD, MEng, PhD

Why is NTM challenging to diagnose?

- Signs and symptoms, such as chronic cough, fatigue, and failed response to antibiotic regimens are common and nonspecific. Nontuberculous mycobacteria (NTM) lung infections can be easily masked by other comorbidities, such as bronchiectasis, and may go untreated for months, even years.1,4
- Delaying a diagnosis for NTM can lead to prolonged and inaccurate treatments. This can result in increasing rates of antibiotic resistance and compounding respiratory problems for patients.2
- In some serious cases, a delay in diagnosis can result in irreversible lung damage, such as cavitary lesions, in more than 50% of patients.1,4

Learn more at the updated NTMfacts.com
**ATS Weighs In on Clean Power Lawsuit**

A battle over climate change is brewing in U.S. courts, and the ATS is fighting for the health of our patients.

The Environmental Protection Agency has finalized regulations—known as the Clean Power Plan—to reduce greenhouse gas carbon pollution emissions from U.S. power plants. Power plants are responsible for one-third of total carbon dioxide emissions in the U.S. The EPA’s Clean Power Plan requires each state to develop its own plan to make significant reductions in carbon pollution emissions for power plants. States are expected to achieve these carbon pollution emissions reductions no later than 2030.

The power, coal, and coal-producing states strongly oppose the Clean Power Plan and are suing the EPA in federal court to block implementation of the Clean Power Plan.

The ATS has taken a firm stand that climate change is a direct threat to human health and has organized a coalition of medical organizations to submit an amicus brief—or “friend of court” petition—in the case to explain to the court why climate change is such a serious health threat to our patients.

The Society’s amicus brief cites multiple studies documenting that climate change is having adverse effects on human health, including:

- Climate-driven heat waves cause excess morbidity and mortality.
- Rising temperatures that can lead to increased ozone pollution, resulting in longer and more intense pollen seasons.
- Climate-forced droughts leading to forest fires, causing injury and illness and reducing air quality.

In a recent ATS survey of its U.S. members, a majority of respondents concurred that climate change is occurring, it is having a direct impact on the health of their patients, these impacts are particularly harmful for children, and even greater climate-driven adverse human health impacts are anticipated. Other medical society surveys have had similar results.

The ATS is joined in the amicus brief by the American Academy of Pediatrics, American College of Occupational and Environmental Medicine, American College of Preventive Medicine, American Medical Association, American Public Health Association, National Medical Association, and National Association for the Medical Direction of Respiratory Care.

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You never know when someone is going to request your headshot, so it’s good to have it on hand. Maybe you won an award, got a promotion, became an assembly chair, or were recognized for volunteer work … all reasons to need a professional headshot. Also make sure your ATS member profile is up to date by visiting the ATS Center. Update your member profile with personal and professional data, including degrees and certifications, assembly choices, contact information, and headshot. Keeping your profile current helps the ATS better inform you of new resources, products, and events to build your career.

An ATS amicus brief cites multiple studies documenting that climate change is having adverse effects on human health.
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* post-operative pulmonary complications
OFEV MEETS SAN FRANCISCO
VISIT BOOTH #1003
Managing IPF With Personalized Treatment

G

eat progress has been made in the treatment of patients with idiopathic pulmonary fibrosis, but the use of molecular markers to implement precision medicine could revolutionize treatment in the near future.

“We need to understand for a given patient at a given stage of disease what core biological mechanisms are driving their disease, so we can identify the best treatment and optimize the risks and benefits,” says Richard Marshall, MD, PhD, one of the moderators for “The Road to Precision Medicine in IPF: Biomarkers and Clinical Predictors.”

Seven presenters will explain the role of molecular markers, the potential value of lung and bronchoalveolar lavage molecular analyses in diagnosis and management, and new findings on the clinical management of patients with IPF.

The session will be presented from 1:30 to 3:30 p.m. Wednesday in the Moscone Center, Room 135 (North Building, Lower Level).

