ATS DAILY BULLETIN

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Tuesday
May 22, 2018
San Diego, CA • May 18-23, 2018

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Rounding Up: Perfecting ICU Rounds

Robin Gross, MD, explored barriers to effective ICU rounds with a standing-room-only audience in the Clinicians Center.

Interprofessional rounding in the ICU is not going away. You may as well adopt it, get good at it, and curate it, according to Jaspal Singh, MD, MHA, MHS.

Dr. Singh joined Robin Gross, MD, and Ellen Hillegass, PT, EdD, CCS, to lead an interactive discussion about the Best and Worst of ICU Rounds on Monday in the Clinicians Center. The trio outlined obstacles to clean, communicative, and productive rounds and asked their audience to weigh in on potential solutions for each.

First on the list: Never-ending rounds. "If you have 17 patients and the attending goes into a dialogue on every single one, how much capability do learners have at that rate?" asked Dr. Singh. "What's going to happen at patient 17 if everyone is mentally checked out by patient six or seven?"

Managing the time component of rounds while still recognizing the importance of the educational component is key.

"It's about finding teachable moments," said Dr. Gross. "Maybe use that time while you're donning your gown and gloves or while you're walking down the hall."

"Or perhaps consider having teaching rounds and patient rounds, dividing the two," added Dr. Hillegass.

As you consider efficiency, don't lose sight of what's best for the patient. If it becomes solely about a checklist, the patient could suffer.

"When the checklist becomes the be-all, end-all, it takes away from the center of what's happening," said Dr. Singh.

Ideas from the audience included setting expectations with the team to tell them how the checklist should be used. Use of the check-

see ICU ROUNDS page 3

Plenary: Emergency Care in Hostile Environments

Tuesday's plenary session will be a mix of Society business and personal accounts of delivering emergency care during natural disasters. The highlight of the session will feature three personal descriptions of delivering emergency medical care and dealing with the public during two of the worst natural disasters in recent U.S. history

Kalpalatha Guntupalli, MD, and Naseem Alavian, MD, volunteered to remain at Ben Taub Hospital in Houston to deliver care during Hurricane Harvey in August 2017. Harvey was the costliest U.S. hurricane on record, causing $125 billion in damage, largely due to catastrophic flooding in the Houston area. Harvey was also responsible for more than 100 deaths, most in the Houston area.

"I have been through eight or nine hurricanes in the 30 years I have lived in Houston," Dr. Guntupalli said. "This is the first time we were the target. There was so much water we were handing out life jackets so people could be safer if they had to venture outside."

John Balmes, MD, volunteered to field media and public medical and health questions during wildfires that swept through Sonoma, Napa, and adjacent counties in Northern California in October 2017. He was also a primary public medical contact during the Thomas fire that blackened nearly 300,000 acres in December near Santa Barbara, California. Wildfires destroyed more than 10,000 structures in California last year, more than the last nine years combined. The final death toll hit 43, more than the past 10 years combined, according the state officials. Fires were driven by a deadly combination of high temperatures, low humidity, and sustained winds up to 60 mph that drove embers and flames faster than firefighters could follow. "People had to literally run for their lives," Dr. Balmes said. "And they didn't always make it."

For more from the plenary speakers, see page 3.

At the end of the session, current ATS President Marc Moss, MD, will pass the presidency to Polly Parsons, MD. The Plenary will run from 11:45 a.m. to 1:15 p.m. in Hall H.

Dr. Parsons talked about her goals and expectations for the coming year with the *Daily Bulletin*. You can read more about that conversation on page 9.

see PLENARY page 3

DON'T MISS THESE EVENTS

Defining Your Niche—How to Make Yourself Marketable in a Competitive Marketplace session
11 a.m.-12 p.m., Center for Career Development

Coffee & Connections networking station
11 a.m. and 1:15 p.m., Exhibit Hall

Advanced Disease State: Financial Principles session
12:50-2 p.m., Clinicians Center

Toast to Innovation Networking Event
1:15-2:15 p.m., Exhibit Hall

KEYNOTE SERIES

Speakers Do a Deep Dive on Seals, Bacteriophage, Pharma and ME

Tuesday and Wednesday mark the final two days of the ATS Keynote Series with presentations on the physiology of deep-diving seals, principles of bacteriophage biology, understanding how Pharma scientists think, and becoming an effective medical educator.

Two sessions are presented from 8:15 to 9 a.m. each day, when no other programming is scheduled. Each day of ATS 2018, the series has highlighted state-of-the-art lectures on a variety of topics to showcase major discoveries in pulmonary, critical care, and sleep medicine.

TUESDAY

On Tuesday, the ATS International Conference will take advantage of its 2018 location and call on some local experts to present on topics that have a San Diego influence.

see KEYNOTE SERIES page 46

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PLENARY

Continued from page 1

Kalpalatha Guntupalli, MD

Professor of Pulmonary Medicine and Frances K. Friedman & Oscar Friedman, M.D. '36 Endowed Professorship for Pulmonary Disorders, Baylor College of Medicine, Chief of Pulmonary, Critical Care, and Sleep Medicine, Ben Taub Hospital, Houston

"There were a lot of situations in the hospital, but nothing we couldn't handle. The worst is just getting to and from work during a natural disaster. It's not sexy, but we had one staffer coming in to ride out the storm who was trapped in his car by rising waters. He had to break a car window and swim to the building.

Naseem Alavian, MD

Chief Resident, Ben Taub Hospital, Houston

"When you are providing care during a natural disaster, your team has to absolutely trust your leadership and you have to absolutely trust your team. We all had the same goal: that we would provide the most exceptional care we could in this setting. My team knew I would kill to get them what they needed, and I would expect them to kill to help our patients. It takes complete and total dedication to the task at hand."

John Balmes, MD

Professor of Medicine
University of California San Francisco Medical School

"In terms of human health, most wildfires are about smoke. Under the right conditions, hot, dry winds, high temperatures, low humidity, these fires move beyond the ability of fire departments to deal. The actual flames took entire communities by surprise and burned them to the ground. With climate change, we are expecting more extreme conditions like we saw last year, more catastrophic wildfires. We have to be better prepared in the future." ■

ICU ROUNDS

Continued from page 1

list should be done in a minute or less, not five minutes.

A barrier to efficient and effective rounds is lack of teamwork, which can lead to misinformation, especially as it relates to orders. If a surgeon stops in to give orders and no one is there to receive them, who ensures they are carried out?

"Rounds are the perfect place for good communication," said Dr. Gross. "Sixty to 70 percent of errors can be linked to communication."

Ultimately, for rounds to be the best they can be, they should include the patients' families, as well. Even though it may seem counterproductive to include families in rounds, it actually increases efficiency.

"Some people think it will add time to rounds, but it doesn't. It actually makes them faster," said Dr. Gross. "They don't ask you to explain technicalities, but are there to weigh in on big-picture items, such as bathing."

Adding a patient's family to rounds also helps them see how doctors come to their conclusions. It creates transparency and is less confusing, added an audience member. Plus, you eliminate the need to explain things again to families after rounds.

"You are part of the team," Dr. Gross said, describing what she tells the family of patients. "You know your loved one so much better than we do. We rely on you." ■

Best of ATS Store

The Best of the ATS Conference collection features recordings of the major part of attendee education at the conference, including postgraduate courses, scientific symposia, core curriculum sessions, and workshops. This yearly compilation of live education is offered in individual sessions or select track packages and can be purchased at the Best of ATS Education Product Booth, located in the Sails Pavilion (Upper Level) of the San Diego Convention Center. A 10 percent discount is available through Wednesday, May 23.

Sean Agbor-Enoh (center) celebrates his BEAR Cage Award with two colleagues.

BEAR Cage Competition Names a Winner

Sean Agbor-Enoh, MD, PhD, took home the fourth annual BEAR Cage prize on Monday afternoon. He pitched a serum-based genomics system to detect early stage antibody-mediated lung allograft rejection to improve survival. The device uses next generation genomic screening to detect cell-free donor DNA in graft recipient plasma.

The combination of cell-free donor DNA and circulating antibodies can identify antibody-mediated rejection three to four weeks earlier than current methods, which require lung biopsy. The procedure costs about $400, compared to up to $5,000 for a biopsy, and requires only a standard blood draw.

This was Dr. Agbor-Enoh's second appearance in the competition. He is a researcher at the National Heart, Lung, and Blood Institute. ■

ATS Daily Bulletin
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Regrettably, we incorrectly identified Dr. Kirsten Bibbins-Domingo as Kristen in yesterday's paper. We apologize for the mistake.

A Life of Lessons at the Women's Forum

She has learned many lessons over a lifetime of service. Some are practical: Chilblains are very painful. Others relate to careers: You must learn to market yourself. Still others are more inspirational: Embrace opportunities and take risks. All of them play a part in what she calls the multicolored quilt of her life.

A. Sonia Buist, professor emerita of medicine at Oregon Health & Science University, was this year's featured speaker at the ATS Women's Forum, an annual event that recognizes the achievements and supports the advancements of women in pulmonary, critical care, and sleep medicine and research. There, she spoke fondly of her colorful life, recalling growing up in India and completing medical school in Scotland. But most of her focus was on the lessons she learned early in her career at OHSU.

Dr. Buist said having mentors taught her the importance of mentorship.

"You NEED a mentor," she said. "If you do not have a mentor, you probably will not succeed, or at least not achieve your potential. If it hadn't been for my mentors, I wouldn't be standing here today."

She said no matter who you are or what your age, you can always benefit from having a mentor. She provided attendees with her own ABCs of mentorship, including finding one who is available, builds you up, and creates opportunities for you.

You should always embrace opportunities and take risks, Dr. Buist said.

"Always be prepared to say yes if you're asked to give a talk, join a committee, take on a responsibility, or go to a meeting. If you say no, the invitations will stop coming. And if you decide to say yes, do a fantastic job."

Dr. Buist said that over her lifetime, she has learned the delicate balance of work, family, and life. There are many barriers to an optimal quality of life, she said. Chief among these is time. But other barriers include the juggling of your professional and private life, traveling for work too much, financial burdens, being chronically tired with no energy, ill health, and geographic location.

"All these lead to supreme guilt. So, what are the lessons learned? I stopped feeling guilty," she said to much applause. "I gave away my guilt, and it changed everything." She said that on the wall in her home and in her office is her motto that she says to herself every day: "What I do today is very important because I am exchanging a day of my life for it."

Finally, Dr. Buist said, she has learned that you have to network like crazy.

"Take a careful look at what you can bring to the party and market yourself. The world is probably not going to come to you, so step out of your comfort zone and go get it."

Among her many achievements, Dr. Buist served as ATS president, started the ATS MECOR (Methods in Epidemiologic, Clinical, and Operations Research) program, and started the BOLD (Burden of Obstructive Lung Disease) Study to get good estimates of COPD prevalence.

Also at the Women's Forum, the 2018 Elizabeth A. Rich, MD Award was presented to V. Courtney Broaddus, MD, professor of medicine and associate director of the Lung Biology Center at the University of California San Francisco. Honoring the memory and work of Elizabeth Rich, MD, the award is given to a woman who has made significant achievements in the practice or science of pulmonary, critical care, or sleep medicine; demonstrated leadership in her field; and has shown dedicated mentorship of junior colleagues. ■

> "Always be prepared to say yes if you're asked to give a talk, join a committee, take on a responsibility, or go to a meeting. If you say no, the invitations will stop coming. And if you decide to say yes, do a fantastic job."
>
> **A. Sonia Buist**

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- Host susceptibility factors that **increase risk** for NTM include bronchiectasis, COPD, asthma, and other conditions or specific genetic disorders that cause structural lung damage and impaired clearance[8-10]
    - Patients with susceptibility factors, such as these underlying lung conditions, who present with pulmonary (eg, chronic cough) and nonspecific systemic symptoms (eg, malaise or fever) **should be assessed for NTM**[9,11]

Visit **NTMFacts.com** for more information.

References: 1. Griffith DE, Aksamit T, Brown-Elliott BA, et al; for the ATS Mycobacterial Diseases Subcommittee. *Am J Respir Crit Care Med.* 2007;175(4):367-416. **2.** Winthrop KL, McNelley E, Kendall B, et al. *Am J Respir Crit Care Med.* 2010;182(7):977-982. **3.** Park HY, Jeong B-H, Chon HR, Jeon K, Daley CL, Koh W-J. *Chest.* 2016;150(6):1222-1232. **4.** Adjemian J, Olivier KN, Seitz AE, Holland SM, Prevots DR. *Am J Respir Crit Care Med.* 2012;185(8):881-886. **5.** Fleshner M, Olivier KN, Shaw PA, et al. *Int J Tuberc Lung Dis.* 2016;20(5):582-587. **6.** Wagner D, van Ingen J, Adjemian J, et al. Poster presented at: European Respiratory Society (ERS) Annual Congress; September 6-10, 2014; Munich, Germany. **7.** Kotilainen H, Valtonen V, Tukiainen P, Poussa T, Eskola J, Järvinen A. *Eur J Clin Microbiol Infect Dis.* 2015;34(9):1909-1918. **8.** Andréjak C, Nielsen R, Thomsen VØ, Duhaut P, Sørensen HT, Thomsen RW. *Thorax.* 2013;68(3):256-262. **9.** Fritscher LG, Marras TK, Bradi AC, Fritscher CC, Balter MS, Chapman KR. *Chest.* 2011;139(1):23-27. **10.** Szymanski EP, Leung JM, Fowler CJ, et al. *Am J Respir Crit Care Med.* 2015;192(5):618-628. **11.** Young JD, Balagopal A, Reddy NS, Schlesinger LS. *J Respir Dis.* 2007;28(1):7-18.

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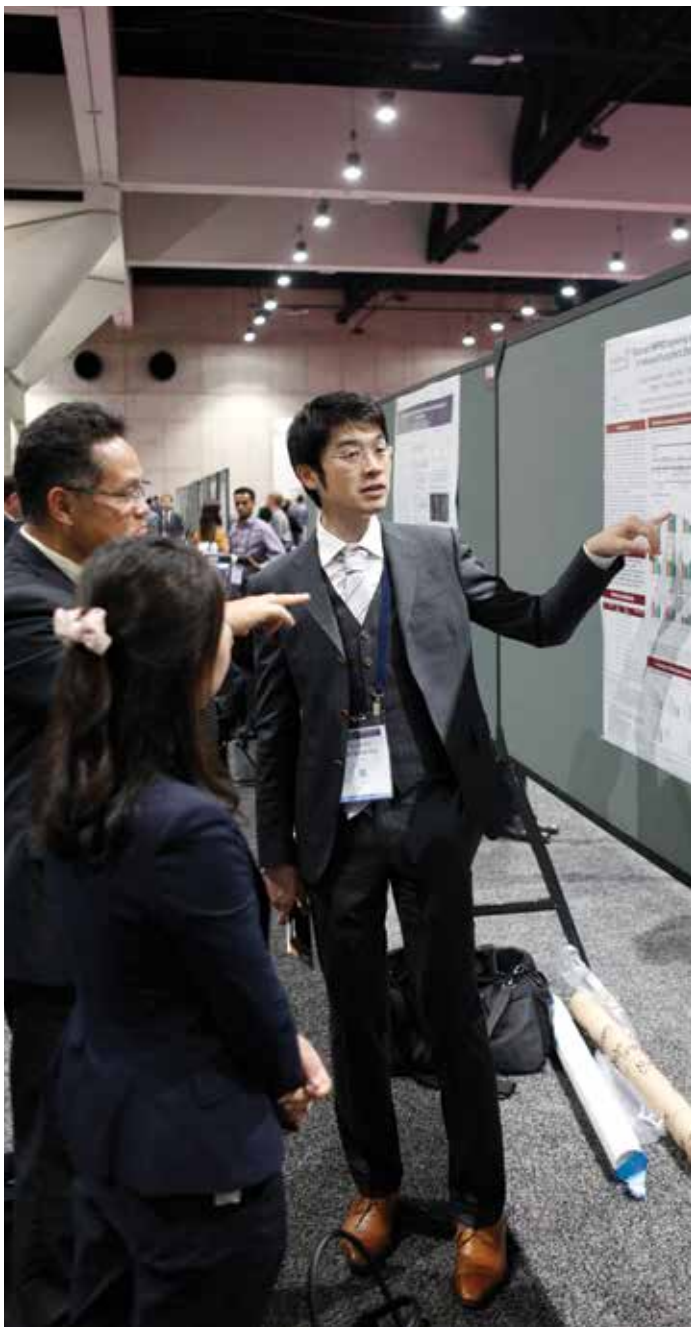
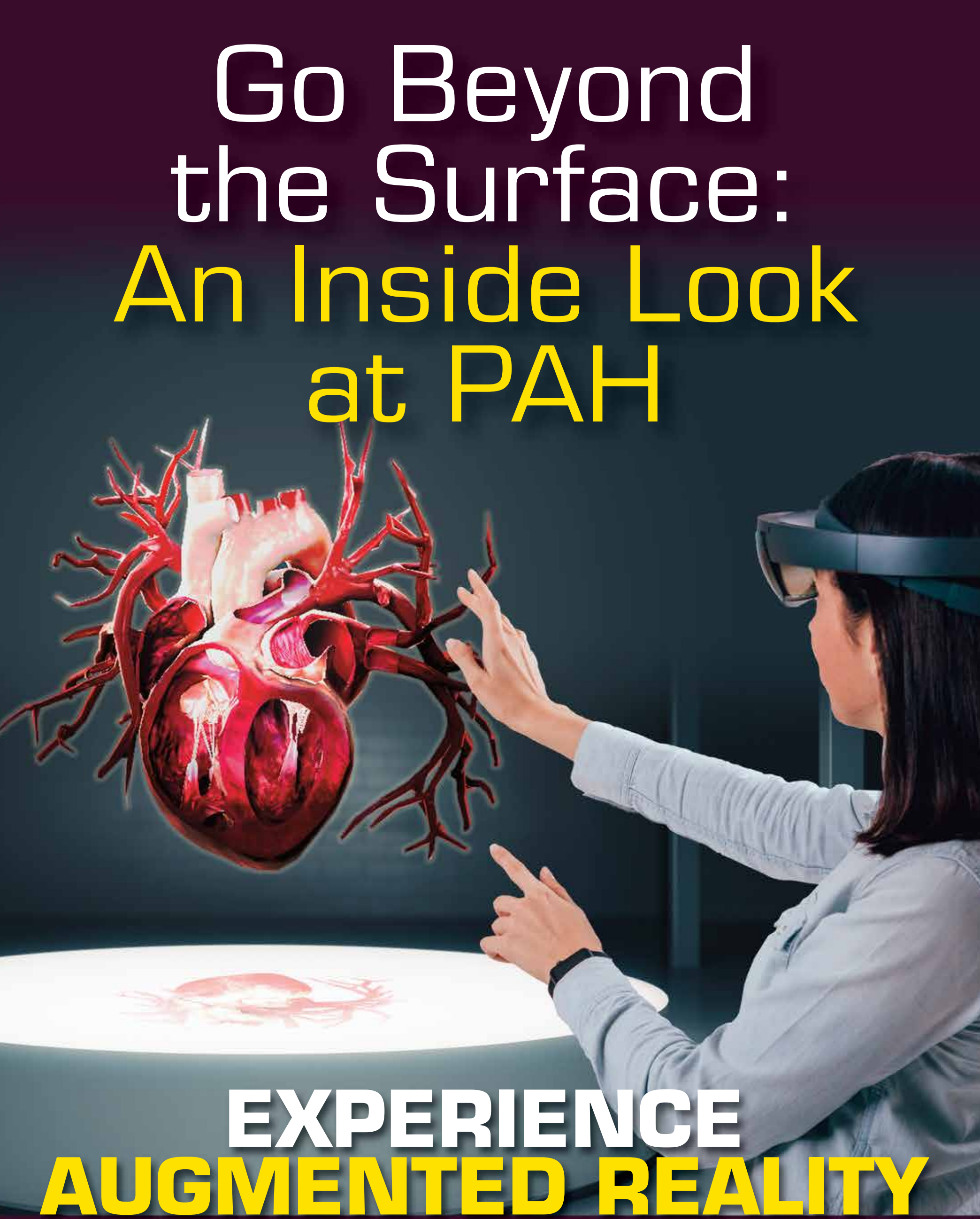


Making the Most of ATS 2018

With the conference in full swing, attendees found plenty of places for networking and learning. Whether it was in a popular session, on the Exhibit Hall floor, or during a poster presentation, they took advantage of everything ATS 2018 has to offer.

