ATS DAILY BULLETIN

Where today's science meets tomorrow's care™

Monday
May 21, 2018
San Diego, CA • May 18-23, 2018

Tobacco's Long & Winding Road

The ATS has long advocated against tobacco use. The ATS and other anti-tobacco groups achieved a decisive victory by forcing tobacco producers to admit their complicity in hiding the truth about the dangers of smoking. The ATS continues its campaign against smoking by discouraging the use of e-cigarettes and candy-flavored tobacco. See disclosure statements and details of the ATS's advocacy efforts on display outside Hall G.

Putting Learning Theory Into Practice

Education is a key skill for every health care provider. Learning how the mind works and how learning happens can make all of us more effective teachers.

"A lot of us are involved in teaching medical students and residents, and we all teach patients," says Garth Garrison, MD, assistant professor of medicine at the University of Vermont Lamer College of Medicine. "But most providers are less involved at a higher level, where we are learning about how to more effectively deliver content."


Garth Garrison, MD

Dr. Garrison will co-chair the first ATS symposium on putting learning theory into practice to help learners learn more, learn faster, and learn more effectively. He will share the podium with Rosemary Adamson, MBBS, Department of Veterans Affairs Puget Sound Health System, and Jeremy B. Richards, MD, MA, Beth Israel Deaconess Medical Center.

Individual sessions at prior ATS conferences have addressed metacognition and learning theory, Dr. Garrison says, but this is the first symposium devoted entirely to exploring the latest developments in learning theory and putting them into practice.

The reality, he says, is that many providers still rely on traditional sage-on-the-stage teaching methods. That kind of didactic lecture may be a practical necessity in some settings, but passive learning, listening to the expert, is far less effective than active learning

see METACOGNITION page 46

DON'T MISS THESE EVENTS

Pulmonary Hypertension, Right Heart Cath session
11:30 a.m.-12:40 p.m., Clinicians Center

Best and Worst ICU Rounds session
12:50-2 p.m., Clinicians Center

ATS Outstanding Clinician Award Reception
4-5 p.m., Clinicians Center

KEYNOTE SERIES

Macrophages and Burnout

The ATS Keynote Series will continue today as speakers address the effects of macrophage phenotypes and disease, and the personal and professional consequences of burnout.

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


Christopher K. Glass, MD, PhD

Nature and Nurture of Tissue-Resident Macrophages in Health and Disease (K3)
Room 6B (Upper Level), San Diego Convention Center
Christopher K. Glass, MD, PhD, professor of medicine and cellular and molecular medicine at the University of California, San Diego, will explain the effects of non-coding genetic variation on macrophage phenotypes and disease.

see KEYNOTE SERIES page 46

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GILEAD

Diversity Forum: You Are Your Own CEO

Kristen Bibbins-Domingo, PhD, urged Diversity Forum attendees to take charge and trust their instincts as they pursued career goals.

Building a successful career is all about mindset. Mentors, coaches, and supporters are key contributors, but the single most important factor is you.

"You are the CEO driving your life and your career," said Kristen Bibbins-Domingo, PhD, MD, MAS, chair and professor of Epidemiology and Biostatistics at the University of California San Francisco School of Medicine. "Your friends, coaches, mentors, and supporters are your board of directors, but you are the person in charge."

Dr. Bibbins-Domingo delivered the keynote address for the 2018 Diversity Forum on Sunday. The lunch also honored the 40 recipients of Minority Trainee Development Scholarships. All of the winners are presenting abstracts this week at ATS International Conference.

Matriculating through public schools to Princeton, the University of Ibadan, Nigeria, and the University of California doesn't happen by chance, especially for minority students and women.

"I was lucky enough to have a great set of public school teachers and guidance counselors who steered me to Princeton," Dr. Bibbins-Domingo said. "Most of us got to where we are because we did the right things at the right times. What I learned from the journey is that you can—you must—take control of that journey. Pay attention to what motivates you, the people around you, your institution."

A single patient she saw at San Francisco General Hospital helped shape her career. A 40-year-old black man died of heart failure. Defying conventional wisdom, his first episode of heart failure occurred at two years of age.

"As a fellow, I decided to study heart failure in young adults," she explained. "My mentor objected, noting that heart failure is a disease of the elderly. Except I knew it wasn't. We now know that heart failure is more common in African-Americans and tends to occur earlier. Knowing that health events begin earlier in poor communities changes how we think about prevention and treatment. A more diverse workforce and more diverse clinical trial populations makes all of the difference in the awareness of disparities across different communities. The things that form the basis of your career are the things that fascinate you or anger you. That emotional commitment will support you through the journey." ■

> "What I learned from the journey is that you can—you must—take control of that journey."
>
> **Kristen Bibbins-Domingo, PhD, MD, MAS**

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

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Stay connected

TODAY'S TOP TWEETS #ATS2018

Congratulations to the **#ATS2018** Award winners! Only 2/15 are women. Sponsorship of women is key. Suggest and promote your female colleagues for awards and other scholarly academic actitivites.

@geetamehta0

Me: "I will have limited access to email and will not be able to respond regularly as I am traveling for **#ATS2018.**"

Also me: "Get ready folks, I'll be live tweeting and blogging the hell out of **#ATS2018.**"

Oh, the irony.

@virenkaul

Wow. Speaker just pointed out that we are sending pts home with families who are often struggling with their own anx/depression/pts as a result of the ICU stay & then expecting them to be primarily care-givers. "How fair is that?" **#ATS2018**

@vitaincerta

So excited to attend **#ATS2018** as one of the student scholars! Can't wait to learn more about Pulm/Crit Care and meet others in the field! I'm going to live tweet some the cool things I learn throughout the conference.

@RAmirahmadi

Excellent hands on teaching at **#ATS2018** Resident Boot Camp **@anna_neumeier @bridget_graney @PDX_PulmCC @doc_connors @CU_PSCCM**

@TristanHuie

Surviving Critical Illness session this morning at **#ATS2018** - Judith Tate comments on "functional reconciliation" in the ICU setting. Sounds like a concept that may have utility in many areas of acute care. Time to look up the paper by D Elliott (2014)

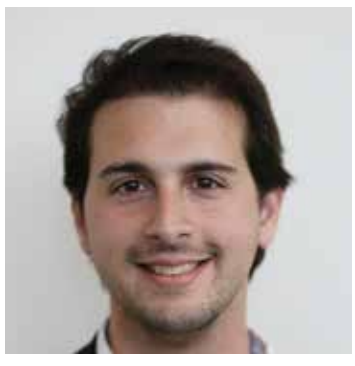
@UBCPulmRehabRes

Instagram

Join the #ATS18photo Instagram Challenge

Question of the Day

What next steps would you take for a patient with obstructive sleep apnea who has been unable to tolerate continuous positive airway pressure (CPAP) therapy?



David De Angel Sola, MD
New Haven, Connecticut
"I'm a pediatrician, so I would try lifestyle modifications, like weight loss and nutrition. I also would medicate them with nasal steroids to decrease the resistance in their airways. After that, my next step would be a tonsillectomy and adenoidectomy."

M. Iyad Saadi, MD
Phoenix, Arizona
"I would ask why they were not able to tolerate the CPAP and see what other things I could help them with. If it's a mask issue, then we can change the masks out. Or if it's a pressure issue, we can adjust the pressure on the CPAP. An alternative would be an appliance."

M. Jeffery Mador, MD
Buffalo, New York
"We try CPAP desensitization. The patient practices wearing the mask, then they practice wearing it during the day, then they practice it throughout the night. Then we might try alternative therapies, like a mandibular advancement device."

Ching Li Chai-Coetzer, MBBS, PhD
Adelaide, Australia
"I would try to find out why they're not tolerating CPAP. I'd try to address any side effects they are having and see if they can be easily overcome. If the patient decides they don't want to continue the CPAP, I'll discuss other treatments, like weight loss, a mouth splint, or posture control therapy."

Reena Mehra, MD
Cleveland, Ohio
"We give it our best with CPAP. We have the ability to do PAP-NAP studies. We also have a sleep apnea management clinic with a respiratory therapist and a sleep provider to help with improvements in adherence to CPAP. After that an oral appliance is a logical alternative. We also have nerve-stimulation and the Inspire device implantation."