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Visit the Best of ATS Education Products booth, located in the Moscone Center, Lobby (South Building, Upper Level), to see the list of select scientific symposia included in the Best of ATS Conference collection. The ATS Store is open from 8 a.m. to 4:30 p.m. through Wednesday.

* Free access is limited to paid conference registrants in the following registration categories: full members, affiliate members, in-training members, senior/emeritus members, nonmembers, and in-training nonmembers who are registered for the full conference.

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Located in Halls A-C Moscone Center

South Building, Lower Level
The use of stem cells to prevent and treat human diseases has led to unprecedented growth in regenerative medicine. Increasing evidence has shown that an individual’s own cells have the potential for development of stem cell-based therapeutic approaches.

Tuesday’s scientific symposium on “Progress in Stem Cell Biology and Disease Applications” will provide a basic scientific, clinical rationale, and current state-of-the-art in this rapidly developing area. The presenters, who are accomplished stem cell investigators from outside the respiratory field, will bring knowledge and perspective to help guide future developments in lung regenerative medicine. The four presentations and their speakers are:

- "Normal and Neoplastic Stem Cells”—Irving Weissman, MD, the Virginia and D.K. Ludwig Professor for Clinical Investigation in Cancer Research, professor of developmental biology, professor of pathology, and professor of developmental biology at Stanford University, California
- "Imaging Cancer Heterogeneity and Therapy Resistance in Real Time”—Tannishtha Reya, PhD, professor of pharmacology and medicine at the University of California, San Diego, in La Jolla
- "Interspecific Blastocyst Complementation: A Novel Approach to Generate Functional Organs Speaker”—Tamir Rashid, MD, King’s College, London, UK
- "Defining the Lung Cell By Cell”—Mark Krasnow, PhD, professor of biochemistry and executive director of the Wall Center for Pulmonary Vascular Disease at Stanford University, California

The symposium co-chairs are Daniel Weiss, MD, PhD, professor of medicine at the University of Vermont, Burlington, and Darrell N. Kotton, MD, professor of medicine and pathology and director of the Center for Regenerative Medicine at Boston University, Massachusetts.

Clinicians, basic science researchers, and other lung health care professionals looking to learn about developments in stem cell biology and their applications to respiratory diseases and critical illnesses are encouraged to attend the symposium. It will be from 9 to 11 a.m Tuesday in the Moscone Center, Room 2016/2017 (West Building, Level 2).

The crisis in the Middle East has raised awareness about the challenges encountered by migrant populations, especially their access to health care. Migrant populations around the world, including those from Mexico and Latin America entering the United States, face similar challenges. “War, economics, and geopolitical factors have forced hundreds of thousands away from their lands and families into countries that are often unprepared to care for their needs,” says Jesse Roman, MD. “The ATS and its Health Equality Subcommittee are concerned about the respiratory health of these populations. They are likely to suffer from tobacco-related disorders, asthma, pulmonary infections, sleep-disordered breathing, and critical care illnesses.”

Dr. Roman and three other physicians are leading “Respiratory Health in Migrant Populations,” which will raise awareness about health care access and delivery in migrant populations. The symposium will be from 1:30 to 3:30 p.m. Wednesday in the Moscone Center, Room 2009/2011 (West Building, Level 2).

“The burden of respiratory disease in migrants is essentially unknown, and appropriate models for delivering health care to these populations have yet to be implemented and tested. The speakers will address the burden of respiratory disease in these populations and the problems encountered in their care,” says Dr. Roman, professor and chair of medicine, professor of pharmacology and toxicology, and chief of the Division of Pulmonary, Critical Care, and Sleep Disorders Medicine at the University of Louisville, Kentucky.

The symposium will address the health inequity in Latinos crossing the border, the impact of asthma and sleep-disordered breathing, and infectious diseases in refugee populations and survivors of torture. It also will highlight the use of tele-health in pulmonary and critical care settings in Syria.