Go Beyond the Surface: An Inside Look at PAH



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Q&A Polly Parsons: From Poster Presenter to ATS President

Polly Parsons, MD, will serve as president of the ATS for the 2018-2019 term. She is the E. L. Amidon Professor of Medicine and chair of the Department of Medicine at the University of Vermont.

Q Do you remember your first ATS International Conference?

A: I attended my first ATS International Conference when I was a fellow at the University of Colorado. It was clear that the ATS was the professional "home" for the faculty in Colorado, and I was thrilled that first year to have a poster accepted for presentation. The program was filled with luminaries in the field—it was exciting, and a bit intimidating.

I was incredibly nervous about presenting my poster even though I had been well prepared by my mentors. In the days prior to my session, I attended others where there was vigorous debate and probing questions, and I wasn't sure what to hope for: that no one would stop by and ask questions or that my poster would generate a lot of questions, even if I couldn't answer them all.

Q How did your presentation go?

A: My fears were unfounded. People with names I recognized as leaders in the field graciously asked me to tell them about my work. They did ask questions, but it was an interactive dialogue with strong encouragement for what I was doing.

Q Did that experience convince you that the ATS was also your professional home?

A: I have attended the ATS almost every year since then, missing only for events such as the birth of my oldest son. As a fellow, I saw the ATS as a place to present my work, hear about cutting-edge science, and begin to develop colleagues and collaborators beyond my own institution. Early on as a junior faculty member, I became involved in my assembly and was invited to serve on an ATS committee. Those opportunities expanded my network of colleagues, allowed me to contribute back to the ATS, and provided ongoing leadership experience.

Q Why did you want to become the ATS president?

A: Being president of the ATS is an extraordinary honor and responsibility. It is not actually a position that I spent my career planning for. When I was a fellow and junior faculty member, the ATS presidents were the senior statesmen and women in the field, far ahead of me in their careers in roles that seemed distant, like professor, division chief, department chair, or medical school dean. Over time, colleagues with whom I had grown up professionally began to assume leading roles in the ATS, and I realized that I, too, might be able to give back to the organization that gave me so much.

The ATS is a strong organization built on a foundation of extraordinary staff and volunteers who dedicate tremendous time and expertise to ensure its success. It is a privilege to be able to serve the ATS.

Q From cutting federal support of health care to rolling back clean air regulations, the current administration in Washington often champions policies that the ATS opposes. What is the ATS doing to ensure that the voices of its members and, more importantly, the patients they serve, are heard in the nation's capital?

A: The ATS tagline, "We help the world breathe," reflects our core mission. Nationally and internationally, the ATS is known for advancing respiratory health through its commitment to science and the dissemination of new knowledge. The ATS has a strong voice in our nation's capital through our advocacy program led by Gary Ewart in our Washington office. The ATS Executive Committee meets regularly with senior leaders at the NIH, EPA, FDA, and other key organizations; members of ATS provide testimony to Congress on key issues; and the ATS pursues court actions.

In addition, Gary and his colleague Nuala Moore organize Hill Day events, during which ATS leaders and members visit Congressional leaders to advocate for all aspects of respiratory health—from scientific funding to clinical care. The impact of these visits are magnified by the presence of the ATS Public Advisory Roundtable representatives who directly bring the voice of our patients into the conversations.

Members of ATS Chapters are also actively involved in the advocacy efforts, and each year the number of chapters increases, which provides more opportunities for regional and state advocacy. The ATS also advocates internationally through the Forum of International Respiratory Societies, which continues to emphasize the global burden of lung disease.

Q At the end of your presidency if you could be known for one thing, what would it be?

A: I think that's the wrong question. The ATS is much bigger than its president. I hope the ATS continues to be known as the leading society for the advancement of lung health. My colleagues on the Executive Committee and I work as a close-knit team and are focused collaboratively on broad initiatives to enhance the value of ATS for each of its members and sustain the growth and success of the organization.

This will also be a year of leadership transition beyond the transition of the presidency from Marc Moss to me. Steve Crane, the ATS executive director for more than 10 years, is retiring, and we welcome Karen Collishaw to the organization. We will miss Steve's expertise and steady hand on the tiller (he is a sailor!), but it is also exciting to welcome someone new to the organization who will bring new ideas and opportunities. ■

Product Showcase

Recognizing CLAD May Improve Transplant Results

Chronic lung allograft dysfunction is nothing new. It even has an established acronym, CLAD. But emerging data show a pathophysiology that is more complex than many clinicians or researchers realize. CLAD comes in multiple phenotypes and at least two distinct flavors.

"We have gotten very good over the past 20 years or so at selecting patients for transplant and getting them through the postoperative phase," says Allan R. Glanville, MBBS, MD, past president of the International Society for Heart and Lung Transplantation and conjoint professor of medicine at the University of New South Wales in Sydney, Australia. "The short-term results have improved dramatically. But the longer-term results, when you look at conditional survival after the first year, haven't improved terribly much."

Allan R. Glanville, MBBS, MD

> "We have gotten very good over the past 20 years or so at selecting patients for transplant and getting them through the postoperative phase."
>
> **Allan R. Glanville, MBBS, MD**

Dr. Glanville will co-chair Wednesday's session. He will share the platform with Elizabeth Anne Belloli, MD, assistant professor of medicine, and Vibha N. Lama, MD, MS, professor of pulmonary/critical care medicine, both from the University of Michigan.

As the number of lung transplants grows, so does the number of patients with CLAD. About 4,000 lung transplants are reported annually to ISHLT registry. Most are conducted in North America. More than 36,000 lung transplants have been conducted between January 1988 and February 2018 in the U.S. alone, according to the Organ Procurement and Transplantation Network.

Understanding Chronic Lung Allograft Dysfunction: Update From the Bedside and Bench (D2)

9:15-11:15 a.m.

Wednesday

Ballroom 20 B-C (Upper Level), San Diego Convention Center

BETWEEN
JANUARY 1988 & FEBRUARY 2018
MORE THAN
36,000
LUNG TRANSPLANTS
HAVE BEEN CONDUCTED IN THE U.S. ALONE

Organ Procurement and Transplantation Network

The growing recognition of different phenotypes of CLAD dawned as researchers began to realize that the traditional focus on bronchiolitis obliterans syndrome could not fully explain the varieties of allograft dysfunction that were being seen in clinical practice. There are at least two mechanisms at work: one destructive of the small airways, the other a restrictive fibrosis that involves the parenchyma of the lung.

Both mechanisms lead to CLAD, but the biomolecular pathways and risk factors have yet to be identified. A working group drawn from the ISHLT, the ATS, and other organizations is looking at how best to define CLAD and how to define the different phenotypes that have been observed.

Neither the destructive nor the restrictive mechanisms have been fully characterized, Dr. Glanville notes. Both appear to be largely the result of rejection, a mix of early cellular rejection and later-stage antibody-mediated rejection. Antibody-mediated rejection in turn may be HLA-dominant or dominated by antibodies produced to cryptic antigens exposed in the graft following infection or some other insult.

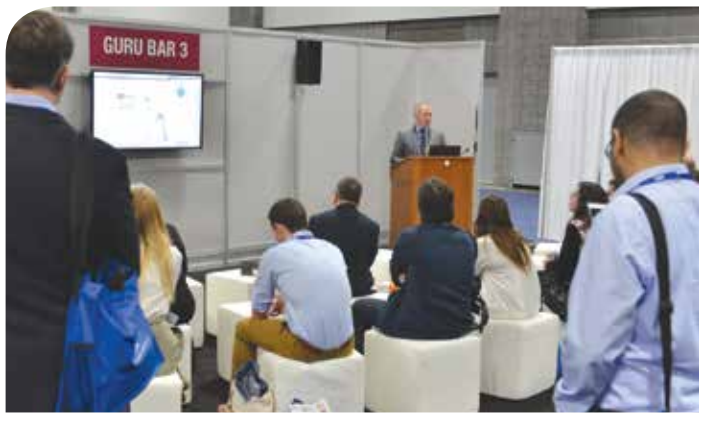
"If the immune system isn't properly controlled following a viral infection or something similar, you can develop antibodies that go on to cause fibrotic damage," Dr. Glanville says. "That is what we think probably happens with grafts that end up fibrosing with CLAD."

One of the key issues dealing with CLAD is the lack of assays and other diagnostics. There is currently no way to stratify patients by their risk of developing CLAD and no clear strategies to reduce risk of either the destructive or the restrictive forms of chronic allograft dysfunction.

"If we can focus attention on the causes, the mechanisms, and the pathophysiology of the different forms of CLAD, we might be able to develop some solutions and more effective management strategies," Dr. Glanville says. "Recognizing that CLAD comes in different forms should be a game changer. We don't have the solutions, but this symposium takes you through real cases to help you think about CLAD more broadly, to think about the evidence, and to use the consensus guidelines to best manage your patients." ■

Guru Bars Invite Interaction

Guru Bars are quick-burst learning sessions that allow you to collaborate with leaders on a variety of topics. Every session offers a 10-minute outline of a problem statement, mitigating factors, the host's perspective/solution, and a challenge or question posted to participants, who discuss it for the remaining 5 to 10 minutes.



Each Guru Bar seats 25 participants to create a dynamic, yet intimate, group with lots of interaction. *Guru Bars are located in the Exhibit Hall (Hall F, Ground Level).*

GURU BAR 1
Education/Awareness/Prevention or Diagnosis

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

Role of Biomarkers in Therapy Selection and Recurrence Prediction

Clinicians face numerous challenges in the management of patients with early stage lung cancer. One of the most difficult aspects is determining the risk of recurrence for early stage patients that are treated surgically. Current treatment options have limited effectiveness, and diagnostic tools often provide very limited recurrence risk information. During this interactive, case-based Guru Bar, you will hear from experts in the field regarding the need for new biomarkers to better assess the risk of recurrence and their future role in clinical practice.

Speaker: **David M. Jablons, MD**, *distinguished professor of thoracic oncology, UCSF Helen Diller Comprehensive Cancer Center*

Company: OncoCyte Corporation

12:30-1 p.m.

More Than an Airway Problem? Understanding Excessive Sleepiness in Obstructive Sleep Apnea

Emerging science suggests that one potential cause of excessive sleepiness in obstructive sleep apnea may be alterations to wake-promoting regions of the brain resulting from chronic intermittent hypoxia and sleep fragmentation. This presentation provides an overview of several relevant studies on this topic. Prevalence and consequences of ES in OSA are also discussed, as well as information related to tools for assessment of ES in clinical practice.

Speaker: **Terri E. Weaver, PhD, RN**, *dean and professor of nursing, University of Illinois at Chicago, College of Nursing*

Company: Jazz Pharmaceuticals, Inc.

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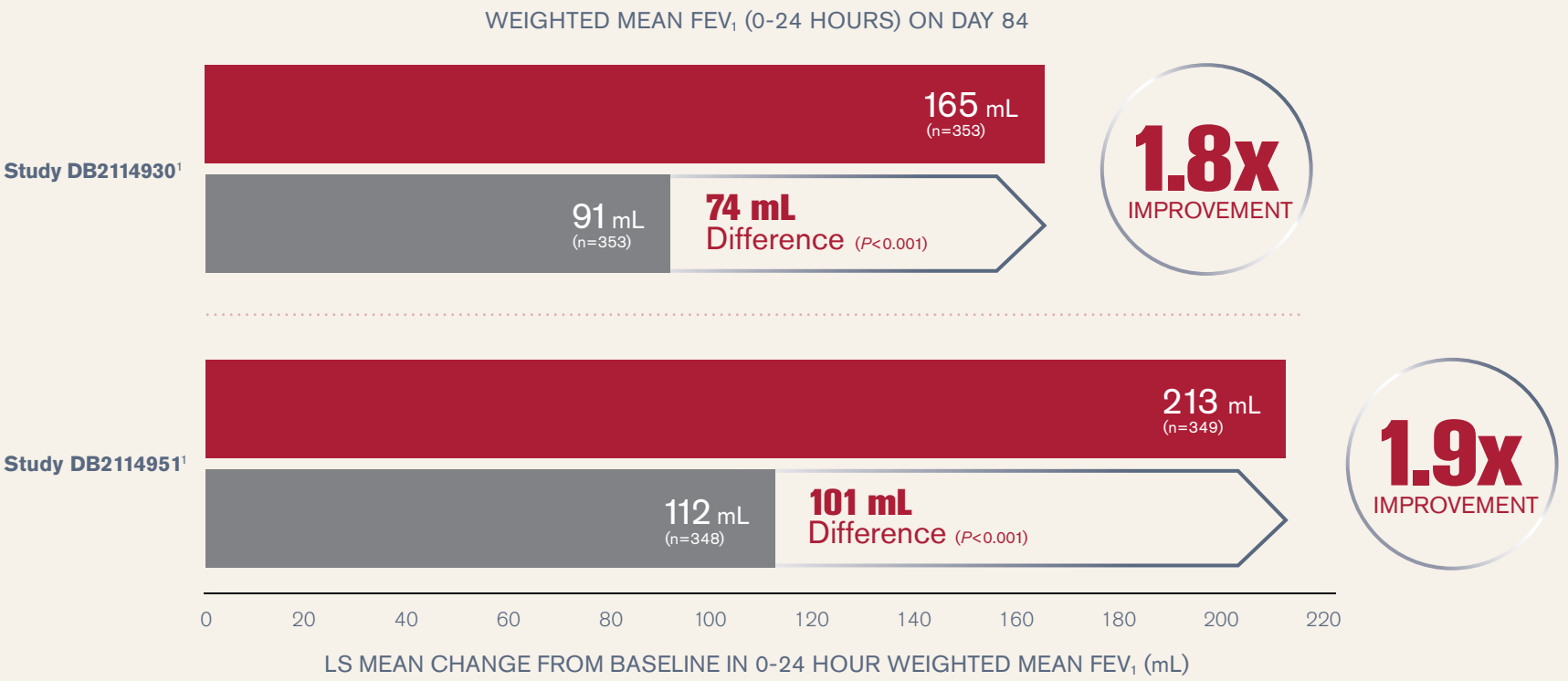


- **ANORO ELLIPTA** is a combination anticholinergic/LABA for the maintenance treatment of airflow obstruction in patients with COPD.
- **FP/SAL 250/50 mcg**, an ICS/LABA, is for the maintenance treatment of airflow obstruction in patients with COPD and for reducing exacerbations in patients with a history of exacerbations.

  Studied in patients with moderate to severe COPD (GOLD 2 or 3).

WHAT WOULD ALMOST 2X THE LUNG FUNCTION IMPROVEMENT MEAN FOR YOUR PATIENTS?

Description of studies[1,2]
The efficacy and safety of a once-daily dose of ANORO ELLIPTA and a twice-daily dose of FP/SAL 250 mcg/50 mcg (administered via the DISKUS inhaler) were evaluated in two 12-week, multicenter, randomized, double-blind, double-dummy, parallel-group studies in patients (mean age range: 63 to 64 years) with COPD with no exacerbations (COPD symptoms requiring oral corticosteroids, antibiotics, and/or hospitalization) in the previous year. At screening, patients had a mean postbronchodilator FEV_1 range of 49.4% to 49.5% predicted. The studies were not powered to compare the safety profiles of the products.

Primary endpoint: Weighted mean FEV_1 (0-24 hours postdose) on Day 84.

FEV_1=forced expiratory volume in 1 second; FP=fluticasone propionate; GOLD=Global Initiative for Chronic Obstructive Lung Disease; ICS=inhaled corticosteroid; LS=least squares; SAL=salmeterol.

Important Safety Information for ANORO ELLIPTA (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- Caution should be exercised when considering the coadministration of ANORO with long-term ketoconazole and other known strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased cardiovascular adverse effects may occur.
- If paradoxical bronchospasm occurs, discontinue ANORO and institute alternative therapy.
- Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of ANORO. Discontinue ANORO 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, or symptoms. If such effects occur, ANORO may need to be discontinued. ANORO should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.
- Use with caution in patients with narrow-angle glaucoma. Instruct patients to contact a healthcare provider immediately if signs or symptoms of acute narrow-angle glaucoma develop.
- Use with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to contact a healthcare provider immediately if signs or symptoms of urinary retention develop.
- Be alert to hypokalemia and hyperglycemia.

ADVERSE REACTIONS

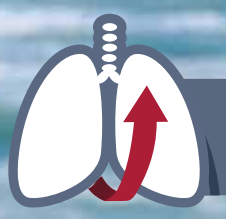
- The most common adverse reactions (≥1% and more common than placebo) reported in four 6-month clinical trials with ANORO (and placebo) were: pharyngitis, 2% (<1%); sinusitis, 1% (<1%); lower respiratory tract infection, 1% (<1%); constipation, 1% (<1%); diarrhea, 2% (1%); pain in extremity, 2% (1%); muscle spasms, 1% (<1%); neck pain, 1% (<1%); and chest pain, 1% (<1%).
- In addition to the 6-month efficacy trials with ANORO, a 12-month trial evaluated the safety of umeclidinium/vilanterol 125 mcg/25 mcg in subjects with COPD. Adverse reactions (incidence ≥1% and more common than placebo) in subjects receiving umeclidinium/vilanterol 125 mcg/25 mcg were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

*Based on IMS US Rx data as of March 2018.

WHY HOLD BACK?