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

Nontuberculous mycobacterial (NTM) lung disease is a chronic, debilitating condition that can significantly increase patient **morbidity and mortality**[1-5]

- Approximately **2/3 of NTM patients** have moderate to severe NTM by the time they are diagnosed[6,7]
- 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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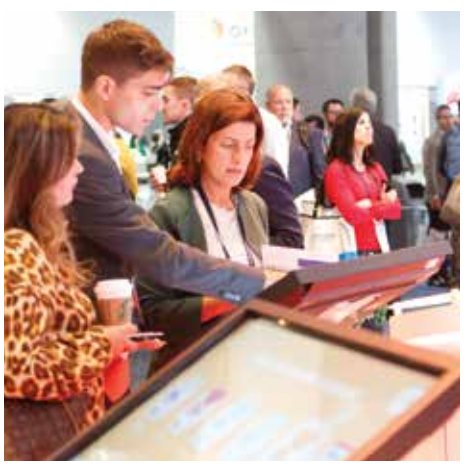
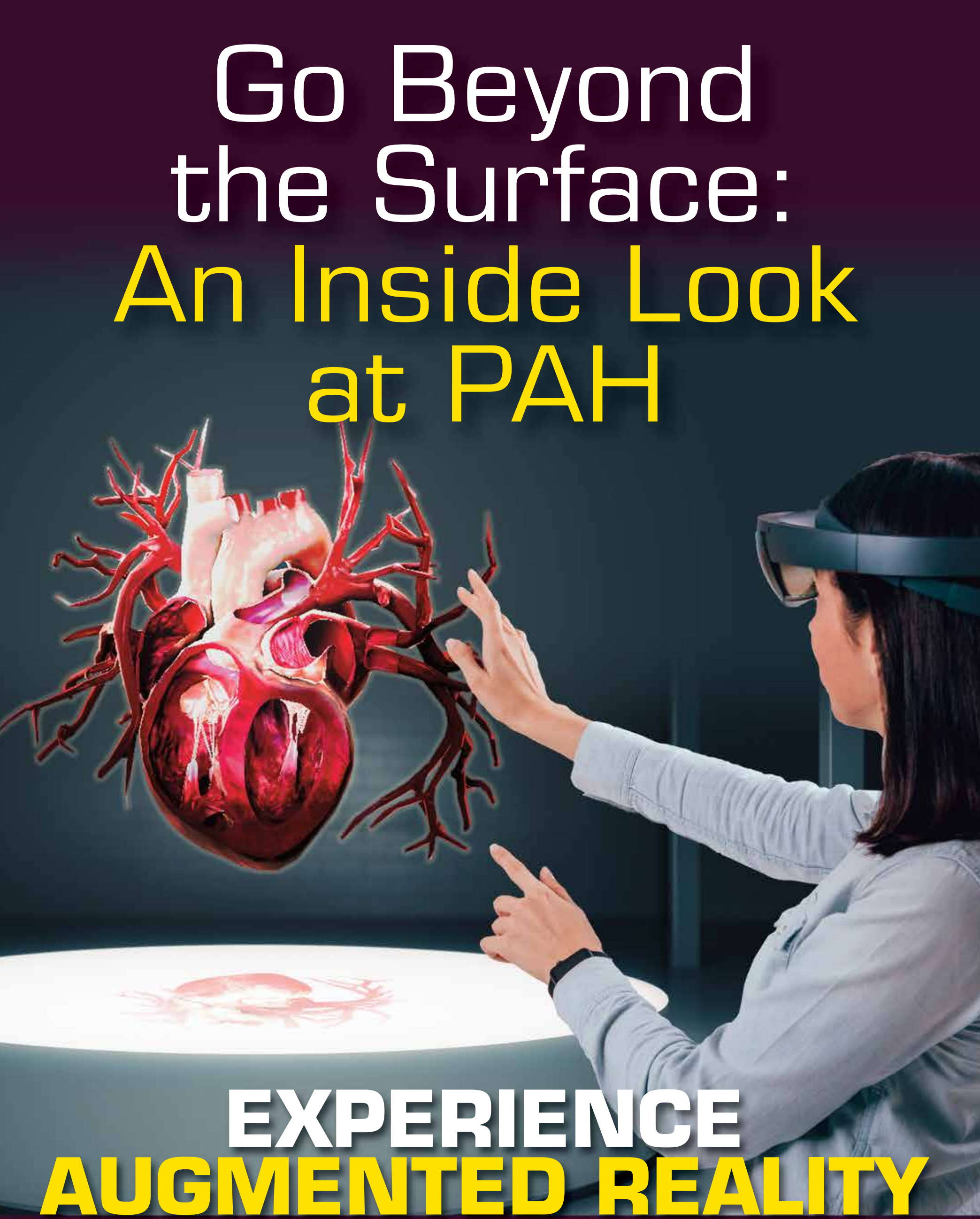


Learning Launches at ATS 2018

Popular sessions on Sunday drew crowds of attendees who filled overflow seating areas as learning took center stage. In between sessions, they headed to networking areas to connect with colleagues, and even made time to de-stress by playing with dogs in the Restoring Joy in Health Care Booth (904).

Go Beyond the Surface: An Inside Look at PAH



EXPERIENCE AUGMENTED REALITY

Booth #2235

ACTELION | A JANSSEN PHARMACEUTICAL COMPANY OF Johnson & Johnson

Meet the Finalists of BEAR Cage 2018

A $5,000 cash prize is on the line for three early career professionals who will "pitch" their innovative research proposals to a panel of translational science experts during the ATS BEAR Cage competition.

The fourth annual Building Education to Advance Research (BEAR) Cage competition, which follows a Shark Tank-style of presentation, will award $5,000 to the top presentation and $2,500 each to the two runners-up.

BEAR Cage

1-3 p.m., Monday

Center for Career Development

Sails Pavilion (Upper Level), San Diego Convention Center

"Precision Genomics: Early Detection of Antibody-Mediated Rejection to Improve Survival"

Sean Agbor-Enoh, MD, PhD
National Heart, Lung, and Blood Institute

Q: *What do you look forward to most during the BEAR Cage?*

A: I would not only like to learn from my opponents' valuable research contributions, but also to see lung transplantation efforts "win" again. In the 1960s, lung transplantation was introduced as a "miracle treatment" for selected patients with end-stage lung disease who would otherwise not survive. Since then, survival remains dismal with a median of five years, despite our collective efforts. Among other extraordinary opportunities, BEAR Cage offers an opportunity to highlight a trend toward improving survival of these patients.

Q: *Why should the panel award you the top prize?*

A: I believe the jury should pick me as the winner because the idea/product I plan to introduce is innovative, inexpensive, has great impact, and is broadly applicable to lung and other allograft transplantation.

Q: *What would you do with the $5,000 should you win?*

A: It is not the amount per se, but the idea of investing the money in a process or startup business could make this assay useful to transplant patients.

"Identifying Novel Disease-Modifying Drugs for the Treatment of Chronic Obstructive Pulmonary Disease"

Carlos Barrero, MD
Temple University

Q: *What do you look forward to most during the BEAR Cage?*

A: First, I am truly honored to be a finalist in the BEAR Cage competition and for the opportunity to present my work. Most of all, though, I look forward to getting mentorship from the project advisory team. Also, I would like to hear the feedback from experts in the field. Regardless of what happens in the competition, I will take those lessons to apply them toward the success of this proposal.

Q: *Why should the panel award you the top prize?*

A: The panel should choose me because I am going to present a project that has the potential to identify a disease-modifying treatment for COPD, a devastating disease that is currently the third leading cause of death in the U.S.

Q *What would you do with the $5,000 should you win?*

A: I am excited to participate in this event. The prize for the BEAR Cage competition is going to be part of the savings to buy the first home for my family. I would love to show my family that my research efforts also translate to them.

"NEMESIS (NEutrophil MEchanical StabillSation): A Novel Extracorporeal Technology to Modulate and Monitor Pathological Inflammatory Responses of Neutrophils (PMN) in Acute Respiratory Distress Syndrome"

Jatinder K. Juss, MD, PhD, FRCPC
St. Michael's Hospital

Q: *What do you look forward to most during the BEAR Cage?*

A: I am thrilled to present NEMESIS, a first-of-its-kind potentially transformative extracorporeal technology at the ATS BEAR Cage competition! What excites me most about the BEAR Cage is that it cultivates strategic links between physician-led science, academia, and industry to deploy innovative technologies that will benefit patient care. This is the first time a Canadian was selected to compete at the ATS BEAR Cage, and I am looking forward to becoming the first female entrepreneur to win the top prize!

Q: *Why should the panel award you the top prize?*

A: NEMESIS has enormous potential that addresses the salient challenges of re-establishing immune homeostasis not only in ARDS patients but also in critically ill patients with conditions characterized by persistent and inappropriate neutrophil activation, including sepsis, burns, major trauma, or surgery.