"Considering the widespread nature of this problem, we are hopeful audience members will return to their workplaces equipped with new knowledge, enabling them to identify problems and tackle them adequately," Dr. Roman says. "Importantly, we hope to raise enthusiasm among trainees interested in devoting their efforts—and perhaps their careers—to these important issues."
For adult patients with asthma uncontrolled on an ICS or whose disease severity clearly warrants an ICS/LABA. BREO is NOT indicated for the relief of acute bronchospasm.
Imported Safety Information (cont’d)

DRUG INTERACTIONS (cont’d)
• Use beta-blockers with caution as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may also 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
• BREO is not indicated for use in children and adolescents. The safety and efficacy in pediatric patients (aged 17 years and younger) have not been established.
• 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.

Please see Brief Summary of Prescribing Information, including Boxed Warning, for BREO on the following pages.

Visit BREOhcp.com for more information, including Patient Assistance Programs.
4.37 \[95\% \text{CI: 1.25, 15.34}\]). The increased risk of asthma-related death is considered a class effect of LABA, and asthma control and maintain the patient on a long-term asthma control medication, such as an ICS. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue BREO) if Acute symptoms should be treated with an inhaled, short-acting beta2-agonist. When beginning treatment with BREO, like all medicines containing sympathomimetic amines, should be used preferably for about 150 mg in adults and 75 mg in adolescents. However, there were no significant increases in either fluticasone furoate or vilanterol exposure compared the safety of another LABA (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related death in subjects receiving salmeterol. This finding with salmeterol was thought to be a class effect of LABA. Current data are inadequate to determine the increased concurrent use of inhaled corticosteroids (ICS) or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe BREO for patients who are adequately controlled on a low- or medium-dose ICS. Do not use BREO for patients whose asthma is not adequately controlled on a low- or medium-dose ICS (see Warnings and Precautions (5.11)).

BREO, like all medicines containing sympathomimetic amines, should be used preferably for asthma control and maintenance, in patients with asthma who are not adequately controlled on a long-term asthma control medication, such as an ICS. The increased risk of asthma-related death is considered a class effect of LABA. Current data are inadequate to determine the increased concurrent use of inhaled corticosteroids (ICS) or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe BREO for patients who are adequately controlled on a low- or medium-dose ICS. Do not use BREO for patients whose asthma is not adequately controlled on a low- or medium-dose ICS (see Warnings and Precautions (5.11)).

Acute symptoms should be treated with an inhaled, short-acting beta2-agonist. When beginning treatment with BREO, like all medicines containing sympathomimetic amines, should be used preferably for children and adolescents. However, there were no significant increases in either fluticasone furoate or vilanterol exposure compared the safety of another LABA (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related death in subjects receiving salmeterol. This finding with salmeterol was thought to be a class effect of LABA. Current data are inadequate to determine the increased concurrent use of inhaled corticosteroids (ICS) or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe BREO for patients who are adequately controlled on a low- or medium-dose ICS. Do not use BREO for patients whose asthma is not adequately controlled on a low- or medium-dose ICS (see Warnings and Precautions (5.11)).
asthma-related death is increased in subjects treated with BREO has been conducted. 

The increased risk of asthma-related death is considered a class effect of LABA, (13/13,176 in subjects treated with salmeterol vs. 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25, 15.34]). Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue BREO) if no exacerbations occur. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after treatment with fluticasone furoate. There were no asthma-related deaths or asthma-related intubations observed in the adolescent age-group.

1.2 Postmarketing Experience In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during use of the individual components of BREO. These adverse reactions are reported voluntarily from a population of uncertain size. It is not always possible to reliably estimate the frequency of occurrence or to establish a causal relationship to drug exposure from these reports. These adverse reactions include: 

- Cataracts and glaucoma.
- Systemic events and disorders: hypokalemia, hyperglycemia.
- Nervous system disorders: headache, dizziness, nervousness, tremor.
- Respiratory, thoracic, and abdominal disorders: sneezing, pharyngitis, sinusitis, upper respiratory tract infection.
- Skin and appendage disorders: acne, skin rash, pruritus.
- Special senses disorders: conjunctivitis.