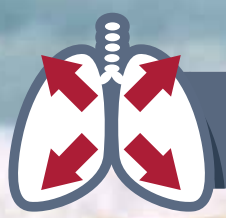
Start strong with ANORO

"My doctor started me on ANORO. Now I'm breathing better and back to doing the things I enjoy."



Superior lung function vs the leading* ICS/LABA for COPD[1]

*Based on IMS US Rx data as of March 2018.



ANORO can play an important role in maximizing bronchodilation[3†]

GOLD 2018

Continues to place a greater emphasis on the role of LAMA/LABA for patients with COPD[4‡]

GOLD recommendations do not include ICS/LABA as preferred initial treatment for most patients[4]

ANORO was studied in patients with moderate or worse COPD.

†Defined as statistically significant improvements in lung function relative to its individual components and placebo in a 24-week, randomized, double-blind study in patients with COPD (N=1532).
‡Compared with GOLD 2016 Report.

Important Safety Information for ANORO ELLIPTA (cont'd)

DRUG INTERACTIONS

- Caution should be exercised when considering the coadministration of ANORO with ketoconazole and other known strong CYP3A4 inhibitors as increased systemic exposure to vilanterol and cardiovascular adverse effects may occur. See prior Warning and Precaution regarding CYP3A4 inhibitors.
- ANORO 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 they may potentiate the effect of vilanterol on the cardiovascular system.
- Use beta-blockers with caution as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.
- Use with caution in patients taking non–potassium-sparing diuretics, as ECG changes and/or hypokalemia associated with these diuretics may worsen with concomitant beta-agonists.
- Avoid coadministration of ANORO with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects.

Please see additional Important Safety Information for ANORO ELLIPTA on the previous pages.

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

References: 1. Donohue JF, Worsley S, Zhu C-Q, et al. Improvements in lung function with umeclidinium/vilanterol versus fluticasone propionate/salmeterol in patients with moderate-to-severe COPD and infrequent exacerbations. *Respir Med.* 2015;109(7):870-881. **2.** Data on file, GSK. **3.** Donohue JF, Maleki-Yazdi MR, Kilbride S, et al. Efficacy and safety of once-daily umeclidinium/vilanterol 62.5/25 mcg in COPD. *Respir Med.* 2013;107(10):1538-1546. **4.** Global Initiative for Chronic Obstructive Lung Disease. *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease.* 2018 report. www.goldcopd.org. Accessed February 5, 2018.

*Based on IMS US Rx data as of March 2018.

Learn more at StartWithANORO.com

ANORO ELLIPTA was developed in collaboration with INNOVIVA

Visit GSK Booth #1734

#1 PRESCRIBED LAMA/LABA IN THE US*

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

ANORO ELLIPTA **BRIEF SUMMARY**

(umeclidinium and vilanterol inhalation powder), for oral inhalation

The following is a brief summary only; see full prescribing information for complete product information.

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in ANORO ELLIPTA, 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 *[see Warnings and Precautions (5.1)]*.

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

1 INDICATIONS AND USAGE

ANORO ELLIPTA is a combination anticholinergic/long-acting beta$_2$-adrenergic agonist (anticholinergic/LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Important Limitations of Use: ANORO ELLIPTA is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Asthma-Related Death

Data from a large placebo-controlled trial in subjects with asthma showed that LABA may increase the risk of asthma-related death. Data are not available to determine whether the rate of death in patients with COPD is increased by LABA.

A 28-week, placebo-controlled, US trial comparing the safety of another LABA (salmeterol) with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in subjects receiving salmeterol (13/13,176 in subjects treated with salmeterol vs. 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25, 15.34]). The increased risk of asthma-related death is considered a class effect of LABA, including vilanterol, one of the active ingredients in ANORO ELLIPTA.

No trial adequate to determine whether the rate of asthma-related death is increased in subjects treated with ANORO ELLIPTA has been conducted. The safety and efficacy of ANORO ELLIPTA in patients with asthma have not been established. ANORO ELLIPTA is not indicated for the treatment of asthma.

5.2 Deterioration of Disease and Acute Episodes

ANORO ELLIPTA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. ANORO ELLIPTA has not been studied in subjects with acutely deteriorating COPD. The initiation of ANORO ELLIPTA in this setting is not appropriate.

ANORO ELLIPTA should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. ANORO ELLIPTA has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist. When beginning treatment with ANORO ELLIPTA, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs and to use them only for symptomatic relief of acute respiratory symptoms. When prescribing ANORO ELLIPTA, the healthcare provider should also prescribe an inhaled, short-acting beta$_2$-agonist and instruct the patient on how it should be used. Increasing inhaled, short-acting beta$_2$-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated.

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If ANORO ELLIPTA no longer controls symptoms of bronchoconstriction; the patient's inhaled, short-acting beta$_2$-agonist becomes less effective; or the patient needs more short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting a reevaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of ANORO ELLIPTA beyond the recommended dose is not appropriate in this situation.

5.3 Excessive Use of ANORO ELLIPTA and Use with Other Long-acting Beta$_2$-agonists

ANORO ELLIPTA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using ANORO ELLIPTA should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

5.4 Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors

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

5.5 Paradoxical Bronchospasm

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

5.6 Hypersensitivity Reactions

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

5.7 Cardiovascular Effects

Vilanterol, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, or symptoms *[see Clinical Pharmacology (12.2) of full prescribing information]*. If such effects occur, ANORO ELLIPTA may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiographic changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Therefore, ANORO ELLIPTA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

5.8 Coexisting Conditions

ANORO ELLIPTA, like all medicines containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis and in those who are unusually responsive to sympathomimetic amines. Doses of the related beta$_2$-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

5.9 Worsening of Narrow-Angle Glaucoma

ANORO ELLIPTA should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

5.10 Worsening of Urinary Retention

ANORO ELLIPTA should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

5.11 Hypokalemia and Hyperglycemia

Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Beta-agonist medicines may produce transient hyperglycemia in some patients. In 4 clinical trials of 6-month duration evaluating ANORO ELLIPTA in subjects with COPD, there was no evidence of a treatment effect on serum glucose or potassium.

6 ADVERSE REACTIONS

LABA, such as vilanterol, one of the active ingredients in ANORO ELLIPTA, increase the risk of asthma-related death. ANORO ELLIPTA is not indicated for the treatment of asthma. *[See Boxed Warning and Warnings and Precautions (5.1).]*

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

- Paradoxical bronchospasm *[see Warnings and Precautions (5.5)]*
- Cardiovascular effects *[see Warnings and Precautions (5.7)]*
- Worsening of narrow-angle glaucoma *[see Warnings and Precautions (5.9)]*
- Worsening of urinary retention *[see Warnings and Precautions (5.10)]*

6.1 Clinical Trials Experience

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

The clinical program for ANORO ELLIPTA included 8,138 subjects with COPD in four 6-month lung function trials, one 12-month long-term safety study, and 9 other trials of shorter duration. A total of 1,124 subjects have received at least 1 dose of ANORO ELLIPTA (umeclidinium/vilanterol 62.5 mcg/25 mcg), and 1,330 subjects have received a higher dose of umeclidinium/vilanterol (125 mcg/25 mcg). The safety data described below are based on the four 6-month and the one 12-month trials. Adverse reactions observed in the other trials were similar to those observed in the confirmatory trials.

6-Month Trials

The incidence of adverse reactions associated with ANORO ELLIPTA in Table 1 is based on four 6-month trials: 2 placebo-controlled trials (Trials 1 and 2; n = 1,532 and n = 1,489, respectively) and 2 active-controlled trials (Trials 3 and 4; n = 843 and n = 869, respectively). Of the 4,733 subjects, 68% were male and 84% were white. They had a mean age of 63 years and an average smoking history of 45 pack-years, with 50% identified as current smokers. At screening, the mean postbronchodilator percent predicted forced expiratory volume in 1 second (FEV_1) was 48% (range: 13% to 76%), the mean postbronchodilator FEV_1/forced vital capacity (FVC) ratio was 0.47 (range: 0.13 to 0.78), and the mean percent reversibility was 14% (range: -45% to 109%).

Subjects received 1 dose once daily of the following: ANORO ELLIPTA, umeclidinium/vilanterol 125 mcg/25 mcg, umeclidinium 62.5 mcg, umeclidinium 125 mcg, vilanterol 25 mcg, active control, or placebo.

Table 1. Adverse Reactions with ANORO ELLIPTA with ≥1% Incidence and More Common than Placebo in Subjects with Chronic Obstructive Pulmonary Disease

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

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

12-Month Trial

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

6.2 Postmarketing Experience

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

Cardiac Disorders

Palpitations.

Eye Disorders

Blurred vision, glaucoma, increased intraocular pressure.

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis, angioedema, and urticaria.

Nervous System Disorders

Dysgeusia, tremor.

Psychiatric Disorders

Anxiety.

Renal and Urinary Disorders

Dysuria, urinary retention.

Respiratory, Thoracic, and Mediastinal Disorders

Dysphonia, paradoxical bronchospasm.

(continued on next page)

7 DRUG INTERACTIONS

7.1 Inhibitors of Cytochrome P450 3A4

Vilanterol, a component of ANORO ELLIPTA, is a substrate of CYP3A4. Concomitant administration of the strong CYP3A4 inhibitor ketoconazole increases the systemic exposure to vilanterol. Caution should be exercised when considering the coadministration of ANORO ELLIPTA with ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) *[see Warnings and Precautions (5.4), Clinical Pharmacology (12.3) of full prescribing information]*.

7.2 Monoamine Oxidase Inhibitors and Tricyclic Antidepressants

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

7.3 Beta-adrenergic Receptor Blocking Agents

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

7.4 Non–Potassium-Sparing Diuretics

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

7.5 Anticholinergics

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects

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

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

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

Nonteratogenic Effects

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

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

8.2 Labor and Delivery

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

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

8.3 Nursing Mothers

ANORO ELLIPTA

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

Umeclidinium

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

Vilanterol

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

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

8.6 Hepatic Impairment

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

8.7 Renal Impairment

There were no significant increases in either umeclidinium or vilanterol exposure in subjects with severe renal impairment (CrCl 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 case of overdose has been reported with ANORO ELLIPTA.

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

10.1 Umeclidinium

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

10.2 Vilanterol

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

ANORO ELLIPTA

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

Umeclidinium

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

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

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

Vilanterol

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

In a 2-year carcinogenicity study in rats, vilanterol caused statistically significant increases in mesovarian leiomyomas in females and shortening of the latency of pituitary tumors at inhalation doses greater than or equal to 84.4 mcg/kg/day (greater than or equal to approximately 20 times the MRHDID in adults on an AUC basis). No tumors were seen at an inhalation dose of 10.5 mcg/kg/day (approximately 1 time the MRHDID in adults on an AUC basis). These tumor findings in rodents are similar to those reported previously for other beta-adrenergic agonist drugs. The relevance of these findings to human use is unknown.

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

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

17 PATIENT COUNSELING INFORMATION

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

Asthma-Related Death

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

Not for Acute Symptoms

Inform patients that ANORO ELLIPTA is not meant to relieve acute symptoms of COPD and extra doses should not be used for that purpose. Advise patients to treat acute symptoms with an inhaled, short-acting beta$_2$-agonist such as albuterol. Provide patients with such medicine and instruct them in how it should be used.

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

- 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 ANORO ELLIPTA without healthcare provider guidance since symptoms may recur after discontinuation.

Do Not Use Additional Long-acting Beta$_2$-agonists

Instruct patients not to use other medicines containing a LABA. Patients should not use more than the recommended once-daily dose of ANORO ELLIPTA.

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

Paradoxical Bronchospasm

As with other inhaled medicines, ANORO ELLIPTA can cause paradoxical bronchospasm. If paradoxical bronchospasm occurs, instruct patients to discontinue ANORO ELLIPTA and contact their healthcare provider right away.

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.

Worsening of Narrow-Angle Glaucoma

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

Worsening of Urinary Retention

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

ANORO ELLIPTA was developed in collaboration with INNOVIVA

GlaxoSmithKline
Research Triangle Park, NC 27709

Revised 10/2017 ANR:5BRS

Printed in USA. 1002556R0 April 2018

An Exciting Time in Pleural Disease Management

How clinical trials are changing patient care

In recent years, multicenter randomized clinical trials have addressed the best approach to common clinical dilemmas in pleural disease management, including malignant pleural effusion, pleural infection, tuberculous pleural effusion, and pneumothorax. The Tuesday symposium State-of-the-Art Pleural Disease Management: Clinical Trials Changing Care Practice addresses these advances.

State-of-the-Art Pleural Disease Management: Clinical Trials Changing Care Practice (C3)

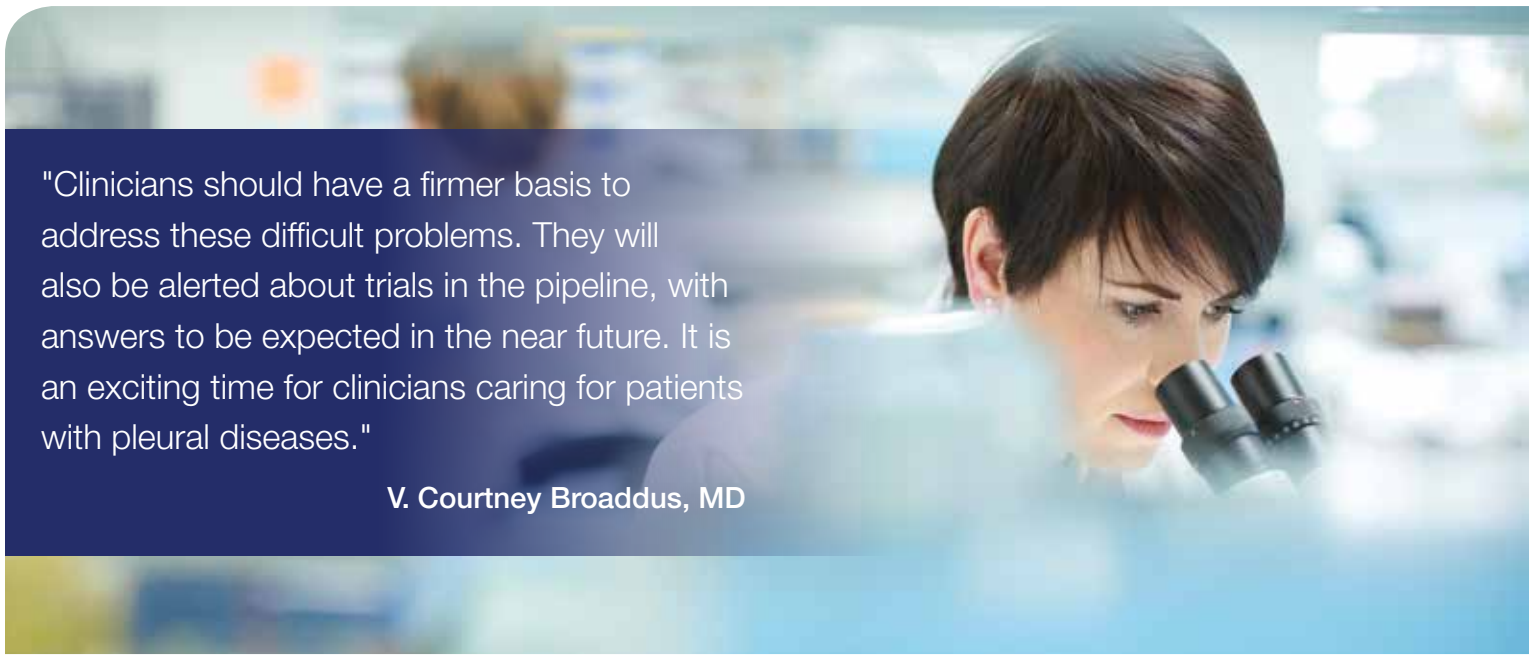
9:15-11:15 a.m.

Tuesday

Ballroom 20D (Upper Level), San Diego Convention Center

Chaired by V. Courtney Broaddus, MD, of the University of California, San Francisco, and David J. Feller-Kopman, MD, of Johns Hopkins Hospital, the session will focus on the results coming from clinical trials that are most relevant to the care of patients.

Dr. Broaddus, the John F. Murray Distinguished Professor of Medicine and chief of the division of pulmonary and critical care medicine at San Francisco General Hospital, highlighted the various topics of discussion during the session and what each presenter will cover.



Malignant pleural effusions. "Malignant pleural effusions, a frequent accompaniment of disseminated cancer, present a problem of persistent effusion formation and symptom management for those with a limited life span," Dr. Broaddus says. Nick Maskell, MD, professor of respiratory medicine at the University of Bristol in the U.K., will cover the randomized trials that have defined the benefits of indwelling pleural catheters over talc pleurodesis (TIME-2 and AMPLE). He will present the most recent study, in which the indwelling pleural catheter was used together with talc pleurodesis (IPC-PLUS). In addition, he will review studies showing how to optimize indwelling pleural catheter drainage.

Pleural infections. "Pleural infections are a common, complex, and costly pleural problem in which the drainage often is inadequate, and the management is controversial," Dr. Broaddus says. Y.C. Gary Lee, MBChB, PhD, professor of medicine at the University of Western Australia in Perth, will show what is new since the MIST studies that established the usefulness of tPA/DNase therapy, such as newer studies that aim to refine the delivery regimes. He plans to present practical tips as well as discuss new findings that improve understanding of the pathogenesis of pleural infection.

Tuberculous pleural effusions. Tuberculous pleural effusions continue to be a major cause of pleural effusions worldwide. Coenraad F.N. Koegelenberg, MD, PhD, of the Division of Pulmonology at the University of Stellenbosch in Cape Town, South Africa, will address the impact of new tuberculosis diagnostic tests, the rising incidence of multidrug resistance mycobacteria, and new therapeutic drugs.

Pneumothorax. "Pneumothorax presents a challenging clinical problem, in which the optimal management is unknown, and the practice patterns vary widely," Dr. Broaddus says. Najib Rahman, BM, MCH, MSc, DPhil, associate professor and clinical director of the Oxford Respiratory Trials Unit at the University of Oxford in the U.K., will present new data on the epidemiology of pneumothorax and the results of a recent randomized clinical trial of chemical pleurodesis at first presentation of a patient with pneumothorax. He also will present results from a study comparing no drainage versus tube drainage for primary pneumothorax that may change practice. Finally, he plans to discuss promising devices and technological approaches currently under trial.

Biomarkers for pleural diseases. Biomarkers for the diagnosis and staging of pleural diseases would be most useful in guiding management. José M. Porcel, MD, professor and chief of internal medicine at the Hospital Universitario Arnau De Vilanova in Lleida, Spain, will present an update on new biomarkers that may impact clinical practice.