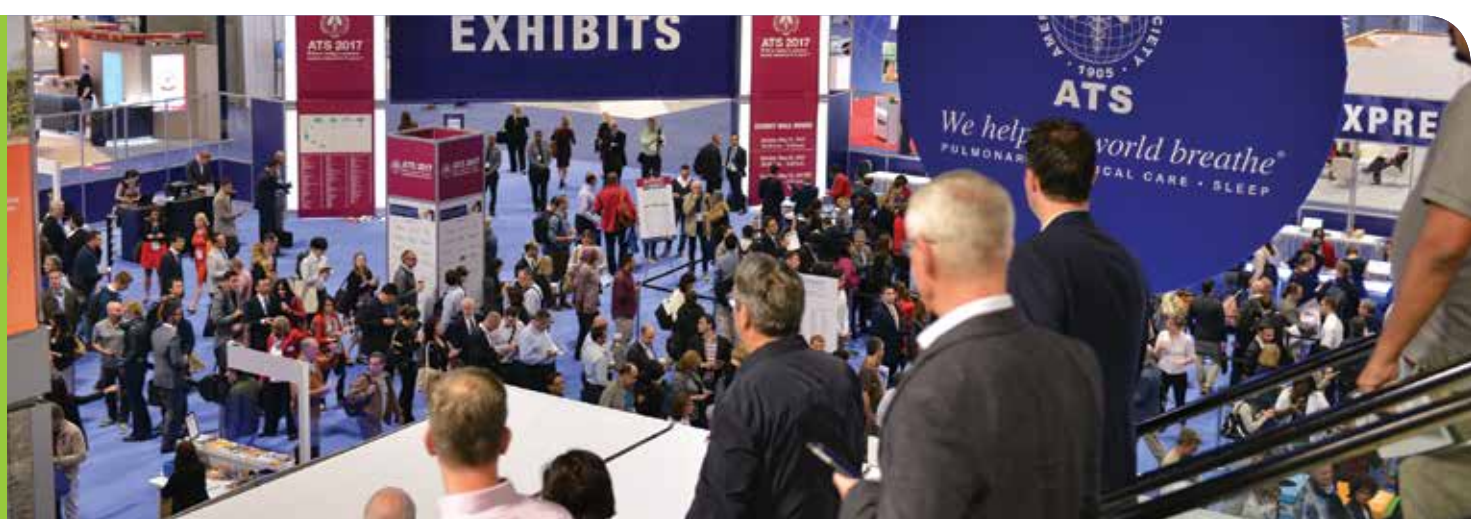
Q: *What would you do with the $5,000 should you win?*

A: Winning the BEAR Cage competition carries enormous prestige beyond any monetary gain. The publicity around this award will heighten visibility of NEMESIS, foster industry partnerships, and provide additional opportunities for public engagement to raise awareness of ARDS and sepsis. ■

Exhibit Hall Hours

MONDAY, MAY 21
10:30 a.m.–3:30 p.m.
Unopposed Hours: 1:15–2:15 p.m.

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



Visit GSK Booth #1734

NUCALA—Prescribe with confidence

The first anti-interleukin 5 (IL-5) for severe eosinophilic asthma

NUCALA is indicated for the add-on maintenance treatment of patients 12 years and older with severe asthma with an eosinophilic phenotype. NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.

DiscoverNucalaHCP.com

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUCALA should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (eg, anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred with NUCALA. These reactions generally occur within hours of administration but can have a delayed onset (ie, days). If a hypersensitivity reaction occurs, discontinue NUCALA.

Acute Asthma Symptoms or Deteriorating Disease

NUCALA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Opportunistic Infections: Herpes Zoster

In controlled clinical trials, 2 serious adverse reactions of herpes zoster occurred with NUCALA compared to none with placebo. Consider vaccination if medically appropriate.

Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with NUCALA. Decreases in corticosteroid doses, if appropriate, should be gradual and under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

Treat patients with pre-existing helminth infections before initiating therapy with NUCALA. If patients become infected while receiving NUCALA and do not respond to anti-helminth treatment, discontinue NUCALA until infection resolves.

ADVERSE REACTIONS

The most common adverse reactions (≥3% and more common than placebo) reported in the first 24 weeks of 2 clinical trials with NUCALA (and placebo) were: headache, 19% (18%); injection site reaction, 8% (3%); back pain, 5% (4%); fatigue, 5% (4%); influenza, 3% (2%); urinary tract infection, 3% (2%); abdominal pain upper, 3% (2%); pruritus, 3% (2%); eczema, 3% (<1%); and muscle spasms, 3% (<1%).

*As of January 2018, more than 20,000 patients have received NUCALA**

*December 2015 to January 2018 data sourced from IQVIA and GSK. Claims data based on total number of unique patients who had at least 1 claim for NUCALA in the United States. Not all patients remain on therapy. Individual results may vary.[1]

In patients with blood eosinophil levels ≥150 cells/µL,

NUCALA provided a strong and consistent reduction in exacerbations[2,3†]

MENSA

53%

Reduction in exacerbation frequency at Week 32

(*P*<0.001)[2]

MUSCA

58%

Reduction in exacerbation frequency at Week 24

(Rate ratio: 0.42; 95% CI: 0.31, 0.56)[3]

Other endpoint; results are descriptive.

CI=confidence interval.

MENSA (Trial 2) Study Description[2]: 32-week study comparing treatment with NUCALA or placebo added to standard of care (SOC) in 576 patients with severe eosinophilic asthma. **Primary Endpoint:** Frequency of exacerbations.† **Results:** Exacerbations/year 0.83 for NUCALA vs 1.74 for placebo.

MUSCA Study Description[3]: 24-week study comparing treatment with NUCALA or placebo added to SOC in 551 patients with severe eosinophilic asthma. **Primary Endpoint:** Mean change from baseline in St George's Respiratory Questionnaire total score at Week 24. **Results:** –15.6 for NUCALA vs –7.9 for placebo; treatment difference of –7.7 (*P*<0.0001). The improvement in both treatment arms was clinically meaningful (defined as a reduction in score of ≥4 points). **Other endpoint:** Included frequency of exacerbations. **Results:** Exacerbations/year 0.51 for NUCALA vs 1.21 for placebo.

†Exacerbations were defined as the worsening of asthma that required use of oral/systemic corticosteroids and/or hospitalization and/or emergency department visits; for patients on maintenance oral/systemic corticosteroids, exacerbations were defined as requiring at least double the existing maintenance dose for at least 3 days.

SOC=regular treatment with high-dose inhaled corticosteroids and at least 1 other controller with or without oral corticosteroids

The approved dose of NUCALA for severe eosinophilic asthma is 100 mg administered every 4 weeks by subcutaneous injection into the upper arm, thigh, or abdomen.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

Systemic Reactions, including Hypersensitivity Reactions: In 3 clinical trials, the percentages of subjects who experienced systemic (allergic and nonallergic) reactions were 3% for NUCALA and 5% for placebo. Manifestations included rash, flushing, pruritus, headache, and myalgia. A majority of the systemic reactions were experienced on the day of dosing.

Injection site reactions (eg, pain, erythema, swelling, itching, burning sensation) occurred in subjects treated with NUCALA.

USE IN SPECIFIC POPULATIONS

A pregnancy exposure registry monitors pregnancy outcomes in women exposed to NUCALA during pregnancy. To enroll call 1-877-311-8972 or visit www.mothertobaby.org/asthma.

The data on pregnancy exposures are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as the pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimesters.

References: 1. Data on file, GSK. **2.** Ortega HG, Liu MC, Pavord ID, et al; for the MENSA Investigators. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Engl J Med.* 2014;371(13):1198-1207. **3.** Chupp GL, Bradford ES, Albers FC, et al. Efficacy of mepolizumab add-on therapy on health-related quality of life and markers of asthma control in severe eosinophilic asthma (MUSCA): a randomised, double-blind, placebo-controlled, parallel-group, multicentre, phase 3b trial. *Lancet Respir Med.* 2017;5(5):390-400.

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

Nucala
(mepolizumab)
for Subcutaneous Injection
100 mg/vial

Printed in USA. 1002800R0 April 2018

BRIEF SUMMARY

NUCALA
(mepolizumab) for injection, for subcutaneous use

The following is a brief summary only and is focused on the indication for maintenance treatment of severe asthma with an eosinophilic phenotype. See full prescribing information for complete product information.

1 INDICATIONS AND USAGE

1.1 Maintenance Treatment of Severe Asthma

NUCALA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Limitation of Use

NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.

4 CONTRAINDICATIONS

NUCALA should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred following administration of NUCALA. These reactions generally occur within hours of administration, but in some instances can have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, NUCALA should be discontinued *[see Contraindications (4)]*.

5.2 Acute Asthma Symptoms or Deteriorating Disease

NUCALA should not be used to treat acute asthma symptoms or acute exacerbations. Do not use NUCALA to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with NUCALA.

5.3 Opportunistic Infections: Herpes Zoster

Herpes zoster has occurred in subjects receiving NUCALA 100 mg in controlled clinical trials *[see Adverse Reactions (6.1)]*. Consider vaccination if medically appropriate.

5.4 Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids (ICS) abruptly upon initiation of therapy with NUCALA. Reductions in corticosteroid dosage, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dosage may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

5.5 Parasitic (Helminth) Infection

Eosinophils may be involved in the immunological response to some helminth infections. Patients with known parasitic infections were excluded from participation in clinical trials. It is unknown if NUCALA will influence a patient's response against parasitic infections. Treat patients with pre-existing helminth infections before initiating therapy with NUCALA. If patients become infected while receiving treatment with NUCALA and do not respond to anti-helminth treatment, discontinue treatment with NUCALA until infection resolves.