2 USE IN SPECIFIC POPULATIONS 2.7 Pregnancy Pregnancy Category C. There are no adequate and well-controlled trials with BREO in pregnancy. In pregnant women, studies with fluticasone furoate and vilanterol individually have not been conducted. BREO or its components should be used in pregnancy only if the potential benefit justifies the possible risk to the fetus. Women should be advised to contact their physicians if they become pregnant while taking BREO. 

2.8 Nursing Mothers Due to the potential for the systemic absorption of fluticasone furoate from a systemic source, use of fluticasone furoate systemic exposure increased by up to 3-fold in subjects with hepatic impairment compared with subjects with normal hepatic function. Use with caution. In the clinical trials program, no data were collected on the effects of fluticasone furoate on the HPA axis in children. The safety and efficacy of fluticasone furoate in pediatric patients have not been established.

4.37 [95% CI: 1.25, 15.34]). The increased risk of asthma-related death is considered a class effect of LABA, (13/13,176 in subjects treated with salmeterol vs. 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25, 15.34]). Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue BREO) if no exacerbations occur. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after treatment with fluticasone furoate. There were no asthma-related deaths or asthma-related intubations observed in the adolescent age-group.

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This lecture will discuss treatment options for reducing the risk of exacerbations in severe COPD patients.

**Speakers:** Donald P. Tashkin, MD, Professor Emeritus of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, California; Ronald C. Balkissoon, MD, MSc, Pulmonary Consultant, Denver, Colorado.

**Company:** AstraZeneca Pharmaceuticals Inc.

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**INDUSTRY THEATER 1**

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

**Thrombosis: DVT/PE An Exploration in Risk Reduction**

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

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

**Company:** Janssen Pharmaceuticals Inc.

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**INDUSTRY THEATER 2**

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

**ORKAMBI® (lumacaftor/ivacaftor) Treatment Initiation and Clinical Management**

**Speaker:** Manu Jain, MD, MSc, Northwestern University.

**Company:** Vertex Pharmaceuticals Inc.

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**MINI INDUSTRY THEATER**

12:30-1 p.m.

**COPD Is a Struggle. Let’s Talk About a Maintenance Therapy Option**

The objective of this presentation is to provide pertinent, balanced information to health care professionals on the efficacy and safety of nebulized long-acting bronchodilator therapy for patients with COPD. It is designed to afford health care professionals the opportunity to review, evaluate, and discuss the role of nebulized long-acting bronchodilator therapy as an option for patients with COPD, including chronic bronchitis and emphysema, in order to make informed treatment decisions for their patients.

**Speaker:** Antonio Anzueto, MD, Professor of Medicine, University of Texas, Health Science Center at San Antonio, San Antonio, Texas.

**Company:** Sunovion Pharmaceuticals Inc.

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**INDUSTRY THEATER 2**

1:15-2 p.m.

**Treatment Strategies for COPD Exacerbation Prevention: New Evidence**

**Speaker:** Amy M. Olson MD, MSPH; National Jewish Health.

**Company:** Boehringer Ingelheim Pharmaceuticals Inc.

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**INDUSTRY THEATER 1**

1:15-2 p.m.

**Insights in IPF: Perspectives on the Disease and Its Diagnosis**

Join us for a 45-minute Insights in IPF educational program examining the evolving understanding of idiopathic pulmonary fibrosis (IPF), including the science of the disease and the complexity of diagnosis. An expert in the field of interstitial lung disease will provide insight into the challenges of managing a patient with IPF, with perspectives on how to address these challenges in the clinic.

**Speaker:** Dr. Sai Parthasarthy.

**Company:** Philips Respironics Inc.
ATS Welcomes Decision on Shorter MDR-TB Regimen

On May 12, the World Health Organization released recommendations aimed to speed up detection and improve treatment outcomes for multidrug resistant tuberculosis (MDR-TB) through the use of a novel, rapid diagnostic test and a shorter, cheaper treatment regimen. The American Thoracic Society welcomes the WHO’s recently released recommendations, which shorten treatment to nine to 12 months, making it easier for patients to complete.