"Overall, this symposium is aimed at covering new and useful results from studies tackling common pleural conditions," Dr. Broaddus says. "As a result, clinicians should have a firmer basis to address these difficult problems. They will also be alerted about trials in the pipeline, with answers to be expected in the near future. It is an exciting time for clinicians caring for patients with pleural diseases." ■

MyATS Launches Collaboration Feature

Last December, ATS launched the MyATS web platform, an online portal that allows ATS members to customize their web experience by identifying their "favorite" web pages on the ATS website and saving them in their MyATS dashboard. This was Phase I of an ongoing initiative to provide members with an online tool that expands the benefits of membership in ATS.

This month, ATS is launching Phase II, which focuses on expanding members' abilities to collaborate. New features include:

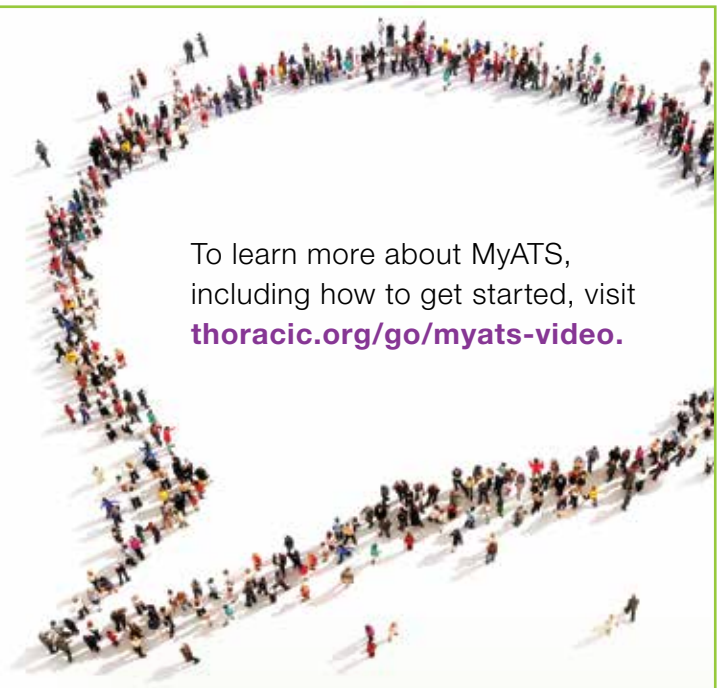
Direct Chat
This allows an ATS member to send a message to other members and initiate an online discussion.

Public Chat Groups
Working through ATS staff, committees, assemblies, and working groups will be able to establish "public" chat groups to discuss interests of common concern, and all ATS members can join the discussion.

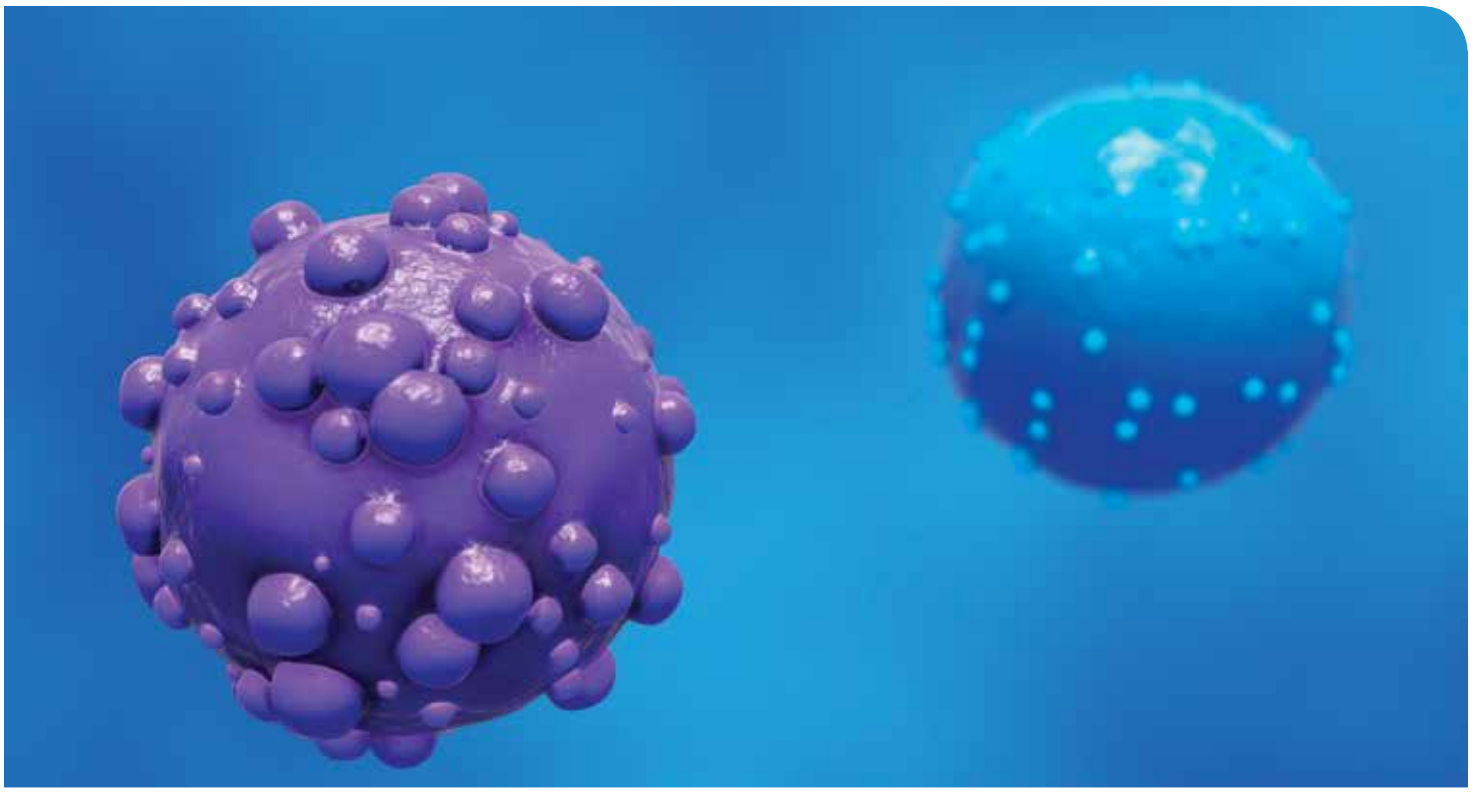
Private Chat Groups
Committees and working groups can establish private chat groups and invite other ATS members to join.

Together, these new features will make MyATS a focal point for future collaboration and networking within ATS.

Additional features are under development, with rollout anticipated at the end of 2018. These include a download and export feature that will facilitate the sharing of information between members engaged in Direct Chat or Chat Groups. ATS also is building a notification via email system so that ATS members will know when they have been invited to join a chat. ■



To learn more about MyATS, including how to get started, visit **thoracic.org/go/myats-video.**



Lung Cancer and the Immune System

New therapies prevent cancer cells from evading immune cell detection and destruction

The relationship between the immune system and cancer is a field under intense investigation. Numerous new therapies that target these interactions are changing the way cancer is treated. This is especially true in lung cancer, as inflammation that is caused by COPD or tobacco smoke is a major risk factor. The Wednesday session, Manipulating Inflammatory and Epithelial Networks for Prevention and Treatment of Lung Cancer, will address these new therapies and more.

> The last three to four years have seen the introduction of immunotherapy to clinical practice. This has dramatically changed how we treat, and even how we think about advanced lung cancer.
>
> **Edwin Ostrin, MD, PhD**

"The session will discuss some of the basic and translational science findings that are providing a better understanding of the interplay between different pieces of the body's inflammatory response and cancer cells," says session moderator Edwin Ostrin, MD, PhD, assistant professor of internal medicine and pulmonary medicine at the University of Texas M.D. Anderson Cancer Center in Houston. "Topics will range from the basic science of new advances in understanding the response of immune cells to cancer cells and the ability of cancer cells to evade detection by immune cells to translational biology, such as harnessing the immune system to prevent lung cancer."

Also speaking will be a patient who will give her perspective on these new therapies, which prevent cancer cells from evading immune cell detection and destruction. Bobbi Johnson-Filipiak was diagnosed with advanced lung cancer, although she was never a smoker, and has had an amazing response to one of the new therapies.

"The last three to four years have seen the introduction of immunotherapy to clinical practice," Dr. Ostrin says. "This has dramatically changed how we treat, and even how we think about advanced lung cancer."

He adds, "Understanding the science behind immune cell/cancer cell crosstalk gives insight into future directions for therapy." ■

Manipulating Inflammatory and Epithelial Networks for Prevention and Treatment of Lung Cancer (D6)

9:15-11:15 a.m.

Wednesday

Room 16 A-B (Mezzanine Level), San Diego Convention Center

Patient Bobbi Johnson-Filipiak provides a perspective on new therapies for lung cancer.

A Patient's Perspective

When Bobbi Johnson-Filipiak went in to the hospital to have her baby, she never expected to leave with a cancer diagnosis. But when she started having strange symptoms after an emergency C-section, a CT scan of her chest revealed stage III lung cancer. Never a smoker, Ms. Johnson-Filipiak was shocked but determined to fight.

She started with a traditional treatment of radiation, chemotherapy, and surgery, which put her into remission for 18 months. But the cancer came back and progressed to stage IV. A biopsy revealed a particular genetic mutation that made her a great candidate for immunotherapy. She joined a clinical trial, and the treatment worked for two years. But then her cancer came back. This time, a biopsy revealed a new mutation that made her eligible for a clinical trial at MD Anderson Cancer Center involving a targeted therapy drug called poziotinib. She began that trial in August 2017, and so far, the results have been good.

"I take just one pill a day now," Ms. Johnson-Filipiak says. "My tumors started shrinking almost immediately, and by the beginning of October 2017, they were half their original size. That just shows you the effectiveness of this drug, which is amazing." Although her dosage had to be reduced twice due to the side effects, her scans since then have been stable, with no growth or reduction.

"I've come to terms with the fact that stable is a good thing in a stage IV situation," she says.

Ms. Johnson-Filipiak says she's looking forward to sharing her story with the attendees at Wednesday's session.

"I think it's important for them to see a patient like myself, who has gone from traditional chemo treatments to advanced immunotherapy treatments through my own advocacy," she said. "It's also an opportunity for me to thank these experts for all of their work and effort in advancing cancer research in the last decade and to encourage them to keep pushing, to keep fighting for me and other cancer patients." ■

ATS Debuts Critical Care Board Review Book

Fellows preparing for the ABIM critical care certification exam on Nov. 12 now have a new resource: the ATS Review for the Critical Care Boards.

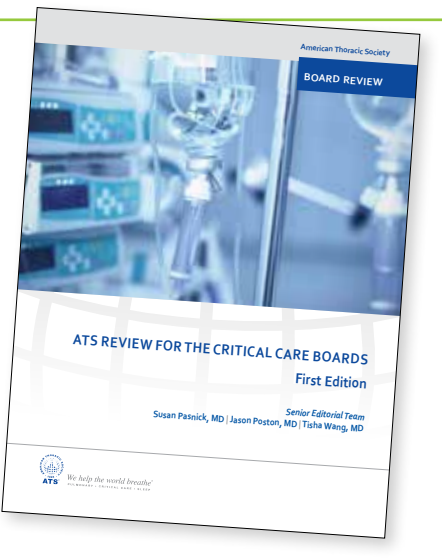
The electronic book's format follows that of the ATS Pulmonary Board Review Book, according to Tisha Wang, MD, a senior editor. "We tried to create a visually appealing book, with short paragraphs, bullet points, tables and graphics, flash cards and key facts highlighted in the margins, and mnemonics," she says of both reviews.

The Critical Care Board Review is divided into 10 chapters, which follow the ABIM blueprint for the exam. Fellows and junior faculty members wrote the chapter content. They peer-reviewed each other's work before it was sent to a faculty reviewer. Two associate editors—W. Graham Carlos, MD, MSCR, and Shazia M. Jamil, MD—reviewed further, and all of the senior editors reviewed the final product.

Other senior editors of this latest review book are Susan Pasnick, MD, and Jason T. Poston, MD. Drs. Wang and Poston are fellowship program directors at UCLA and the University of Chicago, respectively. Dr. Pasnick is director of critical care process improvement at CHRISTUS St. Vincent's in Santa Fe. All three are members of the ATS Education Committee.

"I believe so many people donated so much time because they believe this is a worthwhile project for every physician, from the trainee to the senior clinician," Dr. Wang says.

The review book can be purchased through the *ATS Store*. A companion Question Book with 150 board review questions will be available soon. ■



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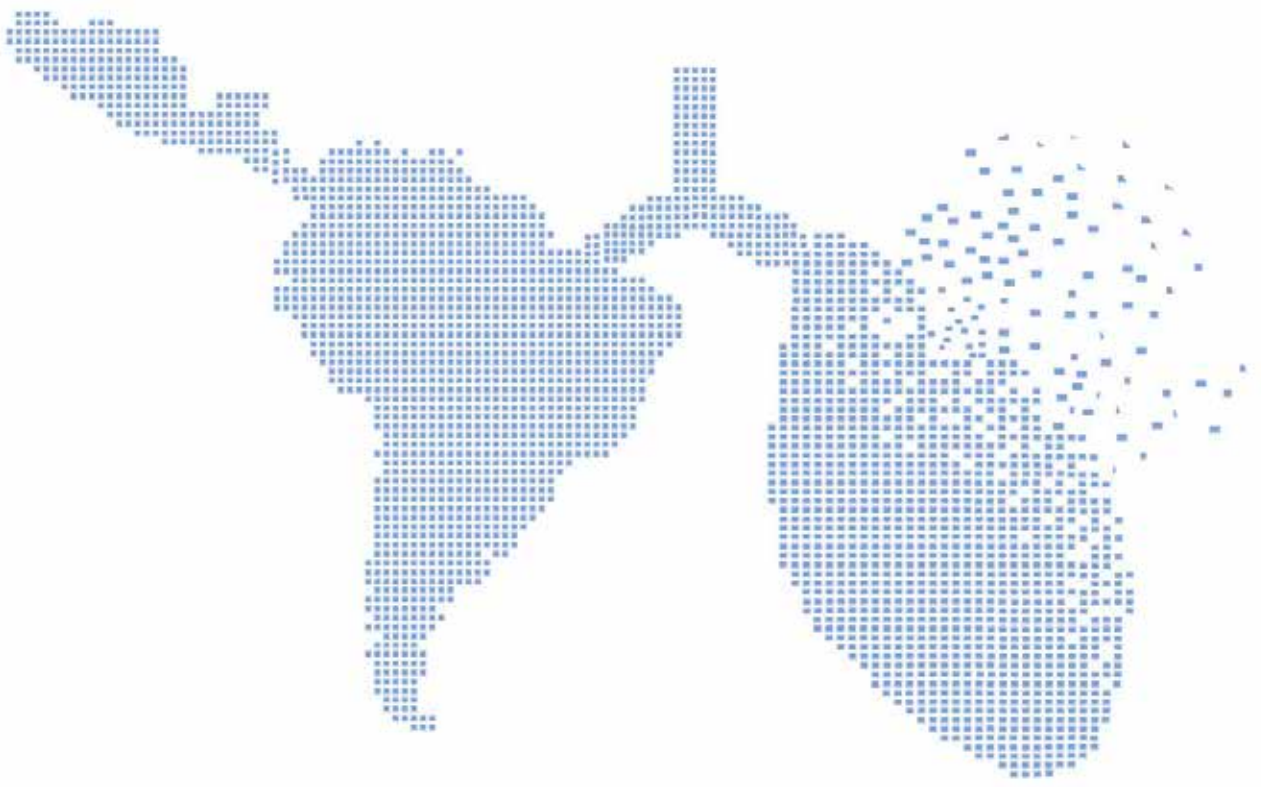

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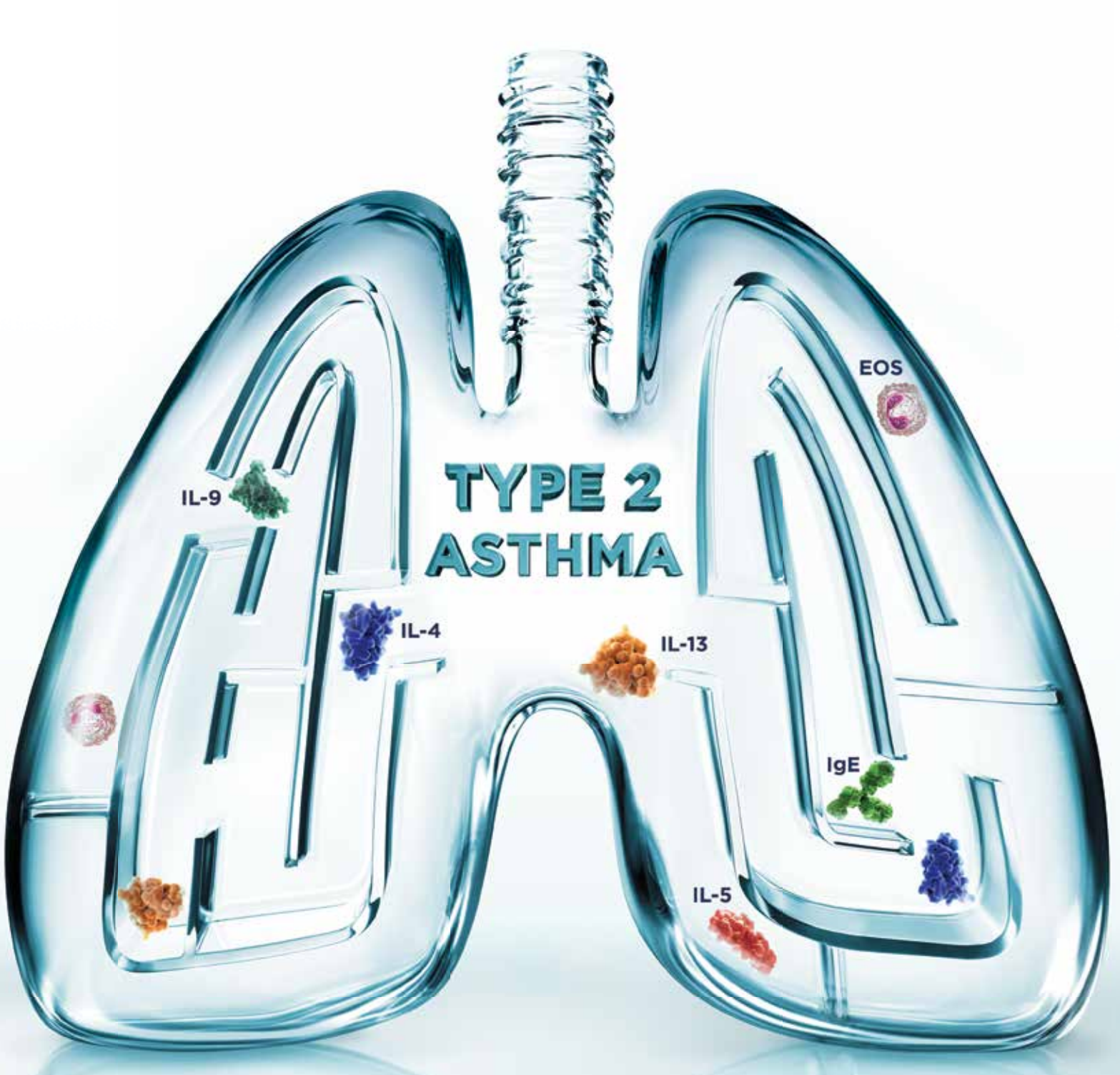

Type 2 asthma encompasses a range of biomarkers driven by Type 2 inflammation.