6 ADVERSE REACTIONS

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

- Hypersensitivity reactions *[see Warnings and Precautions (5.1)]*
- Opportunistic infections: herpes zoster *[see Warnings and Precautions (5.3)]*

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

6.1 Clinical Trials Experience in Severe Asthma

A total of 1,327 subjects with asthma were evaluated in 3 randomized, placebo-controlled, multicenter trials of 24 to 52 weeks' duration (Trials 1, 2, and 3). Of these, 1,192 had a history of 2 or more exacerbations in the year prior to enrollment despite regular use of high-dose ICS plus additional controller(s) (Trials 1 and 2), and 135 subjects required daily oral corticosteroids (OCS) in addition to regular use of high-dose ICS plus additional controller(s) to maintain asthma control (Trial 3). All subjects had markers of eosinophilic airway inflammation *[see Clinical Studies (14.1) of full prescribing information]*. Of the subjects enrolled, 59% were female, 85% were white, and ages ranged from 12 to 82 years. Mepolizumab was administered subcutaneously or intravenously once every 4 weeks; 263 subjects received NUCALA (mepolizumab 100 mg SC) for at least 24 weeks. Serious adverse events that occurred in more than 1 subject and in a greater percentage of subjects receiving NUCALA 100 mg (n = 263) than placebo (n = 257) included 1 event, herpes zoster (2 subjects vs. 0 subjects, respectively). Approximately 2% of subjects receiving NUCALA 100 mg withdrew from clinical trials due to adverse events compared with 3% of subjects receiving placebo.

The incidence of adverse reactions in the first 24 weeks of treatment in the 2 confirmatory efficacy and safety trials (Trials 2 and 3) with NUCALA 100 mg is shown in Table 1.

Table 1. Adverse Reactions with NUCALA with ≥3% Incidence and More Common than Placebo in Subjects with Asthma (Trials 2 and 3)

Adverse Reaction	NUCALA (Mepolizumab 100 mg Subcutaneous) (n = 263) %	Placebo (n = 257) %
Headache	19	18
Injection site reaction	8	3
Back pain	5	4
Fatigue	5	4
Influenza	3	2
Urinary tract infection	3	2
Abdominal pain upper	3	2
Pruritus	3	2
Eczema	3	<1
Muscle spasms	3	<1

52-Week Trial

Adverse reactions from Trial 1 with 52 weeks of treatment with mepolizumab 75 mg intravenous (IV) (n = 153) or placebo (n = 155) and with ≥3% incidence and more common than placebo and not shown in Table 1 were: abdominal pain, allergic rhinitis, asthenia, bronchitis, cystitis, dizziness, dyspnea, ear infection, gastroenteritis, lower respiratory tract infection, musculoskeletal pain, nasal congestion, nasopharyngitis, nausea, pharyngitis, pyrexia, rash, toothache, viral infection, viral respiratory tract infection, and vomiting. In addition, 3 cases of herpes zoster occurred in subjects receiving mepolizumab 75 mg IV compared with 2 subjects in the placebo group.

Systemic Reactions, including Hypersensitivity Reactions

In Trials 1, 2, and 3 described above, the percentage of subjects who experienced systemic (allergic and non-allergic) reactions was 5% in the placebo group and 3% in the group receiving NUCALA 100 mg. Systemic allergic/hypersensitivity reactions were reported by 2% of subjects in the placebo group and 1% of subjects in the group receiving NUCALA 100 mg. The most commonly reported manifestations of systemic allergic/hypersensitivity reactions reported in the group receiving NUCALA 100 mg included rash, pruritus, headache, and myalgia. Systemic non-allergic reactions were reported by 2% of subjects in the group receiving NUCALA 100 mg and 3% of subjects in the placebo group. The most commonly reported manifestations of systemic non-allergic reactions reported in the group receiving NUCALA 100 mg included rash, flushing, and myalgia. A majority of the systemic reactions in subjects receiving NUCALA 100 mg (5/7) were experienced on the day of dosing.

Injection Site Reactions

Injection site reactions (e.g., pain, erythema, swelling, itching, burning sensation) occurred at a rate of 8% in subjects receiving NUCALA 100 mg compared with 3% in subjects receiving placebo.

Long-term Safety

Nine hundred ninety-eight subjects received NUCALA 100 mg in ongoing open-label extension studies, during which additional cases of herpes zoster were reported. The overall adverse event profile has been similar to the asthma trials described above.

6.3 Immunogenicity

In subjects with asthma receiving NUCALA 100 mg, 15/260 (6%) developed anti-mepolizumab antibodies. Neutralizing antibodies were detected in 1 subject with asthma receiving NUCALA 100 mg. Anti-mepolizumab antibodies slightly increased (approximately 20%) the clearance of mepolizumab. There was no evidence of a correlation between anti-mepolizumab antibody titers and change in eosinophil level. The clinical relevance of the presence of anti-mepolizumab antibodies is not known.

The reported frequency of anti-mepolizumab antibodies may underestimate the actual frequency due to lower assay sensitivity in the presence of high drug concentration. The data reflect the percentage of patients whose test results were positive for antibodies to mepolizumab in specific assays. The observed incidence of antibody positivity in an assay is highly dependent on several factors, including assay sensitivity and specificity, assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease.

6.4 Postmarketing Experience

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

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis.

7 DRUG INTERACTIONS

Formal drug interaction trials have not been performed with NUCALA.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women with asthma exposed to NUCALA during pregnancy. Healthcare providers can enroll patients or encourage patients to enroll themselves by calling 1-877-311-8972 or visiting www.mothertobaby.org/asthma.

Risk Summary

The data on pregnancy exposure are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy. In a prenatal and postnatal development study conducted in cynomolgus monkeys, there was no evidence of fetal harm with IV administration of mepolizumab throughout pregnancy at doses that produced exposures up to approximately 9 times the exposure at the maximum recommended human dose (MRHD) of 300 mg SC *(see Data)*.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryofetal Risk: In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of preeclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. The level of asthma control should be closely monitored in pregnant women and treatment adjusted as necessary to maintain optimal control.

Data

Animal Data: In a prenatal and postnatal development study, pregnant cynomolgus monkeys received mepolizumab from gestation Days 20 to 140 at doses that produced exposures up to approximately 9 times that achieved with the MRHD (on an AUC basis with maternal IV doses up to 100 mg/kg once every 4 weeks). Mepolizumab did not elicit adverse effects on fetal or neonatal growth (including immune function) up to 9 months after birth. Examinations for internal or skeletal malformations were not performed. Mepolizumab crossed the placenta in cynomolgus monkeys. Concentrations of mepolizumab were approximately 2.4 times higher in infants than in mothers up to Day 178 postpartum. Levels of mepolizumab in milk were ≤0.5% of maternal serum concentration.

In a fertility, early embryonic, and embryofetal development study, pregnant CD-1 mice received an analogous antibody, which inhibits the activity of murine interleukin-5 (IL-5), at an IV dose of 50 mg/kg once per week throughout gestation. The analogous antibody was not teratogenic in mice. Embryofetal development of IL-5–deficient mice has been reported to be generally unaffected relative to wild-type mice.

8.2 Lactation

Risk Summary

There is no information regarding the presence of mepolizumab in human milk, the effects on the breastfed infant, or the effects on milk production. However, mepolizumab is a humanized monoclonal antibody (IgG1 kappa), and immunoglobulin G (IgG) is present in human milk in small amounts. Mepolizumab was present in the milk of cynomolgus monkeys postpartum following dosing during pregnancy *[see Use in Specific Populations (8.1)]*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NUCALA and any potential adverse effects on the breastfed infant from mepolizumab or from the underlying maternal condition.

8.4 Pediatric Use

The safety and efficacy in pediatric patients younger than 12 years with asthma have not been established. A total of 28 adolescents aged 12 to 17 years with asthma were enrolled in the Phase 3 asthma studies. Of these, 25 were enrolled in the 32-week exacerbation trial (Trial 2) and had a mean age of 14.8 years. Subjects had a history of 2 or more exacerbations in the previous year despite regular use of high-dose ICS plus additional controller(s) with or without OCS and had blood eosinophils of ≥150 cells/mcL at screening or ≥300 cells/mcL within 12 months prior to enrollment. *[See Clinical Studies (14.1) of full prescribing information.]* Subjects had a reduction in the rate of exacerbations that trended in favor of mepolizumab. Of the 19 adolescents who received mepolizumab, 9 received NUCALA 100 mg and the mean apparent clearance in these subjects was 35% less than that of adults. The adverse event profile in adolescents was generally similar to the overall population in the Phase 3 studies *[see Adverse Reactions (6.1)]*.

The safety and efficacy in pediatric patients other than those with asthma have not been established.

8.5 Geriatric Use

Clinical trials of NUCALA did not include sufficient numbers of subjects aged 65 years and older that received NUCALA (n = 46) to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Based on available data, no adjustment of the dosage of NUCALA in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out.

10 OVERDOSAGE

Single doses of up to 1,500 mg have been administered intravenously to subjects in a clinical trial with eosinophilic disease without evidence of dose-related toxicities.

There is no specific treatment for an overdose with mepolizumab. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

(continued on next page)

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of mepolizumab. Published literature using animal models suggests that IL-5 and eosinophils are part of an early inflammatory reaction at the site of tumorigenesis and can promote tumor rejection. However, other reports indicate that eosinophil infiltration into tumors can promote tumor growth. Therefore, the malignancy risk in humans from an antibody to IL-5 such as mepolizumab is unknown.