“The new WHO-recommended MDR-TB treatment regimen is a significant advance for many patients with MDR-TB who will no longer have to endure almost two years of treatment and harsh drug side effects,” says ATS Past President Philip C. Hopewell, MD, professor of medicine and director of the Curry International Tuberculosis Center at the University of California, San Francisco. “Though the new regimen will ease treatment for some MDR-TB patients, there remains an urgent need for shorter, easier treatment for all patients with drug-susceptible and drug-resistant TB, faster point-of-care diagnostics, and effective vaccines to prevent TB in all populations.”

According to the WHO, tuberculosis is a top infectious disease killer worldwide. It notes these staggering statistics:

- In 2014, 9.6 million people fell ill with TB, and 1.5 million died from the disease.
- More than 95 percent of TB deaths occur in low- and middle-income countries, and it is among the top five causes of death for women aged 15 to 44.
- In 2014, an estimated 1 million children became ill with TB and 140,000 children died of TB.
- TB is a leading killer of HIV-positive people: In 2015, one in three HIV deaths was due to TB.
- The WHO’s Millennium Development Goal target of halting and reversing the TB epidemic by 2015 has been met globally. According to the WHO:
  - TB incidence has fallen an average of 1.5 percent per year since 2000, and is now 18 percent lower than the level of 2000.
  - The TB death rate dropped 47 percent between 1990 and 2015.
  - An estimated 43 million lives were saved through TB diagnosis and treatment between 2000 and 2014.

“The battle against TB must be prioritized if we are to halt this pandemic,” says Dr. Hopewell, co-chair of the committee for the WHO International Standards for Tuberculosis Care (third edition, published in 2014), and a member of the ATS Assembly on Microbiology, Tuberculosis & Pulmonary Infections.

For Dr. Hopewell, the ATS is well positioned to advocate for research that leads to the eradication of tuberculosis.

“The ATS is the organization with the most experience in dealing with TB, both as a clinical and a public health problem. We were founded by a group of physicians who were directors of TB sanatoria and hospitals back in 1905, and that progressively broadened to include all of respiratory disease,” Dr. Hopewell says.

In addition to several poster presentations on TB, a symposium on Wednesday will examine “New Concepts in TB Immunity and Targets for Treatment” from 9 to 11 a.m. in the Moscone Center, Room 3016/3018, (West Building, Level 3).
Step Up With the ATS Walking Challenge

Lisa Bacolini (left) and Joyce Alejo-Stone, both of Fibrogen, Inc., joined the ATS Walking Challenge Monday, picking up their complimentary fitness trackers at the ATS Walking Challenge information booth in the Moscone Center Lobby (South Building, Upper Level). Find out who among your ATS colleagues are “high steppers” by watching live results reported on leaderboards in the ATS Walking Challenge booth and at TEVA Respiratory in Booth 419. Or perhaps you would like to add some steps of your own. Check out some San Francisco famed sites that are within walking distance of the Moscone Center, such as Lombard Street, which takes about 3,600 steps.

Join the Conversation on Twitter: #ATS2016

Doctor Chad @chadchima “The opposite of love is not hate. It is indifference.” Impressed to hear Elie Wiesel quoted in healthcare #disparities session at #ATS2016

John Blakey @johnblakey Some great posters from @JHUGlobalHealth at #ATS2016 exploring the effect of the urban environment on asthma in Peru

Maxwell Tran @MaxwellTran Gained 40 followers today after the #entrepreneurship session at #ATS2016. Maybe I should live tweet more often!