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Exploring Advances in Human Lung Biology

New approaches to the study of human lung development are generating a fresh look at multiple considerations, from potential therapies to mechanisms that model development and disease.

Tuesday's session, Human Lung Development: New Tools and Therapeutic Strategies, explores various aspects of human lung development, including early branching, 2-D and 3-D in vitro culture models mimicking human development, the use of human lung iPSCs to model development and disease and the potential of stem cells as a therapeutic avenue for respiratory diseases. Each of these models is unique in its own way, allowing for the study of different key factors and pathways critical in lung development and disease. This includes Wnt and FGF signaling pathways, according to Denise Al Alam, PhD, assistant professor at The Saban Research Institute of Children's Hospital in Los Angeles.

Human Lung Development: New Tools and Therapeutic Strategies (C91)

2:15-4:15 p.m.

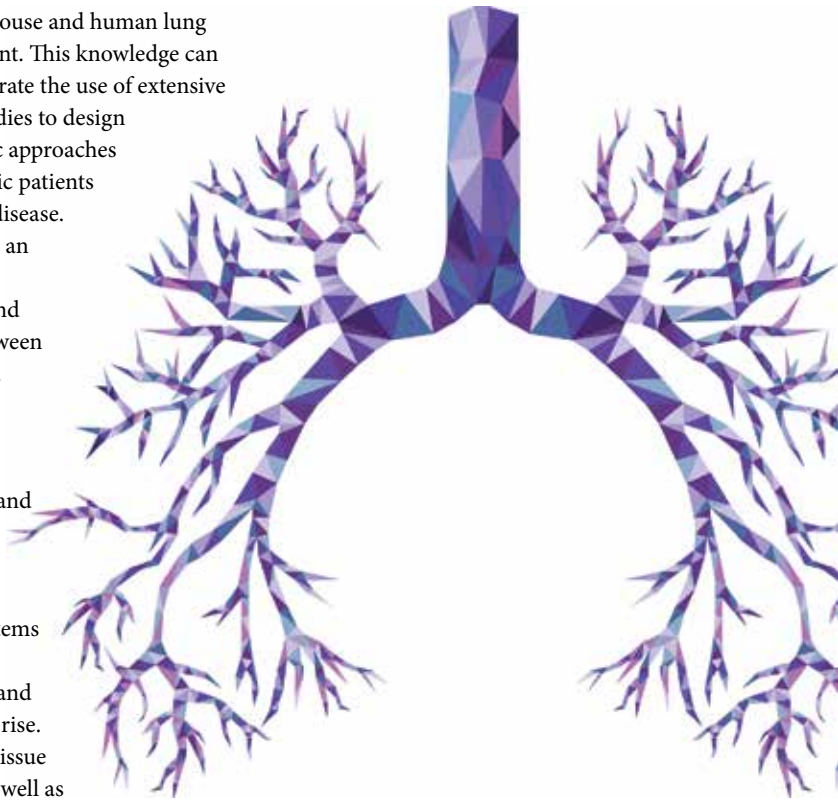
Tuesday

Room 15 A-B (Mezzanine Level), San Diego Convention Center

Denise Al Alam, PhD

"Lung diseases are among the leading causes of death in the United States, both in pediatric and adult populations," Dr. Al Alam says. "Because of the rise in the survival rate of extremely premature infants, the number of patients with lung disease in this population has also been on the rise. Nine out of 10 clinical trials fail to reach the clinic. Therefore, progress in introducing new therapies for pediatric diseases has stalled significantly."

Recent studies suggest there are major differences between mouse models of diseases and human diseases, impeding the success of clinical trials. In addition to the structural, temporal, and scale differences between mouse and human lungs, newer studies have highlighted other major differences between mouse and human lung development. This knowledge can help accelerate the use of extensive animal studies to design therapeutic approaches for pediatric patients with lung disease. It's become an important means to understand the differences between animal models and human systems, thereby extending studies on human lung development and diseases.



According to Dr. Al Alam, novel *in vitro* culture systems that model human lung development and diseases are on the rise. Two-dimensional tissue and cell culture, as well as 3-D organoids cultures, have been the go-to models for studying human lung development and diseases. Both systems allow for manipulating gene expression and cell labeling to model disease and study specific genes or cell-cell interactions and tissue remodeling.

"Attendees will hear about the latest advances in human lung biology. Importantly, the audience will appreciate the differences between animal models and human systems, hence the urgent need to further develop human studies," Dr. Al Alam says.

She adds that the knowledge gained from the novel systems used to model human lung development could be applicable to different studies of development, homeostasis, and disease, which aim to better understand the cellular and molecular pathways important in human lung development/disease.

"We hope that attendees will use this knowledge to help accelerate the translational potential of their studies," Dr. Al Alam says. "Our goal is to encourage and bring together new collaborations between clinicians and basic scientists to accelerate the studies on human lung development." ■

> "Our goal is to encourage and bring together new collaborations between clinicians and basic scientists to accelerate the studies on human lung development."
>
> **Denise Al Alam, PhD**

Exhibit Hall Abuzz With Innovation

Explore the latest products, services, and educational opportunities

Today is your last opportunity to visit the Exhibit Hall. Expand your knowledge in this year's Exhibit Hall. More than 200 exhibitors, of which 69 are new to ATS, are showcasing products, services, and technologies through in-booth presentations, engaging demonstrations, practical workshops, and hands-on activities.

Be sure to check out these highlights:

- Health and wellness solutions and products, such as wearable sensors, activity trackers, and mobile apps, are challenging existing models of care delivery and transforming personal health management. The Innovation Pavilion is a new area where you can learn about industry technologies in a bold new way.
- What does burnout look like and what can we do to combat it both personally and professionally? Visit Restoring Joy in Health Care (Booth 904) to take an anonymous burnout quiz, collect helpful resources, and discuss possible solutions. You also can relax with a free chair massage or de-stress with therapy dogs, which will be in the booth today from 11 a.m. to 2 p.m.
- Hear from subject matter experts at dynamic and engaging Guru Bar sessions. For more information about today's Guru Bars, see "Guru Bars Invite Interaction" on page 10.
- Gain a deeper understanding of disease areas or new products by attending Industry Theaters. ATS provides complimentary boxed lunches, while supplies last.
- If you are interested in being an investigator for clinical trials or are looking for ongoing trials for your patients, make a connection with the seven Clinical Trial Awareness exhibitors in Lobby F.
- Participate in Discovery Quest, an interactive game on the conference mobile app. Visit the participating exhibitor booths and correctly answer a multiple-choice question to be entered into a drawing to win one of four Apple Watches that will be awarded each day.
- Raise a glass to the latest innovations and research advancements at the Toast to Innovation reception today from 1:15 to 2:15 p.m.
- Take a minute to catch your breath or catch up with a colleague while enjoying healthy snacks and drinks in Coffee & Connections. These areas are located throughout the Exhibit Hall in Booths 415, 1031, 2641, and 3307, and refreshments are served between 11 a.m. and 1:15 p.m. today.

TUESDAY, MAY 22
10:30 a.m.–3:30 p.m.
Unopposed Hours:
1:15–2:15 p.m.

There's more: The Exhibit Hall is a great place to connect with colleagues and industry experts. Add these networking opportunities to your schedule:

Use the Online Exhibitor Directory at **ats18.mapyourshow.com** to map out exhibitors and events you'd like to visit and expertly navigate the Exhibit Hall. ■

Challenging conventional treatments for cystic fibrosis and asthma.

BEST CHILDREN'S HOSPITALS
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At Children's Hospital of Pittsburgh of UPMC, our research and clinical teams are investigating every possibility to improve the quality of life for our patients with cystic fibrosis (CF) and asthma. As a longstanding Therapeutics Development Network center, we are testing novel drug therapies and other interventions to find better ways to treat CF. And our Pediatric Asthma Center conducts NIH- and privately funded research on the role of genetics, epigenetics, immunology, diet, obesity, and stress on childhood asthma, taking care to include underserved minority children such as Puerto Ricans and African-Americans. To learn more, visit **UPMCPhysicianResources.com/Pediatrics**.

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THEATERS

Expand Your Learning at Lunch

The theater locations are:
Industry Theater 1: **Booth 3317**
Industry Theater 2: **Booth 345**
Mini Theater: **Booth 1549**

Grab a complimentary lunch and continue learning during Industry Theaters and Mini Theaters on Tuesday in the Exhibit Hall. Listen as supporting companies bring you the latest clinical updates related to pulmonary, critical care, or sleep medicine. Lunches are provided by ATS (while supplies last).

TUESDAY

Industry Theater 1

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

Why Long-Acting Dual Bronchodilation Should Be Used in COPD

Speaker: **Michael Zack, MD**
Company: Sunovion Pharmaceuticals Inc.

1:15-2 p.m.

Uncontrolled Asthma: Connecting Type 2 Inflammation to Airway Pathology

The primary objective of this session is to increase HCP understanding of Type 2 inflammation and how it contributes to airway pathology in asthma. Evidence supporting roles for Type 2 cytokines in epithelial and airway smooth muscle pathology including remodeling, fibrosis, mucus production, and airway hyperresponsiveness will be discussed. How these pathological features contribute to airway narrowing, progressive (and possibly irreversible) lung function decline, and asthma symptoms will be reviewed in the context of poor asthma control.
Company: Sanofi Genzyme & Regeneron

Industry Theater 2

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

Nucala (Mepolizumab): Treating Severe Eosinophilic Asthma Patients With Overlapping Phenotypes

(Open to International attendees only)
The management of severe eosinophilic asthma patients who also exhibit an allergic phenotype is an important clinical question for physicians. To address this issue, this Industry Theater will discuss a meta-analysis of mepolizumab use in patients eligible for omalizumab focusing on relevant biomarkers that may or may not be useful in predicting response in these patients with an overlapping phenotype. This will be followed by a discussion of new clinical data from the OSMO study that included patients with an overlapping phenotype not optimally controlled with omalizumab therapy. Together, this information will help physicians in their treatment decisions for severe eosinophilic asthma patients with an overlapping phenotype.
Speakers: **Eugene Bleecker, BA, MD**, *University of Arizona College of Medicine, Tucson, Arizona;* **Neil Barnes, MB, BS,** *Global Respiratory Franchise, GlaxoSmithKline, London, U.K.;* **Peter Howarth, BSc (Hons), MBBS, DM**, *Global Respiratory Franchise, GlaxoSmithKline, London, U.K.*
Company: GSK

1:15-2 p.m.

The Salford Lung Study: Innovation in Asthma Research

(Open to International attendees only)
This Industry Theater uses data from SLS to investigate what features of a medicine may impact effectiveness and explores the contribution of effectiveness trials to treatment decisions. SLS asthma was an open-label randomized controlled trial conducted in U.K. primary care, which aimed to guide treatment choices by generating effectiveness and safety data in a population representative of everyday clinical practice. Subjects were initiated on Relvar ▼ (fluticasone furoate/vilanterol) or continued with usual care (inhaled corticosteroids or ICS/long-acting β2-agonists) for 52 weeks; treatments could be adjusted at the prescriber's discretion as per normal clinical practice.
Speakers: **Neil Barnes, MB, BS**, *Global Respiratory Franchise, GlaxoSmithKline, London, U.K.;* **Dave Leather, MB ChB**, *Global Respiratory Franchise, GlaxoSmithKline, London, U.K.;* **Nawar Bakerly, MD**, *Salford Royal NHS Foundation Trust, Salford, U.K.*
Company: GSK

Mini Theater

11:30 a.m. – 12 p.m.

What Do You Consider When Patients With COPD Classified as GOLD D Continue to Exacerbate

GSK U.S. Medical Affairs invites you to an overview of COPD, which will include the risk and impact of exacerbations as well as concepts in airway inflammation. Guidance from the GOLD 2017 Report will also be discussed.
Speaker: **Mark Forshag MD, MHA** *GSK*
Company: GSK

1:30-2 p.m.

The Importance of Extra-Fine Triple Therapy in the Management of COPD Patients

(*Open to International attendees only*)
This session will focus on the following key topics:

- The relevance of small airways in COPD physiopathology
- The role of ICS in COPD
- The efficacy of extra-fine BDP/FF/GLY combination.

The 20-minute speech will be followed by a Q&A session.
Speakers: **Alberto Papi**, *professor and chair of respiratory medicine, University of Ferrara;* **Brian J. Lipworth**, *professor at Scottish Centre for Respiratory Research, Ninewells Hospital, University of Dundee;*
Company: Chiesi Farmaceutici S.p.A.

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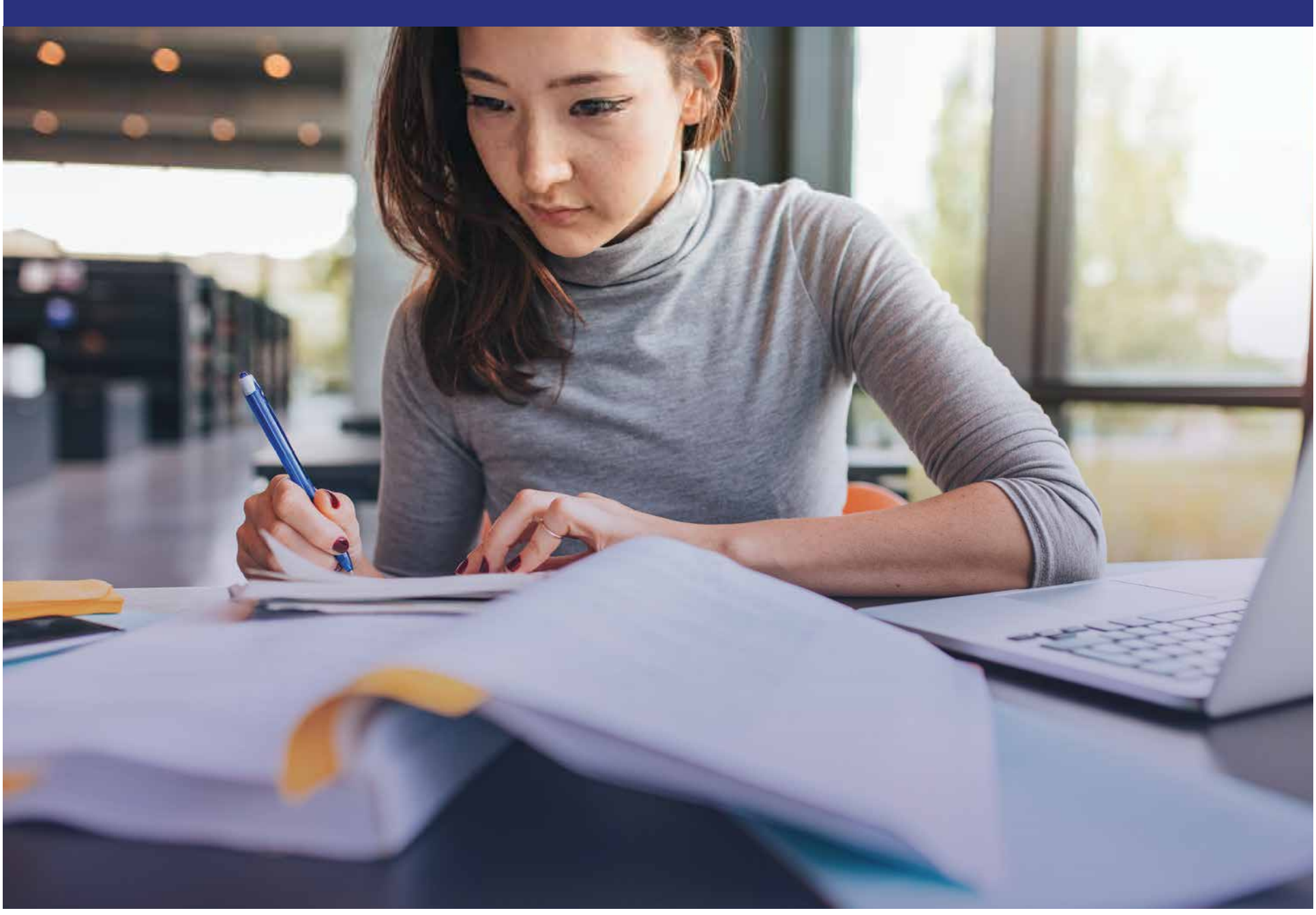
The deadline for a Letter of Intent is Tuesday, June 12, 2018 at 11:59 p.m. (ET).

Learn more and view the portfolio at: thoracic.org/org/go/researchgrants.



Don't Miss Non-CME Symposia Learning Opportunities

Non-CME Symposia are an important part of the ATS 2018 International Conference. The ATS encourages all full-conference participants to attend these programs.