Male and female fertility were unaffected based upon no adverse histopathological findings in the reproductive organs from cynomolgus monkeys receiving mepolizumab for 6 months at IV dosages up to 100 mg/kg once every 4 weeks (approximately 20 times the MRHD of 300 mg on an AUC basis). Mating and reproductive performance were unaffected in male and female CD-1 mice receiving an analogous antibody, which inhibits the activity of murine IL-5, at an IV dosage of 50 mg/kg once per week.

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling.

Hypersensitivity Reactions

Inform patients that hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred after administration of NUCALA. Instruct patients to contact their physicians if such reactions occur.

Not for Acute Symptoms or Deteriorating Disease

Inform patients that NUCALA does not treat acute asthma symptoms or acute exacerbations. Inform patients to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with NUCALA.

Opportunistic Infections: Herpes Zoster

Inform patients that herpes zoster infections have occurred in patients receiving NUCALA and where medically appropriate, inform patients that vaccination should be considered.

Reduction of Corticosteroid Dosage

Inform patients to not discontinue systemic or inhaled corticosteroids except under the direct supervision of a physician. Inform patients that reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Pregnancy Exposure Registry

Inform women there is a pregnancy exposure registry that monitors pregnancy outcomes in women with asthma exposed to NUCALA during pregnancy and that they can enroll in the Pregnancy Exposure Registry by calling 1-877-311-8972 or by visiting www.mothertobaby.org/asthma *[see Use in Specific Populations (8.1)]*.

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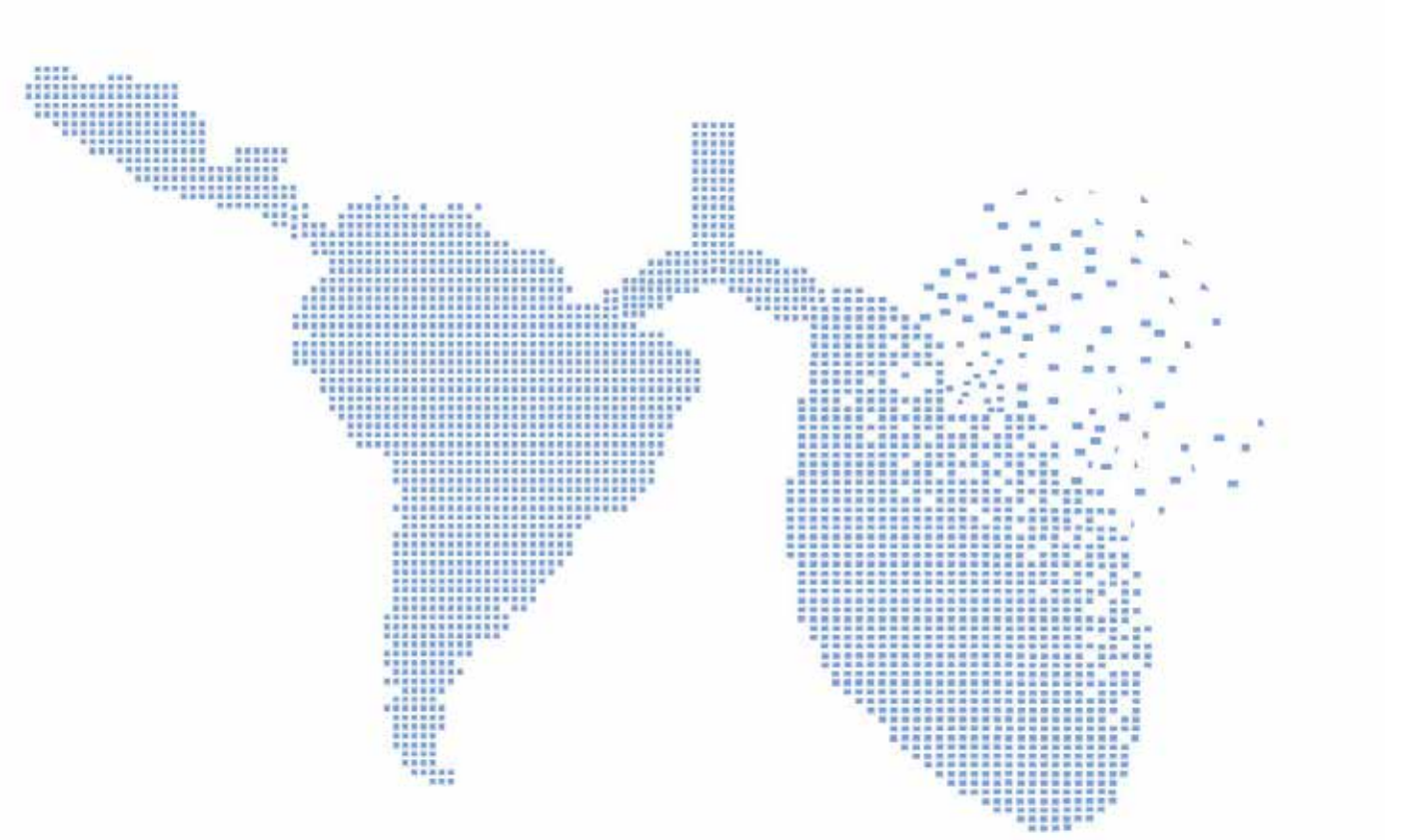

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Bloggers Bring More Session Coverage to ATS

Fear of missing out (FOMO) can be a real thing at ATS 2018, where you can choose from 500 educational sessions. To minimize that FOMO, you can follow the blogs of four physicians who will bring you daily recaps of the sessions they are attending as they share their experiences online. Look for their blogs on the ATS Facebook page. Here is a quick look at the doctors who'll be making sure you don't miss a thing.

Ann Wu, MD

Associate Professor at Harvard Medical School and Harvard Pilgrim Health Care Institute

Blogger Beat: Areas related to asthma, pediatrics, behavioral science/health services research, and more.

Twitter handle: @Asthma3Ways

Q: *How long have you been attending the ATS International Conference?*
A: This is my 13th year attending the conference.

Q: *Why will readers want to follow your blog each day?*
A: There is so much ongoing at the conference that it is impossible to be at every session. Hopefully, my blog posts will give a glimpse at what happened at sessions people were unable to attend, or a different point of view for people who did attend the same sessions. I always try to share observations and experiences that are distinct from the published abstracts.

Q: *What are you most excited to write about/share with readers?*
A: I'm excited to attend some of the Rapid Abstract Poster Discussion (RAPiD) sessions. This is a new format at ATS that was tested last year, and I think the format can generate lively discussions. The Year in Review sessions are always good overviews of the year in research.

Q: *What do you think will be the hot topic at the conference this year?*
A: I think an important hot topic this year is reducing physician burnout and improving well-being. There has been a lot of buzz on this topic recently for good reason.

Q: *What is your favorite thing about the ATS International Conference?*
A: For me, the ATS conference is an exciting time to see colleagues from around the world and to see everyone's latest research studies. It's a fun time to reconnect with collaborators and to meet new potential collaborators.

Viren Kaul, MD

Fellow, Pulmonary and Critical Care Medicine, Icahn School of Medicine at Mount Sinai/Elmhurst Hospital Center

Blogger Beat: Interventional pulmonology, pleural diseases, post ICU syndrome, and more.

Twitter handle:@virenkaul

Q: *How long have you been attending the ATS International Conference?*
A: Five years and counting!

Q: *Why will readers want to follow your blog each day?*
A: The ATS International Conference can be overwhelming with a plethora of options in terms of sessions, workshops, and opportunities. Through the blogpost, I will strive to share high-yield points from the sessions I attend. I will briefly also mention sessions I will live tweet or blog about the next day, so say goodbye to the FOMO!

Q: *What are you most excited to write about/share with readers?*
A: The Center for Career Development has a powerful lineup this year and is a must-attend for everyone interested in MedEd, so I will be reporting live from there a lot. I'm also looking forward to sharing snippets from the Resident Boot Camp, our session focused on International Graduates Interested in Medical Education (my apologies for the shameless plug but the session is at the CCD on May 21 from 3:45 to 4:30 p.m. followed by drinks and appetizers), and Fellow Case Conferences.

Q: *What do you think will be the hot topic at the conference this year?*
A: 2017 and 2018 (so far) have been influential years for fairness/equality for women, especially female physicians, and I am hoping to see a huge push for the same at the IC.

Q: *What is your favorite thing about the ATS International Conference?*
A: The IC reminds me of how supportive, encouraging, and dynamic the pulmonary, critical care, and sleep medicine community is. It evens the playing field and provides opportunities to network and collaborate.

Kevin Gipson, MD, MS

Clinical Fellow, Pediatric Pulmonology, Massachusetts General Hospital

Blogger Beat: Pediatric pulmonology and sleep medicine.

Twitter handle: @kevingipsonmd

Q: *How long have you been attending the ATS International Conference?*
A: Two years.