Oliver @CPC_Munich Incredibly well-deserved: Marlene Rabkowitz gives Amberson Lecture at @ATS2016 @atscommunity @ATS_RCMB

Jack Iwashyna @iwashyna Prognosis is never purely biological, but rather shaped by society’s willingness to invest in support & environmental adaptations #ATS2016

Catherine Disch @CatherineDisch1 At ATS in San Francisco! Amazing Meeting #ATS2016

The ATS Center Shows Global Reach

Learn about all that the American Thoracic Society has to offer, including its activities around the world, at the ATS Center in Booth 937 in the Exhibit Hall at Moscone Center, Halls A-C (South Building, Lower Level). Be sure to visit from 8 a.m. to 2:45 p.m. on Tuesday.

The colorful ATS Center was redesigned to feature a large touchscreen world map that illustrates the center’s theme, “ATS: Providing a World of Opportunity to Improve Global Lung Health.” Thirty four percent of the ATS’s members hail from 129 countries, making it a truly global Society. An overarching goal of this reach is to improve world lung health, and the Society has developed initiatives and related activities to:

- Engage international organizations, such as the World Health Organization.
- Provide global education, research, and research training.
- Engage ATS members to participate in global initiatives.
- Pursue its broad global health policy.
- Provide technical assistance and other capacity to build support.

At the ATS Center, find out about the Society’s involvement in specific global activities, such as the Forum of International Respiratory Societies; Methods in Epidemiologic, Clinical, and Operations Research (MECOR); tuberculosis control efforts; the ATS Global Scholars Program; and peer conferences.

The Pulmonary Fibrosis Foundation

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

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

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

TOGETHER WE IMAGINE A WORLD WITHOUT PULMONARY FIBROSIS

Pulmonary Fibrosis FOUNDATION
FDA-APPROVED ACTHAR

FOR SYMPTOMATIC SARCOIDOSIS

SARCOIDOSIS HAS NUMEROUS CLINICAL MANIFESTATIONS AND RANGES IN SEVERITY1

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

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

INDICATION

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

IMPORTANT SAFETY INFORMATION

- Acthar should never be administered intravenously.
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immuno-suppressive 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, Cushings’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.

infection (20, 46); General disorders and administration site conditions: Infections and irritability (7, 19), pyrexia (5, 8); Gastrointestinal disorders: syndrome. During an Collagen Diseases: Disorders: However, there is no evidence that it affects the ultimate outcome or natural history of the disease. shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. For complete prescribing information (including Medication therapy, and bone density should be monitored in patients on long term therapy. Effects are reversible once H.P. Acthar Gel therapy is stopped. Growth and development in children and adolescents may be delayed. Although the effects of high dose, or even several large doses, have the potential for serious adverse reactions compared to a standard dose. See also Warnings and Precautions. OVERDOSAGE If an overdose occurs, wash the affected skin area with soap and water. The symptoms of adrenal insufficiency in infants treated for infantile spasms can be difficult to recognize, especially in the neonatal period. Adverse events may occur with any dose level of H.P. Acthar Gel, but are generally more frequent and of greater severity at higher doses. While Data from animal studies can be used to provide meaningful incidence rates or to permit a meaningful comparison to the control groups.