TUESDAY

6:30-9:30 p.m.
Manchester Grand Hyatt San Diego, Grand Hall A (Lobby Level)

Treating Adults With Uncontrolled Severe Eosinophilic Asthma

A review of considerations in the diagnosis and management of eosinophilic asthma.
Speakers: **Mario Castro, MD, MPH; Warner W. Carr, MD**
Company: Teva

6:30-9:30 p.m.
Manchester Grand Hyatt San Diego, Seaport Ballroom G-H (Second Level, Seaport Tower)

Exploring Eosinophilic Granulomatosis With Polyangiitis: A Rare Disease

Eosinophilic Granulomatosis with Polyangiitis, formerly known as Churg-Strauss syndrome, is a rare vasculitis that often involves the respiratory tract, affects small to medium vessels, and is associated with asthma and eosinophilia. EGPA is difficult to diagnose and manage due to its rarity and complexity. Early recognition is critical to avoid organ damage. This educational session will review the pathogenesis, clinical manifestations, classification criteria, diagnosis and prognosis of EGPA.
Speaker: **Michael Wechsler, MD, MMSc**, *National Jewish Health and University of Colorado School of Medicine*
Company: GlaxoSmithKline

6:30-9:30 p.m.
Manchester Grand Hyatt San Diego, Grand Hall D (Lobby Level)

The Future of Pneumonia Diagnostics: How Multiplex PCR Will Change Patient Management

The complex microbiology of lower respiratory samples has thwarted attempts to develop broad molecular diagnostic panels in this area. BioFire has developed a test (currently IUO) which will identify 18 bacteria, nine viruses, and seven genetic markers of resistance in commonly collected lower respiratory specimens all in one hour. This symposium will feature Dr. Buchan and Dr. Stromich from the Medical College of Wisconsin, a clinical trial site for the BioFire Pneumonia Panel. Dr. Stromich will present patient cases from the clinical trial and discuss which patient populations will benefit most from the panel. Dr. Buchan will present an analysis exploring how frequently a pneumonia panel result can effectively tailor antimicrobial therapy.
Speakers: **Blake Buchan, PhD**, *Medical College of Wisconsin;* **Jeremiah Stromich, MD**, *Medical College of Wisconsin*
Company: BioFire Diagnostics

6:30-9:30 p.m.
Hilton San Diego Bayfront, Sapphire Ballroom A/B/E/F (Sapphire Level, Level 4)

Type 2 Inflammation in Asthma: Defining Features and Lung Function

Our moderator and expert panel will lead an interactive discussion of three asthma patient case studies highlighting the importance of Type 2 inflammation in asthma control, severity, and lung function. Using an ARS response system, attendees will help evaluate the significance of patient clinical features and Type 2 biomarkers. Discussion throughout will focus on how clinical features, biomarkers, and lung function results (e.g., FEV1) together may inform patient severity, control, and exacerbation risk. We will also discuss how indicators of irreversible lung function decline, as well as uncontrolled Type 2 inflammation, could reflect airway structural changes.
Company: Sanofi Genzyme & Regeneron

6:30-9:30 p.m.
Hilton San Diego Bayfront, Indigo Ballroom D/H (Indigo Level, Level 2)

Compete and Win! Pulmonary Hypertension at the Crossroads of Current Clinical Challenges and Novel Therapeutic Strategies

Familiarity with key diagnostic criteria, the ability to differentiate between various types of PH, and understanding how recent clinical trial data impacts the application of treatment options are vital components of PAH and CTEPH management. Utilizing a fun and interactive game-based teaching approach, expert-led presentations on diagnosis, differentiation and treatment will be enhanced by related assessment questions which, when answered via audience-response devices, will record an ongoing score and associated leaderboard. Each participant will be part of a larger team, and the group with the top score at the end of the session will be hailed as victors along with enhanced ability to manage of patients with PAH and CTEPH.
Speakers: **Nick H. Kim, MD**, *University of California San Diego;* **Richard N. Channick, MD,** *Massachusetts General Hospital, Harvard Medical School;* **Vallerie V. McLaughlin, MD**, **Kim A. Eagle, MD**, *University of Michigan*
Company: This non-CME educational program is sponsored by PVI, PeerView Institute for Medical Education, and supported through an educational grant from Bayer US.

6:30-9:30 p.m.
Hilton San Diego Bayfront, Indigo Ballroom C/G (Indigo Level, Level 2)

Win the Room! Updates in Interstitial Lung Disease: Making Strides in Accurate Diagnosis and Optimized Treatment

Optimal management of patients with ILD, including IPF, begins with accurate diagnosis and relies on safe and effective incorporation of newly approved and investigational therapies into individualized patient treatment paradigms. In this program, audience-response devices will allow the room to be segmented into teams competing via score-based questions. The game will be driven by faculty presentations focused on distinguishing IPF and other ILDs via distinct radiographic patterns and pathologic features, late-breaking clinical data on approved and emerging regimens, and strategies for applying evidence-based recommendations to optimize IPF management. The team with the highest point total will be crowned as having "Won the Room."
Speakers: **Lisa H. Lancaster, MD**, *Vanderbilt University Medical Center;* **Marilyn K. Glassberg, MD**, *University of Miami Miller School of Medicine;* **Steven D. Nathan, MD**, *Inova Fairfax Hospital, Virginia Commonwealth University-Inova Fairfax Campus*
Company: This non-CME educational program is sponsored by PVI, PeerView Institute for Medical Education, and supported by an independent educational grant from Boehringer Ingelheim Pharmaceuticals, Inc.

6:30-9:30 p.m.
Hilton San Diego Bayfront, Sapphire Ballroom I/J/M/N (Sapphire Level, Level 4)

Update on the Treatment of Sarcoidosis: Results of a Delphi Study

This interactive dinner symposium will present consensus findings from Delphi studies assessing the treatment of sarcoidosis and the current treatment patterns and management of repository corticotropin injection for pulmonary sarcoidosis. We will also discuss the clinical phenotypes of sarcoidosis and the challenges of diagnosing and treating cardiac sarcoidosis. The objective is to increase the understanding and awareness of the current consensus on best practices among pulmonary sarcoidosis experts to improve patient outcomes. The format will be didactic presentations, moderator-driven Q&A, and panel discussions.
Moderator: **Daniel A. Culver, DO**, *Cleveland Clinic*
Speakers: **Robert P. Baughman, MD**, *University of Cincinnati Medical Center;* **Mary Beth Scholand, MD**, *University of Utah Medical Center, Salt Lake City, Utah;* **Franck F. Rahaghim, MD, MHS**, *Cleveland Clinic Florida, Weston, FL;* **Edward J. Miller, MD, PhD**, *Yale University School of Medicine, New Haven, Connecticut*
Company: AXON Communications (supported by a medical education grant from Mallinckrodt Pharmaceuticals)

6:30-9:30 p.m.
Hilton San Diego Bayfront, Indigo Ballroom A/E (Indigo Level, Level 2)

Uncovering a Genetic Cause of COPD: Alpha1-Antitrypsin

Alpha-1 Antitrypsin Deficiency (Alpha-1) is a genetic cause of COPD that is severely underdiagnosed, with as many as 90 percent of the individuals living with the condition undetected. Learn about how this condition presents, which patients may be at risk, and genetic testing used to diagnose. You'll also gain insights into the patient journey from an experienced patient and advocate.
Speakers: **Kamyar Afshar, DO**, *pulmonologist, UC San Diego;* **Len Geiger**, *Alpha-1 patient advocate*
Company: Grifols USA, LLC.

Tap Into The ATS Center

There are so many resources waiting for you at the ATS Center, where you have access to educational information and career-enhancing opportunities available through the American Thoracic Society. The ATS Center is located in Booth 733 of the Exhibit Hall (Hall F, Ground Level).

Browse ATS scientific journals

Learn about educational opportunities

Access patient information sheets

Discover ATS activities near your home

Identify grant opportunities

The ATS MECOR in Vietnam is one example of the worldwide educational opportunities offered by ATS in low- and middle-income countries.

ATS 2017 Annual Report Highlights Global Impact and Initiatives

The ATS is a truly international organization. Nearly half the attendees here in San Diego for ATS 2018 have arrived from a country other than the United States. One third of the Society's members are international, living and working in 128 countries around the world. And many ATS programs are specifically focused on making a difference in respiratory health in their home countries.

In 2017, the ATS made important advances in its global initiatives. Here are some of the international highlights from the past year drawn from the ATS 2017 Annual Report, available at the ATS Center and online at **thoracic.org**.

EDUCATION

- The ATS launched the South American Critical Care Conference with the Latin American Thoracic Association and the Brazilian Thoracic Society in July in São Paulo, Brazil. The conference focusing on respiratory failure and mechanical ventilation drew 350 people. A second conference will be held in September in São Paulo.
- The ATS provided 115 International Abstract Scholarship Awards and 43 International Trainee Scholarship Awards to help early career professionals who had submitted abstracts to ATS 2017 attend the conference.
- Select fliers in the ATS Patient Education Series, which now numbers nearly 200 pieces, were translated into Arabic, Japanese, Serbian, and Turkish, as well as Spanish.

RESEARCH AND CLINICAL CARE

- The ATS MECOR—Methods in Epidemiologic, Clinical, and Operations Research—held education programs in Brazil, China, India, Indonesia, Turkey, and Vietnam. MECOR aims to build research capacity and leadership in low- and middle-income countries. The MECOR curriculum was totally revamped in 2017 and introduced earlier this year.
- The ATS Foundation Research Program awarded five research grants to MECOR graduates, who now number 1,800 worldwide.
- The ATS published six clinical practice guidelines, five with international sister societies, including the European Society of Intensive Care Medicine, the European Respiratory Society, and the Japanese Respiratory Society.
- Nearly 1,400 articles were submitted to the Society's three journals—the American Journal of Respiratory and Critical Care Medicine, the American Journal of Respiratory Cell and Molecular Biology, and the Annals of the American Thoracic Society—from researchers working outside the United States. Articles published in the journals were translated into Chinese, French, German, Italian, Portuguese, Russian, and Spanish.

GLOBAL HEALTH AND ADVOCACY

- The Forum of International Respiratory Societies, or FIRS, of which the ATS is a founding member, released "The Global Impact of Respiratory Disease" during the 70th World Health Assembly. The report recommends specific actions that world leaders should take to reduce respiratory disease and improve global health.
- FIRS coordinated the first World Lung Day, on Sept. 25, and used the visibility to make world leaders aware that the United Nations' Sustainable Development Goals will not succeed without addressing lung disease.
- The ATS was successful in increasing, or at least maintaining, tuberculosis funding from key agencies. Working with its partners, ATS secured an 8 percent increase in TB funding from the United States Agency for International Development, stable TB funding from the U.S. Centers for Disease Control and Prevention, and an increase in funding for TB research from the National Institutes of Health. ■

Visit GSK Booth #1734

For patients with COPD taking fluticasone furoate/vilanterol who need additional lung function improvement

LESS TO TAKE.
MORE TO TAKE IN.

TRELEGY– the only once-daily triple therapy (ICS/LABA/LAMA) for COPD delivered in a single inhaler

COPD=chronic obstructive pulmonary disease; ICS=inhaled corticosteroid; LABA=long-acting beta$_2$-adrenergic agonist; LAMA=long-acting muscarinic antagonist.

INDICATION

TRELEGY is for maintenance treatment of patients with COPD, including chronic bronchitis and/or emphysema, who are on fluticasone furoate and vilanterol (FF/VI) and need additional treatment of airflow obstruction or who are already taking umeclidinium and FF/VI. TRELEGY is NOT indicated for relief of acute bronchospasm or asthma.

IMPORTANT SAFETY INFORMATION

WARNING: ASTHMA-RELATED DEATH

LABA, such as vilanterol, one of the active ingredients in TRELEGY, 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.

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

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

INNOVIVA

TRELEGY ELLIPTA
(fluticasone furoate 100 mcg, umeclidinium 62.5 mcg, and vilanterol 25 mcg inhalation powder)

Patients experienced greater lung function with TRELEGY vs patients taking fluticasone furoate/vilanterol (FF/VI)

Primary endpoint: Change from baseline in trough FEV_1 at Day 85[1,2]

In patients with COPD run-in on FF/VI 100/25, TRELEGY provided

124 mL ADDITIONAL LUNG FUNCTION IMPROVEMENT

vs FF/VI
($P < 0.001$)

Similar results were demonstrated in a replicate study.

STUDY DESCRIPTION

Design: 12-week, randomized, double-blind, parallel-group study. Following a 4-week run-in period on FF/VI 100/25, patients were randomized to treatment with UMEC 62.5 mcg (n=206) or placebo (n=206) added to FF/VI 100/25 mcg (each administered once daily in the morning by the ELLIPTA inhaler). Treatment with TRELEGY refers to patients who received UMEC 62.5 added to FF/VI 100/25.

Patients: COPD patients (mean age: 64 years). At screening, patients had a mean postbronchodilator percent predicted FEV_1 of 46%, a mean postbronchodilator FEV_1/FVC ratio: 0.48, and a mean mMRC score of 2.5.

FEV_1=forced expiratory volume in 1 second; FVC=forced vital capacity; mMRC=modified Medical Research Council; UMEC=umeclidinium.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- TRELEGY is contraindicated in patients with severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any of the excipients.

WARNINGS AND PRECAUTIONS

- TRELEGY should NOT be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD.
- TRELEGY is NOT a rescue medication and should NOT be used for the relief of acute bronchospasm or symptoms. Acute symptoms should be treated with an inhaled, short-acting $beta_2$-agonist.
- TRELEGY should not be used more often or at higher doses than recommended or with another LABA for any reason, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs, like LABA.
- Oropharyngeal candidiasis has occurred in patients treated with orally inhaled drug products containing fluticasone furoate. Advise patients to rinse their mouths with water without swallowing after inhalation.
- Physicians should remain vigilant for the possible development of pneumonia in patients with COPD, as clinical features of pneumonia and exacerbations frequently overlap. Lower respiratory tract infections, including pneumonia, have been reported following use of inhaled corticosteroids, like fluticasone furoate.
- 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.
- Particular care is needed for patients transferred from systemic corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer. Taper patients slowly from systemic corticosteroids if transferring to TRELEGY.

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

Visit GSK Booth #1734

TRELEGY contains FF/VI, an ICS/LABA proven to reduce COPD exacerbations

This study did not evaluate the effect of TRELEGY on COPD exacerbations.

Primary endpoint: Annual rate of moderate/severe exacerbations[1,3]

In patients with a history of COPD exacerbations, FF/VI 100/25 provided

21% EXACERBATION REDUCTION

in annual rate vs vilanterol

0.90 vs 1.14 for FF/VI 100/25 and VI, respectively; $P=0.024$

Similar results were demonstrated in a replicate study.

STUDY DESCRIPTION

Design: 12-month, randomized, double-blind, parallel-group study that evaluated the effect of FF/VI 100/25 mcg (n=403) and VI 25 mcg* (n=409) (each administered once daily by the ELLIPTA inhaler) on the rate of moderate/severe exacerbations. Patients with a history of ≥1 moderate or severe exacerbation in the previous year were randomized to treatment following a 4-week run-in period on fluticasone propionate/salmeterol 250/50 mcg twice daily.

Patients: COPD patients (mean age: 64 years). At screening, patients had a mean postbronchodilator percent predicted FEV_1 of 46% and a mean postbronchodilator FEV_1/FVC ratio: 0.46.

Exacerbation severity criteria: Moderate if treatment with systemic corticosteroids and/or antibiotics was required and severe if hospitalization was required.

*Vilanterol is not approved as monotherapy.

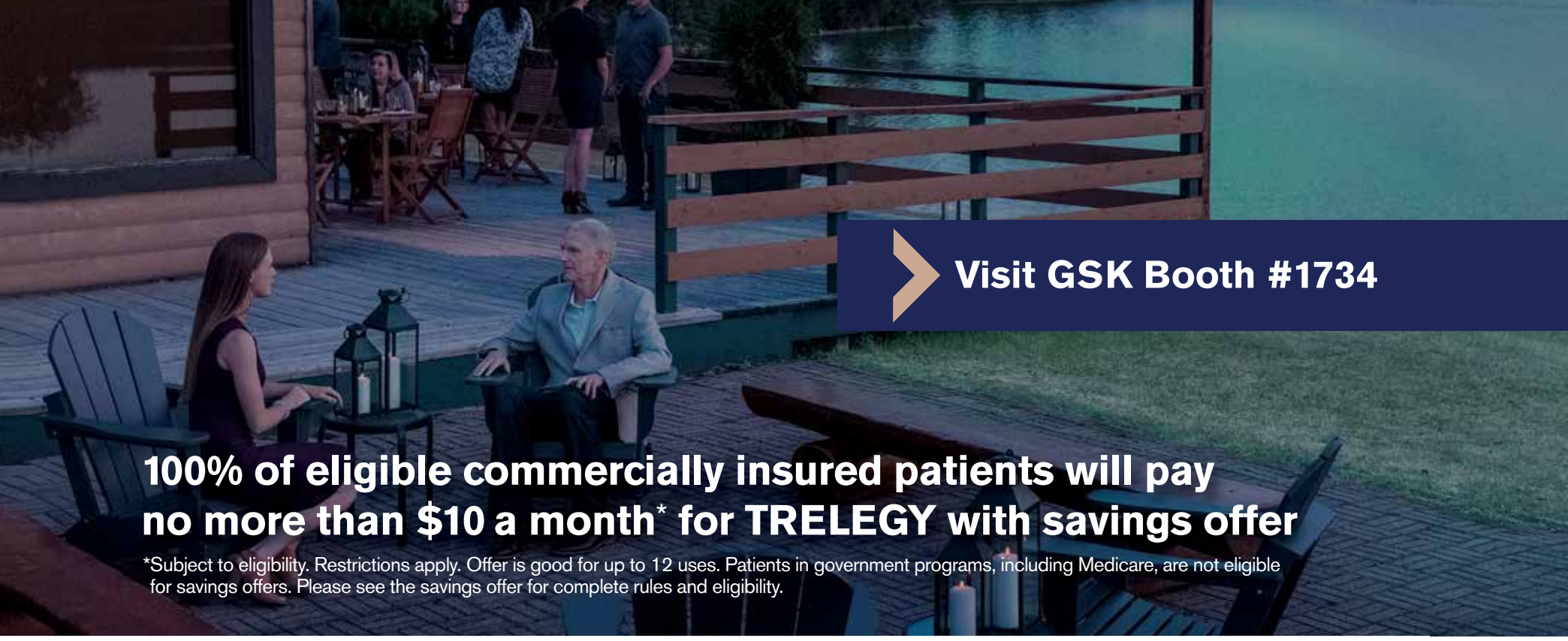
IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- Hypercorticism and adrenal suppression may occur with higher than the recommended dosage or at the regular dosage of inhaled corticosteroids in susceptible individuals. If such changes occur, appropriate therapy should be considered.
- Caution should be exercised when considering the coadministration of TRELEGY with long-term ketoconazole and other known strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and cardiovascular adverse effects may occur.
- If paradoxical bronchospasm occurs, discontinue TRELEGY and institute alternative therapy.
- Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of TRELEGY. Discontinue TRELEGY 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, TRELEGY may need to be discontinued. TRELEGY should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

To learn more, go to DiscoverTrelegy.com

TRELEGY ELLIPTA
(fluticasone furoate, umeclidinium, and vilanterol inhalation powder)



IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- Decreases in bone mineral density 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 (eg, anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care prior to initiating TRELEGY and periodically thereafter.
- Glaucoma, increased intraocular pressure, and cataracts have been reported following the long-term administration of inhaled corticosteroids or inhaled anticholinergics; therefore, monitoring is warranted.
- Use with caution in patients with narrow-angle glaucoma. Instruct patients to contact a healthcare provider immediately if signs or symptoms of acute narrow-angle glaucoma develops.
- Use with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to contact a healthcare provider immediately if signs or symptoms of urinary retention develops.
- 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

- The most common adverse reactions (≥1% and more common than placebo) reported in two 12-week clinical trials with umeclidinium + FF/VI, the components of TRELEGY, (and placebo + FF/VI) were: headache, 4% (3%); back pain, 4% (2%); dysgeusia, 2% (<1%); diarrhea, 2% (<1%); cough, 1% (<1%); oropharyngeal pain, 1% (0%); and gastroenteritis, 1% (0%).

DRUG INTERACTIONS

- TRELEGY 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 they may potentiate the effect of vilanterol on the cardiovascular system.
- Use beta-blockers with caution, as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.
- Use with caution in patients taking non–potassium-sparing diuretics, as ECG changes and/or hypokalemia associated with these diuretics may worsen with concomitant beta-agonists.
- Avoid coadministration of TRELEGY with other anticholinergic-containing drugs, as this may lead to an increase in anticholinergic adverse effects.