Q: *Why will readers want to follow your blog each day?*
A: I plan to tweet high-impact reports from the conference and hope to supplement this with a few longer blog posts throughout the week.

Q: *What are you most excited to write about/share with readers?*
A: As an upcoming sleep fellow, I'm most excited about learning about new therapies for pediatric sleep patients, with a particular focus on patients with chronic pulmonary and neuromuscular disorders. I'm also interested in the interface of emerging technologies and medicine, and so will be keeping my eye out for exciting new devices and projects.

Q: *What do you think will be the hot topic at the conference this year?*
A: The rapidly evolving field of pulmonary genetics is going to be a major driver of pulmonary practice in the near future. It will definitely be worth seeking out any number of the excellent talks on this topic at this year's program, as ever-improving genetic sequencing and powerful supporting informatic techniques will redefine clinical medicine in the coming decades.

Q: *What is your favorite thing about the ATS International Conference?*
A: The best thing about this conference absolutely has to be the opportunity to meet new colleagues and reconnect with old friends.

Nitin Seam, MD

Associate Professor of Medicine at George Washington University

Blogger Beat: Areas related to the Resident Boot Camp, medical education, and critical care.

Twitter handle: @NitinSeam

Q: *How long have you been attending the ATS International Conference?*
A: Ten years.

Q: *Why will readers want to follow your blog each day?*
A: I will post about the exciting educational experiences at the conference and new research related to critical care medicine that breaks at the conference.

Q: *What are you most excited to write about/share with readers?*
A: The Resident Boot Camp is a great initiative in which residents who will start pulmonary/critical care fellowships get two days of intense, interactive training in the basics of pulmonary and critical care medicine from expert teachers from around the country.

Q: *What do you think will be the hot topic at the conference this year?*
A: ATS President Marc Moss has made physician wellness and burnout a priority for the conference. This is one of the most important issues we face as a medical community.

Q: *What is your favorite thing about the ATS International Conference?*
A: Meeting old friends, seeing new research in my field, and exploring opportunities to collaborate.

Restoring Joy in Health Care

What does burnout look like and how can we change things personally and professionally for the better? Explore the Restoring Joy in Health Care booth (#904) and take an anonymous burnout identification quiz, crowdsource ways to improve the professional environment, get a chair massage, and visit with a therapy dog to bring you back to center. Therapy dogs are in the booth from 10:30 a.m. to 3:30 p.m. each day.

Want to learn more? ATS 2018 offers well-being/burnout-related programming, too.

Reducing Burnout and Promoting Engagement: Individual and Organizational Approaches to Physician Well-Being
Keynote Session (K4)
Room 6 C/F (Upper Level), San Diego Convention Center
Monday, 8:15-9 a.m.
Speaker: Tait D. Shanafelt, MD, Stanford, CA

Enhancing Provider Well-Being, Competency, and Communications Skills: Highlights of Medical Education Research
Poster Discussion Session (C22)
Room 11 A-B (Upper Level), San Diego Convention Center
Tuesday, 9:15-11:15 a.m.

Battling Burnout: Overcoming the Biggest Threat to Health Care Quality and Safety
Scientific Symposium (D11)
Room 1 A-B (Upper Level), San Diego Convention Center
Wednesday, 9:15-11:15 a.m.

Well-Being Kick-Off Meeting
Harbor Ballroom A (Second Level) Harbor Tower, San Diego Convention Center
Tuesday, 4:30-6 p.m.

For additional information about ATS well-being-related resources, contact bewell@thoracic.org. ■

Guru Bars Offer Quick-Burst Learning

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 organized by categories of interest:

Guru Bars 1 and 2: Education/Awareness/Prevention or Diagnosis
Guru Bars 3 and 4: Treatment of Adherence/Compliance

Guru Bars run every 30 minutes from 11 a.m. to 2 p.m. Sunday through Tuesday in the Exhibit Hall (Hall F, Ground Level).

MONDAY

GURU BAR 1
Education/Awareness/Prevention or Diagnosis

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.

1:30-2 p.m.

Current Paradigm of Selecting Therapy for Early Stage Lung Cancer Patients. What is Missing?
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: **Michael J. Mann, MD**, *professor of surgery, UCSF Helen Diller Comprehensive Cancer Center*
Company: OncoCyte Corporation

GURU BAR 2
Education/Awareness/Prevention or Diagnosis

1-1:30 p.m.

Breaking the Vicious Cycle of Non-CF Bronchiectasis: The Role of Airway Clearance Therapy
Dr. Alan F. Barker will discuss the diagnosis and treatment of non-CF bronchiectasis with a focus on the role of airway clearance therapy in breaking the vicious cycle of non-CF bronchiectasis and recurrent chest infections. Prevalence of non-CF bronchiectasis in the U.S. COPD population, symptoms, and confirmation of the disease by a high-resolution CT scan will be discussed. Dr. Barker will also provide an overview of treatment options, including high frequency chest wall oscillation airway clearance vest therapy.
Speaker: **Alan F. Barker, MD**, *professor of medicine, Division of Pulmonary and Critical Care Medicine, Oregon Health & Science University*
Company: International Biophysics

GURU BAR 3
Treatment or Adherence/Compliance

12:30-1 p.m.

Concomitant Idiopathic Pulmonary Fibrosis and Emphysema: Strategies to Improve Patient Management
This town hall-style Guru Bar will educate attendees on the presence of concomitant emphysema in some patients with IPF. It will also provide an opportunity to discuss management strategies with an expert pulmonologist. Topics to be discussed will include management and compliance issues faced by patients with CPFE and strategies to address them.
Speaker: **Lucas Pitts, MD**, *assistant professor, pulmonary and critical care medicine, University of Kansas Medical Center*
Company: Boehringer Ingelheim Pharmaceuticals, Inc. ■

Evaluating the Gaps in Patient Care for COPD

Success in the diagnosis, prevention, and treatment of COPD is at an all-time high in 2018. Still, gaps remain in the recommendations for certain aspects of care due to contradictory evidence in current medical literature.

Gerard Criner, MD

The widely accepted global reference for the diagnosis and treatment of patients—the 2017 major update of the Global Obstructive Lung Disease Initiative (GOLD) Report—addresses controversies in COPD care. These controversies include the diagnosis and assessment of COPD, risk factors for disease development, advances in treatment of the stable patient, and the assessment and treatment of exacerbations.

"We hope to initiate and spur a creative, multidisciplinary approach to addressing these gaps in current knowledge, as well as a sustained dialogue about the issues," says Gerard J. Criner, MD, chair of thoracic medicine and surgery at Temple University Hospital.

Among Dr. Criner's objectives is to examine whether airflow obstruction is necessary to diagnose and treat COPD. For example, airflow limitation, or spirometric obstruction, must be present when diagnosing COPD. However, in recent studies, similar respiratory symptoms without airflow obstruction have been seen in patients who smoke. Patients indicate the symptoms are severe and negatively impact their quality of life. Therefore, clinicians have posed the question as to whether these patients suffer from COPD, and whether it's necessary to diagnose COPD without the presence of airflow obstruction.

Controversies in the Diagnosis and Treatment of COPD (B82)

2:15-4:15 p.m.

Monday

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

Another controversy, according to Dr. Criner, is whether a personalized treatment plan for COPD is feasible. Genetic and environmental influences differ in patients diagnosed with COPD, which suggests selected treatments may be a better approach to care.

"More research is needed to discover tools that can enhance phenotypic characterization, especially in the area of blood biomarkers, such as peripheral eosinophils for the diagnosis, prognosis, and response to therapy," Dr. Criner says.

Finally, the session will explore whether the medical community needs a new concept or definition of what constitutes an exacerbation of COPD. Current definitions of exacerbations of COPD are restricted to examining the frequency of symptoms, non-specificity of symptoms for lung versus cardiac origin, and the differences in clinician responses to the patient's report of symptoms. The issue with the current definition is that it lacks an objective biomarker that indicates the onset of COPD, as well as its severity and prognosis. Current discussion focuses on the need to develop a simple and objective definition of exacerbation that incorporates symptom change with biomarker characterization.

Dr. Criner also says it's important for clinicians to determine whether the cause of a COPD exacerbation is pulmonary or non-pulmonary to better treat the disease. Bacterial causes would support the use of antibiotics, while acute exacerbations are limited to increased use of short-acting bronchodilators, systemic glucocorticoids, and antibiotics. Novel and more effective treatments are necessary to treat the infections, inflammation, and oxidative stress that occur during an acute exacerbation. ■

Controversies in the Diagnosis and Treatment of COPD (B82) is supported by educational grants from AstraZeneca LP, GlaxoSmithKline, and Sunovion Pharmaceuticals Inc.

> "We hope to initiate and spur a creative, multidisciplinary approach to addressing these gaps in current knowledge, as well as a sustained dialogue about the issues."
>
> **Gerard J. Criner, MD**

Buist to Share Life Lessons During Women's Forum

"What I do today is very important because I am exchanging a day of my life for it." This motto is one that A. Sonia Buist, MD, repeats daily. She is this year's featured speaker at the ATS Women's Forum, an annual event that recognizes the achievements and supports the advancement of women in pulmonary, critical care, and sleep medicine and research.