The incidence of adverse reactions reported in clinical trials with H.P. Acthar Gel may diverge from the overall incidence observed in the postmarketing period. Adverse events associated with the use of H.P. Acthar Gel have been identified from postmarketing experience with H.P. Acthar Gel. Only the 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. The incidence of infections that occurred at ≥2% were H. pylori (infants only), vaginitis (infants only), and vaginitis (adults only). Possible Additional Sterilogenic Effects Based on sterilogenic 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 absorption, acne, anterior and posterior subcapsular lens opacities, skin thinning (adults only), facial erythema and increased sweating (adults only). Hyperplastic striae, easy bruisability, decreased bone mineralization, weight gain, muscle weakness, decreased bone density, and an increase in the incidence of fractures have been reported following therapy with H.P. Acthar Gel. There is an increased risk of aseptic necrosis of the femoral head in infants and young children treated with H.P. Acthar Gel. As with other corticosteroids, therapy with H.P. Acthar Gel may produce a serious, non-specific clinical response in certain individuals. This response may obscure the clinical course of infection. The list of adverse reactions is not all-inclusive. Adverse reactions are listed by body system or organ class. Unless otherwise noted these adverse events have been observed in infants, children and adults. Allergic Reactions Allergic reactions have presented as redness, rash, and swelling (adults only). Cardiovascular Necrotizing angitis (adults only) and congestive heart failure. Dermatologic Skin thinning (adults only), hyperpigmentation (adults only), acne, anterior and posterior subcapsular lens opacities, acne, skin thinning (adults only), facial erythema and increased sweating (adults only). Musculoskeletal Muscle weakness and muscle atrophy. Musculoskeletal disorders include: Osteoporosis, osteopenia, rickets, osteomalacia, myopathy, and muscle atrophy. Ophthalmic Visual disturbances, visual field defects, color vision abnormalities, cataracts, retinal detachment, optic neuritis, keratoconus, glaucoma, and retinal and optic nerve disorders. Gastrointestinal disorders include: Appetite changes, nausea, vomiting, diarrhea, constipation, abdominal pain. Infections include: H. pylori (adults only), vaginitis (adults only), vulvovaginal candidiasis (adults only). The list of adverse events is not all-inclusive. Adverse reactions are listed by body system or organ class. Unless otherwise noted these adverse events have been observed in infants, children and adults. A specific incidence could not be obtained from source data derived from retrospective chart reviews and clinical trials in children under 2 years of age or in all pediatric age groups. CONTRAINDICATIONS The use of corticosteroids during the period of stress. The adrenal insufficiency may be minimized in adults and infants by pretreatment with a corticosteroid, and in the presence of symptoms of hyponatremia. While H.P. Acthar Gel can cause elevation of blood pressure, salt and water retention, and increased excretion of sodium and water. The signs and symptoms that may indicate the development of hypothyroidism can be misleading in infants. Corticosteroids may increase susceptibility to infections. Although dramatic improvement may be observed in certain patients with severe ulcerative colitis, patients with idiopathic ulcerative colitis who have shown a response with corticosteroids. Infections and irritability (7, 19), pyrexia (5, 8); Gastrointestinal disorders: syndrome. During an Collagen Diseases: Disorders: However, there is no evidence that it affects the ultimate outcome or natural history of the disease. shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. For complete prescribing information (including Medication therapy, and bone density should be monitored in patients on long term therapy. Effects are reversible once H.P. Acthar Gel therapy is stopped. Growth and development in children and adolescents may be delayed. Although the effects of high dose, or even several large doses, have the potential for serious adverse reactions compared to a standard dose. See also Warnings and Precautions. 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Leaving Our Hearts in San Francisco
Forums Celebrate Diversity and Inclusivity

Two popular forums gave attendees the opportunity to recognize and support diversity and women in the fields of pulmonary, critical care, and sleep medicine.

Sonia C. Flores, PhD, (top left) professor of medicine, Division of Pulmonary Sciences, University of Colorado Anschutz Medical Campus, Aurora, spoke about the challenges she faced as a minority in medicine during Sunday’s Diversity Forum.

Irina Petrache, MD, (top center, left) professor of medicine and chief of pulmonary, critical care, and sleep medicine at National Jewish Health, Denver, Colorado, accepts the 2016 Elizabeth A. Rich, MD, Award, from Yolanda Mageto, MD, MPH, ATS Membership Committee chair, during the Women’s Forum on Monday.

Catherine R. Lucey, MD, (top right) the Faustino and Martha Molina Bernadett Presidential Chair for Medical Education, professor of medicine, and vice dean for education at the University of California, San Francisco, School of Medicine, spoke about the leadership skills needed by today’s health care leaders during the Women’s Forum.

Recipients of Minority Trainee Development Scholarships (bottom), selected for the quality of science in their submitted abstracts, were recognized at the Diversity Forum.
ANNOUNCING . . .
Gilead Sciences Research Scholars Programs

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

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

Cystic Fibrosis
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