USE IN SPECIFIC POPULATIONS

- Use TRELEGY with caution in patients with moderate or severe hepatic impairment, as fluticasone furoate systemic exposure may increase by up to 3-fold. Monitor for corticosteroid-related side effects.

Please see additional Important Safety Information for TRELEGY on the previous pages.
Please see Brief Summary of Prescribing Information, including Boxed Warning, for TRELEGY following this ad.

References: 1. Data on file, GSK. **2.** Siler TM, Kerwin E, Sousa AR, Donald A, Ali R, Church A. Efficacy and safety of umeclidinium added to fluticasone furoate/vilanterol in chronic obstructive pulmonary disease: results of two randomized studies. *Respir Med*. 2015;109(9):1155-1163. **3**. 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.

To learn more, go to DiscoverTrelegy.com

TRELEGY ELLIPTA was developed in collaboration with INNOVIVA

Printed in USA. 1001205R0 March 2018

TRELEGY ELLIPTA
(fluticasone furoate, umeclidinium, and vilanterol inhalation powder)

BRIEF SUMMARY

TRELEGY ELLIPTA (fluticasone furoate, umeclidinium, and vilanterol inhalation powder), for oral inhalation

The following is a brief summary only; see full prescribing information for complete product information.

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in TRELEGY, 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 *[see Warnings and Precautions (5.1)]*.

The safety and efficacy of TRELEGY in patients with asthma have not been established. TRELEGY is not indicated for the treatment of asthma *[see Warnings and Precautions (5.1)]*.

1 INDICATIONS AND USAGE

TRELEGY is indicated for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol.

Important Limitations of Use

TRELEGY is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

4 CONTRAINDICATIONS

The use of TRELEGY is contraindicated in the following conditions: severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any of the excipients *[see Warnings and Precautions (5.11), Description (11) of full prescribing information]*.

5 WARNINGS AND PRECAUTIONS

5.1 Asthma-Related Death

Data from a large placebo-controlled trial in subjects with asthma showed that LABA may increase the risk of asthma-related death.

A 28-week, placebo-controlled, US trial that compared the safety of another LABA (salmeterol) with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in subjects receiving salmeterol (13/13,176 in subjects treated with salmeterol vs. 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25,15.34]). The increased risk of asthma-related death is considered a class effect of LABA, including vilanterol, one of the active ingredients in TRELEGY.

No trial adequate to determine whether the rate of asthma-related death is increased in subjects treated with TRELEGY has been conducted. The safety and efficacy of TRELEGY in patients with asthma have not been established. TRELEGY is not indicated for the treatment of asthma.

5.2 Deterioration of Disease and Acute Episodes

TRELEGY should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. TRELEGY has not been studied in subjects with acutely deteriorating COPD. The initiation of TRELEGY in this setting is not appropriate.

TRELEGY should not be used for the relief of acute symptoms, ie, as rescue therapy for the treatment of acute episodes of bronchospasm. TRELEGY 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 TRELEGY, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (eg, 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.

COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If TRELEGY no longer controls symptoms of bronchoconstriction; the patient's inhaled, short-acting beta$_2$-agonist becomes less effective; or the patient needs more short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting, a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of TRELEGY beyond the recommended dose is not appropriate in this situation.

5.3 Excessive Use of TRELEGY and Use With Other Long-acting Beta$_2$-agonists

TRELEGY 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 TRELEGY should not use another medicine containing a LABA (eg, 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 TRELEGY. When such an infection develops, it should be treated with appropriate local or systemic (ie, oral) antifungal therapy while treatment with TRELEGY continues, but at times therapy with TRELEGY 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

Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as clinical features of pneumonia and exacerbations frequently overlap. Lower respiratory tract infections, including pneumonia, have been reported following the inhaled administration of corticosteroids.

In two 12-week studies of subjects with COPD (N=824), the incidence of pneumonia was less than 1% for both treatment arms: umeclidinium 62.5 mcg + fluticasone furoate/vilanterol 100 mcg/25 mcg or placebo + fluticasone furoate/vilanterol 100 mcg/25 mcg. Fatal pneumonia occurred in 1 subject receiving placebo + fluticasone furoate/vilanterol 100 mcg/25 mcg. In a mortality trial with fluticasone furoate/vilanterol with a median treatment duration of 1.5 years in 16,568 subjects with moderate COPD and cardiovascular disease, the annualized incidence rate of pneumonia was 3.4 per 100 patient-years for fluticasone furoate/vilanterol 100 mcg/25 mcg, 3.2 for placebo, 3.3 for fluticasone furoate 100 mcg, and 2.3 for vilanterol 25 mcg. Adjudicated, on-treatment deaths due to pneumonia occurred in 13 subjects receiving fluticasone furoate/vilanterol 100 mcg/25 mcg, 9 subjects receiving placebo, 10 subjects receiving fluticasone furoate 100 mcg, and 6 subjects receiving vilanterol 25 mcg (less than 0.2 per 100 patient-years 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.

ICS 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 ICS because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available ICS. 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 TRELEGY may control COPD 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 or a severe COPD exacerbation, 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 or a severe COPD exacerbation.

Patients requiring oral corticosteroids should be weaned slowly from systemic corticosteroid use after transferring to TRELEGY. Prednisone reduction can be accomplished by reducing the daily prednisone dose by 2.5 mg on a weekly basis during therapy with TRELEGY. Lung function (forced expiratory volume in 1 second [FEV$_1$]), beta-agonist use, and COPD 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.

Continued on next page

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

During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal (eg, 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 fluticasone furoate in TRELEGY. 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 ICS in sensitive patients, patients treated with TRELEGY 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, appropriate therapy should be considered.

5.9 Drug Interactions With Strong Cytochrome P450 3A4 Inhibitors

Caution should be exercised when considering the coadministration of TRELEGY with long-term ketoconazole and other known strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and increased cardiovascular adverse effects may occur *[see Drug Interactions (7.1), Clinical Pharmacology (12.3) of full prescribing information]*.

5.10 Paradoxical Bronchospasm

As with other inhaled medicines, TRELEGY can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs following dosing with TRELEGY, it should be treated immediately with an inhaled, short-acting bronchodilator; TRELEGY 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 TRELEGY. Discontinue TRELEGY 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 TRELEGY *[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, TRELEGY 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 *[see Clinical Pharmacology (12.2) of full prescribing information]*. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

TRELEGY, like other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

In a mortality trial with fluticasone furoate/vilanterol with a median treatment duration of 1.5 years in 16,568 subjects with moderate COPD and cardiovascular disease, the annualized incidence rate of adjudicated cardiovascular events (composite of myocardial infarction, stroke, unstable angina, transient ischemic attack, or on-treatment death due to cardiovascular events) was 2.5 per 100 patient-years for fluticasone furoate/vilanterol 100 mcg/25 mcg, 2.7 for placebo, 2.4 for fluticasone furoate 100 mcg, and 2.6 for vilanterol 25 mcg. Adjudicated, on-treatment deaths due to cardiovascular events occurred in 82 subjects receiving fluticasone furoate/vilanterol 100 mcg/25 mcg, 86 subjects receiving placebo, 80 subjects receiving fluticasone furoate 100 mcg, and 90 subjects receiving vilanterol 25 mcg (annualized incidence rate ranged from 1.2 to 1.3 per 100 patient-years for the treatment groups).

5.13 Reduction in Bone Mineral Density

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing ICS. 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 (eg, 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 TRELEGY and periodically thereafter. If significant reductions in BMD are seen and TRELEGY 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, Worsening of Narrow-Angle Glaucoma

Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with COPD following the long-term administration of ICS or with use of inhaled anticholinergics. TRELEGY should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should also be alert for signs and symptoms of acute narrow-angle glaucoma (eg, eye pain or discomfort, blurred vision, visual halos, or colored images in association with red eyes from conjunctival congestion and corneal edema). Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops. Close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, narrow- or open-angle glaucoma, and/or cataracts.

5.15 Worsening of Urinary Retention

TRELEGY, like all medicines containing an anticholinergic, should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (eg, difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develops.

5.16 Coexisting Conditions

TRELEGY, 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.

5.17 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.

6 ADVERSE REACTIONS

LABA, such as vilanterol, one of the active ingredients in TRELEGY, increase the risk of asthma-related death. TRELEGY is not indicated for the treatment of asthma. *[See Boxed Warning and Warnings and Precautions (5.1).]*

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

- *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)]*
- Paradoxical bronchospasm *[see Warnings and Precautions (5.10)]*
- Cardiovascular effects *[see Warnings and Precautions (5.12)]*
- Reduction in bone mineral density *[see Warnings and Precautions (5.13)]*
- Worsening of narrow-angle glaucoma *[see Warnings and Precautions (5.14)]*
- Worsening of urinary retention *[see Warnings and Precautions (5.15)]*

6.1 Clinical Trials Experience

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

The safety of TRELEGY is based on the safety data from two 12-week treatment trials with the coadministration of umeclidinium and the fixed-dose combination fluticasone furoate/vilanterol, the components of TRELEGY, compared with placebo + fluticasone furoate/vilanterol, and on the long-term (≥12 months) safety profiles from the fixed-dose combination of fluticasone furoate/vilanterol, the fixed-dose combination of umeclidinium/vilanterol, and umeclidinium monotherapy. *[see Description (11), Clinical Pharmacology (12.3), and Clinical Studies (14.1) of full prescribing information]*.

Confirmatory Trials

Two 12-week treatment trials (Trial 1 and Trial 2) evaluated the coadministration of umeclidinium + fluticasone furoate/vilanterol, the components of TRELEGY, compared with placebo + fluticasone furoate/vilanterol. A total of 824 subjects with COPD across two 12-week, randomized, double-blind clinical trials received at least 1 dose of umeclidinium 62.5 mcg + fluticasone furoate/vilanterol 100 mcg/25 mcg or placebo + fluticasone furoate/vilanterol 100 mcg/25 mcg administered once daily (mean age: 64 years; 92% white, 66% male across all treatments) *[see Clinical Studies (14.1) of full prescribing information]*. The incidence of adverse reactions associated with the use of umeclidinium 62.5 mcg + fluticasone furoate/vilanterol 100 mcg/25 mcg presented in Table 1 is based upon the two 12-week trials.

Continued on next page

Table 1. Adverse Reactions With Umeclidinium + Fluticasone Furoate/Vilanterol With ≥1% Incidence and More Common Than Placebo + Fluticasone Furoate/Vilanterol (Trials 1 and 2)

Adverse Reaction	Umeclidinium + Fluticasone Furoate/ Vilanterol (n=412) %	Placebo + Fluticasone Furoate/ Vilanterol (n=412) %
Nervous system disorders		
Headache	4	3
Dysgeusia	2	<1
Musculoskeletal and connective tissue disorders		
Back pain	4	2
Respiratory, thoracic, and mediastinal disorders		
Cough	1	<1
Oropharyngeal pain	1	0
Gastrointestinal disorders		
Diarrhea	2	<1
Infections and infestations		
Gastroenteritis	1	0

Supporting Long-Term Safety Data

The long-term (≥12 months) safety profiles from the fixed-dose combination of fluticasone furoate/vilanterol, the fixed-dose combination of umeclidinium/vilanterol, and umeclidinium monotherapy are similar to that reported in the 12-week clinical trials described in Table 1. *[See full prescribing information for BREO ELLIPTA (fluticasone furoate and vilanterol inhalation powder), ANORO ELLIPTA (umeclidinium and vilanterol inhalation powder), and INCRUSE ELLIPTA (umeclidinium inhalation powder).]*

7 DRUG INTERACTIONS

7.1 Inhibitors of Cytochrome P450 3A4

Fluticasone furoate and vilanterol are 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 TRELEGY with long-term ketoconazole and other known strong CYP3A4 inhibitors (eg, 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, but may also produce severe bronchospasm in patients with COPD. Therefore, patients with COPD should not normally be treated with beta-blockers. However, under certain circumstances, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents for these patients; cardioselective beta-blockers could be considered, although they should be administered with caution.

7.4 Non–Potassium-Sparing Diuretics

The electrocardiographic changes and/or hypokalemia that may result from the administration of non–potassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, 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.

7.5 Anticholinergics

There is potential for an additive interaction with concomitantly used anticholinergic medicines. Therefore, avoid coadministration of TRELEGY with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects *[see Warnings and Precautions (5.14, 5.15)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are insufficient data on the use of TRELEGY or its individual components, fluticasone furoate, umeclidinium, and vilanterol, in pregnant women to inform a drug-associated risk.

Clinical Considerations

Labor and Delivery: TRELEGY should be used during late gestation and labor only if the potential benefit justifies the potential for risks related to beta-agonists interfering with uterine contractility.

8.2 Lactation

Risk Summary

There is no information available on the presence of fluticasone furoate, umeclidinium, or vilanterol in human milk; the effects on the breastfed child; or the effects on milk production. Umeclidinium is present in rat milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TRELEGY and any potential adverse effects on the breastfed child from fluticasone furoate, umeclidinium, or vilanterol, or from the underlying maternal condition.

8.5 Geriatric Use

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

In Trials 1 and 2 (coadministration trials), 189 subjects aged 65 years and older, of which 39 subjects were aged 75 years and older, were administered umeclidinium 62.5 mcg + fluticasone furoate/vilanterol 100 mcg/25 mcg. 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

TRELEGY has not been studied in subjects with hepatic impairment. Information on the individual components is provided below.

Fluticasone Furoate/Vilanterol

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. Monitor patients for corticosteroid-related side effects *[see Clinical Pharmacology (12.3) of full prescribing information]*.

Umeclidinium

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

10 OVERDOSAGE

No human overdosage data has been reported for TRELEGY.

TRELEGY contains fluticasone furoate, umeclidinium, and vilanterol; therefore, the risks associated with overdosage for the individual components described below apply to TRELEGY. Treatment of overdosage consists of discontinuation of TRELEGY 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 4000 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 Umeclidinium

High doses of umeclidinium may lead to anticholinergic signs and symptoms. However, there were no systemic anticholinergic adverse effects following a once-daily inhaled dose of up to 1000 mcg umeclidinium (16 times the maximum recommended daily dose) for 14 days in subjects with COPD.

10.3 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 (eg, 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 *of full prescribing information*).

Asthma-Related Death

Inform patients that LABA, such as vilanterol, one of the active ingredients in TRELEGY, increase the risk of asthma-related death. TRELEGY is not indicated for the treatment of asthma.

Not for Acute Symptoms

Inform patients that TRELEGY is not meant to relieve acute symptoms of COPD, 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.

Continued on next page

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 TRELEGY 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.

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 (ie, oral) antifungal therapy while still continuing therapy with TRELEGY, but at times therapy with TRELEGY 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 TRELEGY 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 TRELEGY.

Paradoxical Bronchospasm

As with other inhaled medicines, TRELEGY can cause paradoxical bronchospasm. If paradoxical bronchospasm occurs, instruct patients to discontinue TRELEGY and contact their healthcare provider right away.

Hypersensitivity Reactions, Including Anaphylaxis

Advise patients that hypersensitivity reactions (eg, anaphylaxis, angioedema, rash, urticaria) may occur after administration of TRELEGY. Instruct patients to discontinue TRELEGY 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 TRELEGY.

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 ICS may increase the risk of some eye problems (cataracts or glaucoma); consider regular eye examinations.

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

Worsening of Urinary Retention

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

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.

TRELEGY ELLIPTA was developed in collaboration with INNOVIVA

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TRELEGY ELLIPTA
(fluticasone furoate 100 mcg, umeclidinium 62.5 mcg, and vilanterol 25 mcg inhalation powder)

2018 ATS Assembly Awards

	Name of Award	2018 Awardees
Assembly on Allergy Immunology & Inflammation	Early Career Achievement Award	Yvonne J. Huang, MD
	Scientific Accomplishment Award	Mitchell A. Olman, MD, MA
	International Early Career Award	Serge Grazioli, MD
Assembly on Behavioral Science & Health Services Research	Lifetime Achievement Award	Andrea J. Apter, MA, MD, MSc
	Early Career Achievement Award	Laura C. Feemster, MSc, MD
Assembly on Critical Care	Lifetime Achievement Award	Margaret S. Herridge, MD
	Early Career Achievement Award	Hallie C. Prescott, MD, MSci
	Mid Career Award	Hannah Wunsch, MSc, MD
Assembly on Clinical Problems	Annual Educator Award	Peter F. Clardy, MD
	Annual Mentoring Award	Steven M. Kawut, MD, MS
	Early Career Achievement Award	Joanna Hart, MD, MS
	Early Stage Investigator Award in COPD Honoring Sreedhar Nair, MD	Fernando Sergio Leitao Filho, MD, PhD
	Lifetime Achievement Award in COPD Honoring Sreedhar Nair, MD	Barry J. Make, MD
Assembly on Environmental, Occupational and Population Health	John Peters Award	Susan M. Tarlo, MBBS
	David Bates Award	Daniel Croft, MD, MPH
	Velayudhan "Val" Vallyathan Award (Junior)	Amanda Mathew, PhD
	Velayudhan "Val" Vallyathan Award (Senior)	Jack R. Harkema, DVM, PhD
Assembly on Pulmonary Infections and Tuberculosis	Junior Level Award - Early Career Achievement Award	Christina Yoon, MD, MPH, MSCR
	Mid Career Award	Charles Dela Cruz, MD, PhD
	Senior Level Award	David M. Lewinsohn, MD, PhD
Assembly on Nursing	Marilyn Hansen Award	Jennifer R. Mammen, PhD, NP-C
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Assembly on Pulmonary Circulation	Robert Grover Prize	Barbara O. Meyrick, PhD
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	Scientific Abstract Awards	Divya Chhabra, MD, MMSc
	Scientific Abstract Awards	Erik Hysinger, MD, MS
Assembly on Pulmonary Rehabilitation	Recognition Award - From North America	Carolyn L. Rochester, MD
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Assembly on Respiratory Cell and Molecular Biology	Carol Basbaum Award	Darcy E. Wagner, PhD
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Best of ATS Video Lecture Series	1st Prize - Fall Cycle	Caitlin Clancy, MD
	2nd Prize - Fall Cycle	Arun Kannappan, MD
	3rd Prize - Fall Cycle	Ala Eddin S. Sagar, MD
	1st Prize - Spring Cycle	Zachary Fulkerson, MD, PhD
	2nd Prize - Spring Cycle	Dmitriy Golovyan, MD
	3rd Prize - Spring Cycle	Rosemary Adamson, MBBS
ATS Interest Group of Pulmonary/Critical Care and Sleep Medicine Professionals of South Asian Sub-Continent Origin Interest Group on Neonatal and the Developing Lung	Abstract Achievement Award	Srishti Saha, MBBS

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

Snapchat may seem to be just an app to use for fun filtered pictures, but it is so much more than that. It's a great way to stay connected during the conference. Use Snapchat to send photos and videos to friends and followers.