ATS Women's Forum

11:45 a.m.-1:15 p.m.

Monday

Grand Hall B (off lobby), Manchester Grand Hyatt Hotel

Dr. Buist, professor emerita of medicine at Oregon Health & Science University, is an ATS past president and the founder of the ATS MECOR (Methods in Epidemiologic, Clinical, and Operations Research) program. She is a passionate advocate for advancing global public health policy through research, and truly embodies the ATS vision of "helping the world breathe."

Dr. Buist will outline lessons she has learned, personally and professionally, as she talks about her life during today's forum. She will speak on the importance of mentorship, being involved and taking chances, and trying to find balance in work, family, and life. Her talk will be followed by a question-and-answer period.

During the Women's Forum, the 2017 Elizabeth A. Rich, MD Award, which honors the memory and work of Elizabeth Rich, MD, will be presented to a female ATS member. The awardee will be 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. The award recipient will also address the audience.

A. Sonia Buist, MD

The forum provides a valuable opportunity for women to meet new colleagues and ATS leaders. Men are also welcome to attend the forum. Attendees will find value in the inspirational messages and career insights the speakers share as well as vibrant networking opportunities.

The forum is organized and presented by the ATS Membership Committee, and will be hosted by Janet Lee, MD, chair of the committee. ■

Registration is required. There is no fee to attend this event and tickets will not be issued; however, conference badges are required for admission. A plated lunch will be served.

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Learning Doesn't Stop at Lunch

Grab a complimentary lunch and continue learning during Industry Theaters and Mini Theaters on Monday and 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).

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

MONDAY

Industry Theater 1

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

Inhaler Choice Matters in COPD: The Impact of Peak Inspiratory Flow on Drug Dispersion and Delivery from Inhalers

Company: Boehringer Ingelheim Pharmaceuticals, Inc.

1:15-2 p.m.

Latest Evidence Informing the COPD Treatment Paradigm

(*Open to international attendees only*)
The treatment goals of alleviating symptoms and reducing exacerbation risk in management of COPD remain unchanged but the updated guidelines give more clarity on which patients are suited for treatment with bronchodilators and which patients may require additional therapy. The industry theater will focus on the importance of dual bronchodilator therapy (LAMA/LABA) for patients with persistent symptoms and will explore the latest evidence to support single-inhaler triple therapy (ICS/LAMA/LABA) for patients with at least one moderate/severe exacerbation in the prior year. Adoption of these recommendations allows physicians to use a more personalized treatment approach for their COPD patients.
Speakers: **Chris Cooper, MD, MS**, *professor, Global Respiratory Franchise, GSK, U.S.;* **Bernardino Alcazar Navarrete, MD**, *Hospital de Alta Resolución de Loja, Granada, Spain;* **Jean Bourbeau, MD, MSC**, *professor, McGill University Montreal, Quebec, Canada;* **Chris Cooper, MD, MS**, *professor, Global Respiratory Franchise, GSK, U.S.*
Company: GSK

Industry Theater 2

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

New Evidence in Treating Severe Eosinophilic Asthma With Targeted Therapy

Eosinophils are a known contributor to asthma exacerbations. Reducing exacerbations is the key objective when treating patients with severe asthma. Questions remain regarding targeting blood eosinophils in patients with severe eosinophilic asthma who also have allergic markers. Come learn about new evidence from a targeted treatment that reduced the frequency of asthma exacerbations.
Speakers: **Rohit Katial, MD**, *allergy and immunology, GSK Local Medical Expert;* **Jean-Pierre Llanos-Ackert, MD**, *pediatric pulmonology, GSK U.S. Medical Affairs Lead*
Company: GSK

1:15-2 p.m.

The First and Only Nebulized LAMA for COPD

Speaker: **Brian Carlin, MD**, *senior staff physician, Pittsburgh Critical Care Associates*
Company: Sunovion Pharmaceuticals Inc.

Mini Theater

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

Lower Dose, Shorter Duration Therapy: OPTALYSE PE Trial – Acute and One-Year Results

Treat bilateral Pulmonary Embolism with as little as 8 mg tPA total and in as little as two-hours. Identify which patients will benefit the most from this new lower-dose, shorter-duration therapy. Learn how PE patients' right ventricular dysfunction can be effectively treated in as little as two hours. Hear about the remarkable one-year post-treatment results in efficacy, safety, and quality-of-life measures.
Speaker: **Gregory Piazza, MD, MS**, *assistant professor of medicine, Harvard Medical School, Brigham and Women's Hospital*
Company: BTG

12:30-1 p.m.

Cost-Effectiveness of Home Oxygen Therapy-Home Mechanical Ventilation (HOT-HMV) for Treatment of Chronic Obstructive Pulmonary Disease

The potential health economic impact of HOT-HMV in the United States.
Speaker: **Gerard J. Criner, MD**, *chair and professor, thoracic medicine and surgery, Temple University*
Company: Philips

1:30-2 p.m.

COPD

Company: Fisher & Paykel Healthcare ■

Bioengineering Meets Respiratory Medicine

Bioengineering is making major inroads on the path from basic science discoveries to practical lung regeneration in patients. Cellular and tissue engineering are still far removed from routine clinical use, but a variety of experimental lung platforms show promise for *in vitro* lung pathophysiological modeling and regeneration as well as early *in vivo* work in patients.


Zea Borok, MD

"There have been several major advances in the past four or five years related to the identification of a number of different progenitor cell populations in the distal lung capable of contributing to regeneration," says Zea Borok, MD, chief of pulmonary and critical care medicine and director of the Hastings Center for Pulmonary Research at the University of Southern California Keck School of Medicine. "The continuing challenge in the field is how do we actually bring these new basic science advances to patients? We have to harness the basic science to improve outcomes in real diseases in the real world."

Dr. Borok will co-chair today's symposium with Barry Stripp, PhD, director of pulmonary stem cell research and professor of medicine and biomedical sciences at Cedars-Sinai Medical Center in Los Angeles.

Researchers have developed two different strategies to harness progenitor cells.

The most obvious way forward is to transplant progenitor cells and promote their proliferation and activity.

Another option is to explore the pathways that regulate progenitor cells and promote their survival *in vivo*, then exploit those pathways to protect and promote their regenerative activity.

"I think the lay public would like to believe that the answer is simply going to be delivering stem cells to the lung, and I don't know that that's correct, at least in the short-term," Dr. Borok says. "Transplantation may be possible, but it's the moon shot. Along the way, we are already learning how to improve the function of cells that can serve a progenitor function by identifying pathways that promote, protect, and improve their therapeutic activity."

Two presenters will look at different strategies that allow researchers to screen for pathways that might improve progenitor cell function.

Christina Barkauskas, MD, assistant professor of medicine and affiliate of the Regeneration Next Initiative at Duke University School of Medicine, will explore the current uses and future promise of lung organoids. Kambez H. Benam, PhD, assistant professor of pulmonary sciences and critical care medicine at the University of Colorado at Denver will look at the latest in microfluidic technology used to model human airway disease by engineering airway-on-a-chip and breathing-smoking-lung-on-a-chip. Both of these approaches allow for screening of molecules that can affect progenitor cell function and differentiation to other cell types.

Xi Ren, PhD, assistant professor of biomedical engineering at Carnegie Mellon University, will discuss the latest developments in engineering native biomaterials for pulmonary regeneration. His laboratory is developing biologically and chemically selective approaches to modulating the extracellular matrix to boost pulmonary injury/repair and potentially whole-organ bioengineering.

Emmanuel Martinod, MD, PhD, professor of medicine at Descartes University, Paris, will discuss the latest advances in transplanting bioengineered tracheas.

Reinoud Gosens, PhD, assistant professor of translational pharmacology at the Groningen Research Institute for Asthma and COPD at the University of Groningen, The Netherlands, will take a different approach. Rather than implanting engineered organs, his laboratory is exploring strategies to modulate the WNT pathway as a mechanism to regenerate damaged lung tissue, for example, in chronic obstructive pulmonary disease.

"This is cutting-edge science," Dr. Borok says. "We are finally getting to the stage where we can talk about engineering materials on which lung cells can actually survive and thrive and modulating the pathways that can make it happen. We may finally be looking at the beginnings of clinical cell therapy in respiratory medicine." ■

At the Interface of Engineering and Respiratory Medicine: Updates and Applications (B91)

2:15-4:15 p.m.