Get creative. Remember that Snapchat is the least serious of the social network platforms and have fun with it. Make notes on top of a photo. Circle items you want to highlight.

Use infinity. If you are making a video, keep it short and use the infinity feature so that viewers can re-watch it.

Measure momentum. See how many times your story was viewed or if someone took a screenshot of it. Simply click on your story and swipe up. ■

Assembly Awards Donor Acknowledgment

The **Early Stage Investigator Award in COPD Honoring Sreedhar Nair, MD**, and the **Lifetime Achievement Award in COPD Honoring Sreedhar Nair, MD**, are funded by a generous donation from the National Emphysema Foundation.

The **Velayudhan "Val" Vallyathan Award (Junior)** and **Velayudhan "Val" Vallyathan Award (Senior)** are funded by a generous donation from the National Emphysema Foundation honoring Velayudhan "Val" Vallyathan, MD.

The **Ann Woolcock Memorial Award** is supported by GlaxoSmithKline and the Thoracic Society of Australia and New Zealand. The **Joseph R. Rodarte Award** and the **Lifetime Achievement Award in Honor of Robert A. Crapo, MD**, are supported by a generous donation from MGC Diagnostics.

American Thoracic Society

The ATS Would Like to Acknowledge its 2018 Corporate Members

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For more information, please visit **www.thoracic.org**

APPLY FOR ATS FELLOW

Be considered for this mark of distinction and be recognized for your commitment and contributions to the Society.

ATS FELLOW
American Thoracic Society

Members of five years of more are welcome to apply, including non-clinicians (PhDs), nurses, and other allied health practitioners.

Applications will be accepted starting June 1. For more information or to apply, please visit **thoracic.org/members/membership/ats-fellows.php**.

Advanced Sarcoidosis: Who is at risk?

An industry-organized symposium at the American Thoracic Society 2018 International Conference

A session presented by

Debasis Sahoo, MD

Cleveland Clinic

WHEN

Tuesday, May 22

6:30 to 9:30 PM

WHERE

Manchester Grand Hyatt San Diego
Seaport Ballroom D-E
(Second Level, Seaport Tower)

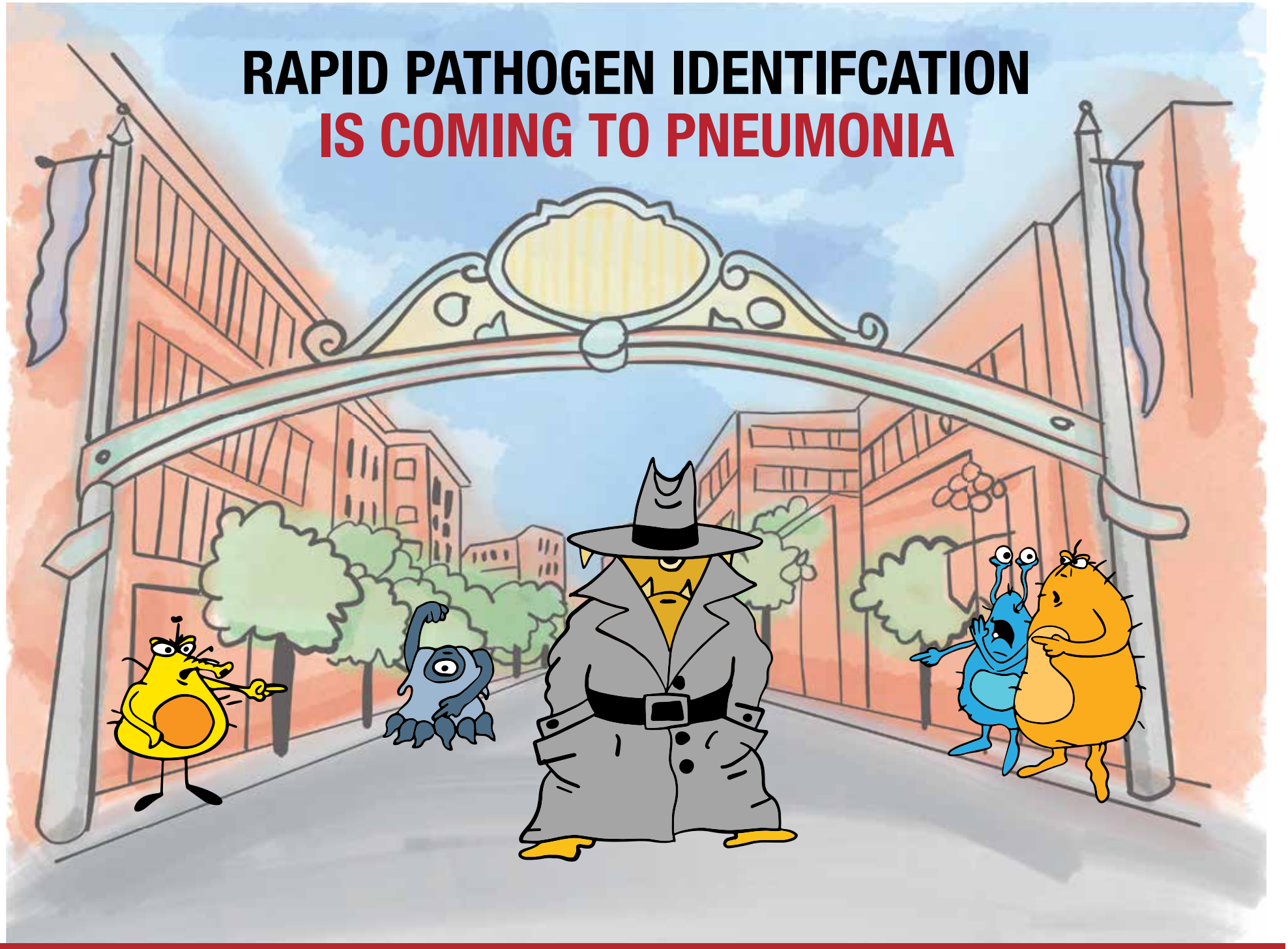
A non-CME educational program sponsored by

Mallinckrodt Pharmaceuticals

A presentation at the ATS 2018 International Conference. This event is sponsored by Mallinckrodt. Due to regulatory restrictions, this event is only available to attendees from the United States.

Please note that, per PhRMA guidelines and Mallinckrodt policy, attendance is restricted to US licensed healthcare professionals (HCPs). The cost of any meals and refreshments provided to HCPs attending this Mallinckrodt-sponsored program will be subject to public disclosure as part of the federal Open Payments/Physician Payments Sunshine Act and/or state law equivalents, as required by law. Federal employees, Vermont HCPs, and prescribers who are licensed in New Jersey or Minnesota may not receive food or beverage due to their respective federal regulations or state laws. Please keep in mind that HCPs may only attend one Mallinckrodt event per conference. This event is not CME accredited.

RAPID PATHOGEN IDENTIFCATION
IS COMING TO PNEUMONIA



NEW CLINICAL TRIAL DATA

Blake W. Buchan, PhD
Assistant Professor of Pathology
Associate Director, Clinical Microbiology
Medical College of Wisconsin

Jeremiah Stromich, MD
Sr. Fellow of Medical College of Wisconsin
Department of Medicine,
Division of Infectious Disease

BioFire has recently submitted a test to the FDA which will identify 18 bacteria, 8 viruses, and 7 genetic markers of resistance in commonly collected lower respiratory specimens, all in one hour!*

To discuss the incredible potential of this new test, we are honored to present Dr. Blake Buchan and Dr. Jeremiah Stromich from the Medical College of Wisconsin, a clinical trial site for the new BioFire® Pneumonia Panel.* Dr. Buchan will present an analysis from the clinical trial exploring how frequently a pneumonia panel result can effectively tailor antimicrobial therapy. Dr. Stormich will present patient cases from the clinical trial and discuss patient populations that will benefit most from the panel.

Come hear how this panel could change the way you practice medicine!

Tuesday May 22, 2018 6:30 pm–9:30 pm	Manchester Grand Hyatt San Diego Grand Hall D	Enjoy a cocktail hour followed by dinner & presenters

BIOFIRE®
A BIOMÉRIEUX COMPANY

biofiredx.com | ATS Booth #2905

An Industry-Organized Symposium at the ATS 2018 International Conference
A non-CME educational program sponsored by BioFire open to all ATS 2018 International Conference attendees

*Investigational Use Only

Get in the Game with Discovery Quest

Have you done the Discovery Quest yet? If not, don't miss your final chance to win an Apple watch. All it takes is visiting 12 different booths in the Exhibit Hall and scanning a QR code using your ATS mobile app.

Once you scan the code, the app will ask a simple multiple-choice question. You might find the answer on booth signs and information posters or you might need to talk with a booth staffer. Either way, the answer will be clear.

After you scan all 12 codes, ATS staff enters you in a random drawing for one of four Apple watches.

Participating Exhibitors

BD	Booth 1634
Imbio, LLC	Booth 2320
Jazz Pharmaceuticals	Booth 430
MedQIA	Booth 1030
Monaghan Medical Corporation	Booth 2443
Mount Sinai Health System	Booth 510
nSpire Health	Booth 2435
NTM Info & Research	Booth 539
PracticeLink	Booth 414
Pulmonary Fibrosis Foundation	Booth 722
RB	Booth 930
Reata Pharmaceuticals	Booth 4

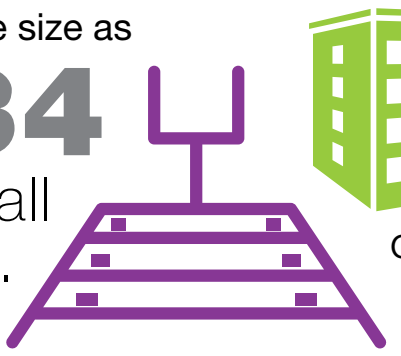
Fun Facts for ATS 2018

The ATS and its 17,000 International Conference attendees are using the entire San Diego Convention Center, and all of the meeting space in the Marriott Marquis, Manchester Grand Hyatt, and the San Diego Hilton Bayfront.

That's **2.5 million sq ft**
of space for sessions and exhibits

the same size as

434 football fields.



Our attendees are staying in **31 hotels** across the city.

The next grant cycle begins on July 17, 2018!

ENTELLIGENCE™

Young Investigator Program

www.entelligencemd.org

Established in 2005, ENTELLIGENCE is a program for basic science, translational, and clinical research in the field of cardiopulmonary medicine. The program provides opportunities for individual young investigators to promote quality medical care and enhance patients' lives by supporting research in pulmonary hypertension related to expanding our knowledge of the pathways involved in pulmonary vascular pathobiology.

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

ENTELLIGENCE Milestones

Year established: **2005**
Review cycles completed: **12**
Awards distributed: **59**
Funding: **>$5 million**

The application process is simple

1. Submit a Letter of Intent (LOI) proposal with an introduction, background, hypothesis, objectives, and specific aims
2. Have a mentor
3. If the LOI is selected, submit a full grant

The ENTELLIGENCE Young Investigator Program is supported through an educational grant from Actelion Pharmaceuticals US, Inc.

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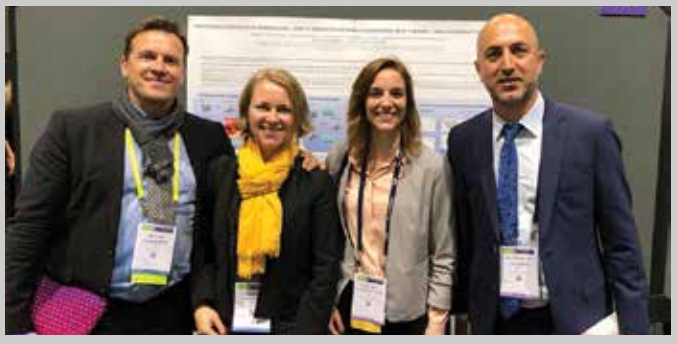
TODAY'S TOP TWEETS #ATS2018

Overflowing session on **#IPF** & **#ILD** complete with some robust debate from some well known 'elder statesmen' **#ATS2018** - fabulous learning environment.

@debra_sandford

An overlooked gem of **#ATS2018**. Spontaneously meeting and discussing science with friends from home, where we rarely have unassigned time. **#academicbliss @CU_PSCCM @com543 @atsearlycareer @atscommunity @m_konigshoff @KaminskiMed @DenPulm @KambezBenam @CoPARCUCD @jamesbeck_ATS** – at San Diego Marriott Marquis & Marina



@Eickelberg_MD

Humanizing care in the ICU is vital to improving long-term outcomes of patients/families treated in an intensive-care setting. **@SarahJBeesleyMD** discusses latest research from **@Intermountain**. **#ATS2018**

@IntermtnMedCtr

Trending at ATS 2018

30 million impressions at #ATS2018

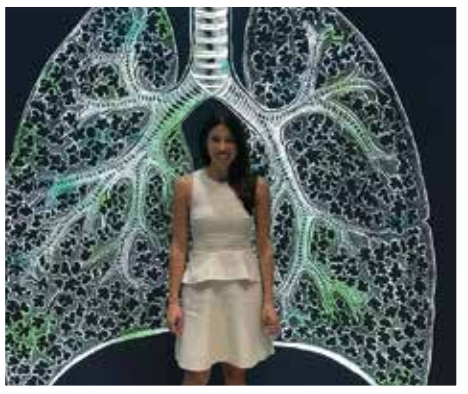
11,000 individual tweets

Do we need a new definition of COPD exacerbation? Of course we do. Our current method of distinguishing an exacerbation is like trying to cut a steak with a spoon - we get there, but it's hardly elegant. **#ATS2018**

@DundeeChest

Instagram

Join the #ATS18photo Instagram Challenge



Question of the Day

What are the correct targets for fluid administration in a patient with sepsis?

Bruno Digiovine, MD, MPH
Detroit, Michigan
The correct targets would be hemodynamic stability and assessment of fluid responsiveness using a variety of measures, such as straight leg raise or strip line variation.

Mustafa Abdulmahdi, MD
Baltimore, Maryland
Lactic-guided resuscitation in sepsis has been found in many meta-analyses to be superior to early goal-directed therapy in usual care. Using these dynamic volume assessment measures can be helpful, but it never showed mortality benefit. The only thing that did was lactic-guided resuscitation.

Kathleen Moffitt, MD
Portland, Oregon
Numerically, we target a goal of 30cc/kg. Clinically, we target markers of profusion.

Alex Botsch, NP
Akron, Ohio
We've chased CVP for a long time. 30ml/kg is the one they do the most. You could use a non-invasive set of monitoring with certain indices. It also might be facility-based.

Richard Schwartzstein, MD
Boston, Massachusetts
Initially, 2 liters, then reassess. Potentially, another 2 liters. We usually stop at 4 to 5. We don't usually make a weight modification.

KEYNOTES SERIES

Continued from page 1

Hypoxemic and Ischemic Protection in Deep-Diving Seals (K5)

Room 6B (Upper Level), San Diego Convention Center

Paul Ponganis, MD, PhD

Paul Ponganis, MD, PhD, a researcher at the Center for Marine Biotechnology and Biomedicine at the University of California, San Diego, will explain the level of arterial hemoglobin in seals during deep dives versus on land.

In addition to being a trained anesthesiologist, Dr. Ponganis has dedicated much of his life to studying the physiology of animals, especially diving animals, such as seals, penguins, and sea lions. He has been a leading contributor to the field of diving physiology of marine mammals and birds for decades, furthering the understanding of the exceptional physiological adaptations of numerous species of diving animals.

Bacteriophage Therapy for Serious Multidrug-Resistant Bacterial Infections (K6)

Room 6 C/F (Upper Level), San Diego Convention Center

Three speakers will present the second lecture. They are Robert T. Schooley, MD, professor of medicine in the Department of Medicine, Division of Infectious Diseases and Global Public Health, at the University of California, San Diego; Steffanie A. Strathdee, PhD, associate dean of Global Health Sciences and Harold Simon Professor in the Department of Medicine at the University of California, San Diego; and Thomas Patterson, PhD, professor in residence in the Psychiatry Department at the University of California, San Diego. The trio will discuss the potential clinical utility of bacteriophages in the treatment of serious multidrug resistant bacterial infections from the perspectives of the physician, the patient, and an actively engaged family member.

Robert T. Schooley, MD

Steffanie A. Strathdee, PhD

Thomas Patterson, PhD

Dr. Schooley began his research career studying the immunopathogenesis of herpes virus infections in immunocompromised patients but shifted his focus to AIDS in 1981 when the first cases of this syndrome began to appear in Boston. His research group was among the first to delineate the humoral and cellular immune responses to HIV infection.

Dr. Strathdee is an infectious disease epidemiologist who has spent the last two decades focusing on HIV prevention in underserved, marginalized populations in developed and developing countries, including injection drug users, men having sex with men, and sex workers.

Dr. Patterson was a founding editor of the journal AIDS and Behavior and has served as co-editor and on the editorial boards of a number of other journals.

WEDNESDAY

On Pharma: The Complexity of Innovation (K7)

Room 6B (Upper Level), San Diego Convention Center

Theodore F. Reiss, MD, MBE

Theodore F. Reiss, MD, MBE, a lecturer in clinical and translational research at University of Pennsylvania Institute for Translational Medicine and Therapeutics, will address how innovation involves collaborative interdependencies among scientific disciplines.

Dr. Reiss began his career with Merck & Co. in clinical pharmacology and pulmonary-immunology and eventually was responsible for other therapeutic areas within the company including gastroenterology. He currently serves as vice chair for the Foundation for American Thoracic Society and chairs the ATS's Drug, Device, Discovery and Development committee. He is a member of the FDA Science Board, and provides advice to the Commissioner on scientific issues.

The Pulmonologist as Medical Educator: A Personal Perspective (K8)

Room 6 C/F (Upper Level), San Diego Convention Center

Steven Weinberger, MD

Steven Weinberger, MD, former executive vice president and CEO of the American College of Physicians, will identify current trends in medical education and talk about recognizing opportunities that will enhance professional advancement as a clinician educator.

Dr. Weinberger is an adjunct professor of medicine at the University of Pennsylvania School of Medicine, where he has been teaching since 2004. ■

Applications Now Being Accepted

Gilead Sciences Research Scholars Program In Cystic Fibrosis

The program supports innovative scientific research that will advance knowledge in the field of cystic fibrosis, and provides support for 3 junior faculty researchers in Canada, Europe, or the United States for a 2-year period

Each award will be funded up to USD130,000, to be paid in annual installments of up to USD65,000

Awards are subject to separate terms and conditions

SCIENTIFIC REVIEW COMMITTEE

Applications will be reviewed by a committee comprised of internationally recognized experts in basic and clinical research in the field of cystic fibrosis

Application Deadline:
Friday, July 20, 2018, 11:59 PM Daylight Savings Time

For more information and to apply for an award, please visit:
http://researchscholars.gilead.com
Click on the CF program logo

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