Monday

Pacific Ballroom 18-19 (North Tower, First Floor), Marriott Marquis San Diego Marina

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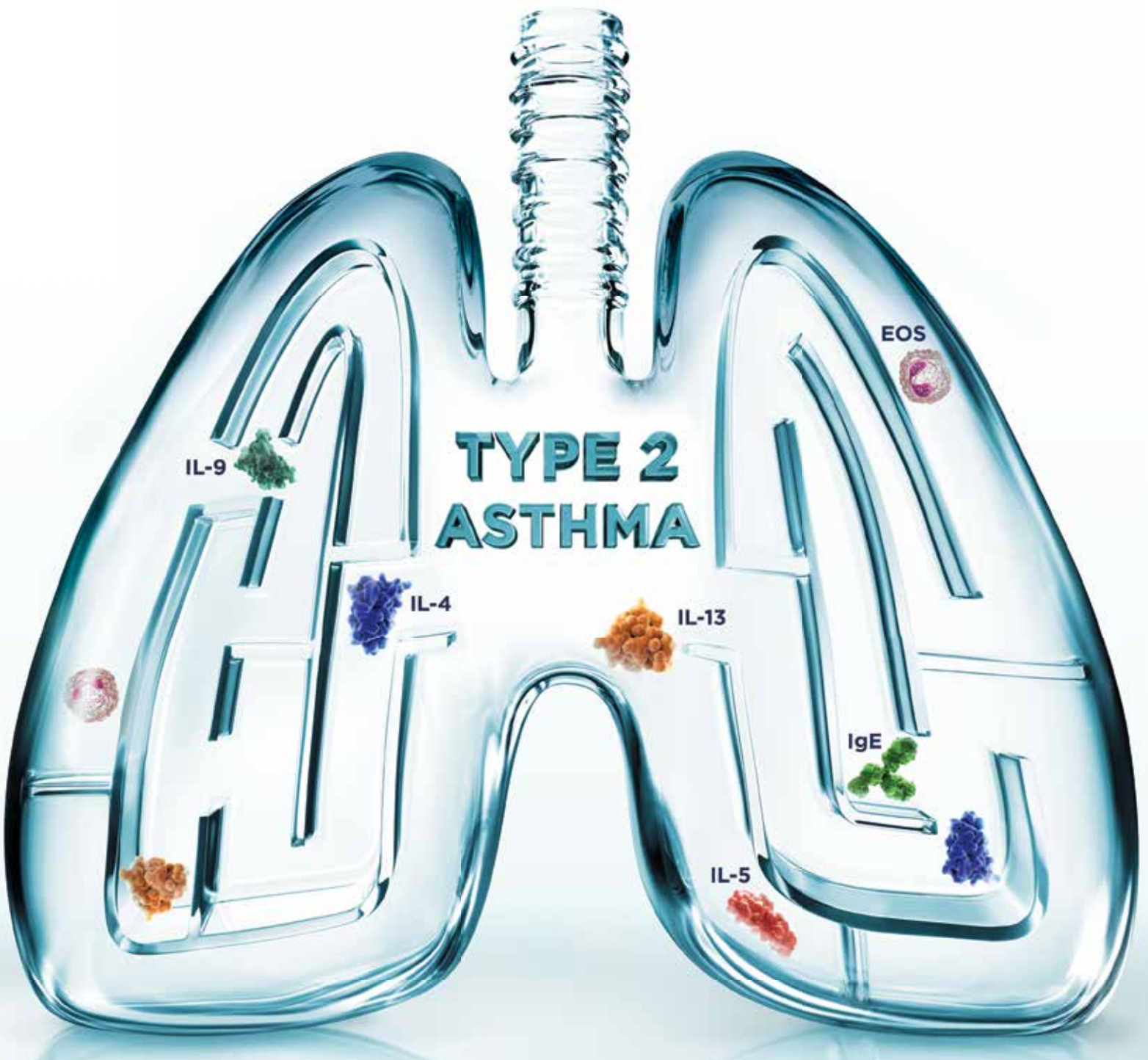

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Who *Really* Needs Lung Cancer Screening?

Lung cancer screening works. But screening isn't an unallied benefit for everyone being screened. As ever-larger patient populations undergo screening, it is becoming clear that some patients are better off not being screened. The question is who.

"One eye-opener is how unclear some of the guidelines are in terms of recommendations for certain patient populations that might have higher potential risks related to screening than potential benefits," says Jonathan M. Iaccarino, MD, MSc, assistant professor of medicine at Boston University Medical Campus. "We are still learning how to tease out which patients will benefit from screening as opposed to those who will experience harm or might be at higher risk for harm than others."

Jonathan M. Iaccarino, MD, MSc

Dr. Iaccarino is the lead chair for a translational symposium on Lung Cancer Screening: Who's In and Who's Out? A Pro/Con Debate. Why set up a debate when the data are less than conclusive?

"This is how, clinically, these issues are being thought about," Dr. Iaccarino says. "The pro-con format is a natural conversation that reflects how clinicians face these issues with real patients in the real world. Some clinicians are really in favor of screening certain patient populations because there really is benefit. And some clinicians are against screening those same patients because there is potential risk. We all have to make that judgment."

Lung cancer survival has not changed significantly in a generation, Dr. Iaccarino says. That was one reason the National Lung Cancer Screening trial created such a stir when it showed a 20 percent reduction in lung cancer mortality for individuals screened using low-dose computed tomography and a 6.7 percent all-cause survival advantage for low-dose CT versus single-view posteroanterior chest radiography.

"Whenever you have a finding like that, there is always a push to start implementing it in as many patients as possible," Dr. Iaccarino says. "There is going to be some over-screening. This is a natural result when you introduce any new screening program. It takes time to learn where you need to step back in order to ensure that you aren't doing more harm than good."

The screening procedure itself is relatively low risk, but the lung biopsies and other procedures that can follow a positive finding are anything but trivial.

There are some populations—for instance, long-term smokers with no other health concerns--who can clearly benefit from screening. These patients are at highest risk for lung cancer and at the lowest risk for complications from screening.

How about long-term smokers with other comorbidities such as COPD or severe heart failure? They could well benefit from screening, but the severity of their comorbidities puts them at much higher risk for complications from a lung biopsy or other follow-ups to screening.

What about patients with the most severe comorbidities? At which point does reduced life expectancy from COPD or cardiovascular disease compare to life expectancy from any lung cancer that might be detected on screening? At what point does it make more sense to not screen for lung cancer?

Lung Cancer Screening: Who's In and Who's Out? A Pro-Con Debate (B10)

9:15-11:15 a.m.

Monday

Room 32 A-B (Upper Level), San Diego Convention Center

There are similar questions at the other end of the spectrum. Smokers with a shorter history of smoking are likely to be younger, healthier, and less likely to be harmed by a lung biopsy. They may also be at lower risk for lung cancer. Screening these patients may not be cost effective or particularly beneficial.

"The one thing that is clear is that we can't just screen without considering risks and benefits," Dr. Iaccarino says. "We are subjecting millions of new patients to screening while we don't fully understand the implications. Lung cancer screening has the real potential to save lives and the significant potential to do harm. This is a conversation that we should be having with all patients we are considering for lung cancer screening." ■

> "We are subjecting millions of new patients to screening while we don't fully understand the implications. Lung cancer screening has the real potential to save lives and the significant potential to do harm."
>
> **Jonathan M. Iaccarino, MD, MSc**

American Thoracic Society

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Recognition Award Winners to Present Research

Four outstanding scientists have been selected to receive the Recognition Award for Scientific Accomplishments. The awards recognize scientific contributions in basic or clinical research that enhance the understanding, prevention, and treatment of respiratory disease or critical illness. Awardees will each make a 25-minute presentation on their research.

Recognition Awards for Scientific Accomplishments (G3)

2:15-4:15 p.m., Monday

Room 32 A-B (Upper Level), San Diego Convention Center

Steven Brody, MD

Dorothy R. and Hubert C. Moog Professor of Pulmonary Medicine
Division of Pulmonary and Critical Care Medicine
Washington University School of Medicine

Dr. Brody will present Cellular and Genetic Factors in Cilia Assembly and Disease.

Dr. Brody's work concerns the regulation of airway epithelial cell differentiation in acute and chronic airway diseases. One effort is to identify factors that are required for the differentiation of the ciliated cells that line the airway and their role in different steps of ciliogenesis.

In the course of this work, his lab has characterized gene mutations that cause the genetic disease of motile cilia known as primary ciliary dyskinesia and has uncovered fundamental pathways for ciliogenesis.

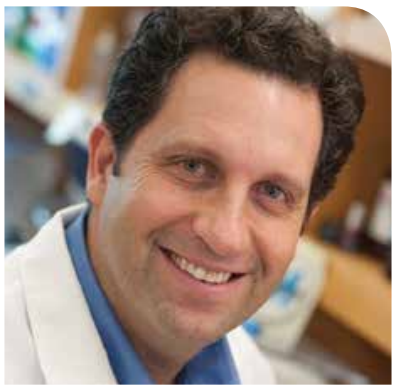
Jeffrey J. Fredberg, PhD

Professor of Bioengineering and Physiology
Program in Molecular and Integrative Physiological Sciences (MIPS)
Department of Environmental Health
Harvard T. H. Chan School of Public Health

Dr. Fredberg will present Geometry of Cell Jamming: New Biology, Surprising Physics, and Useful Ideas about Airway Epithelium.

Dr. Fredberg and his team bridge the physical sciences with the life sciences. His laboratory investigates cellular deformability, contractility, malleability, and motility and also deals with the cellular collective as it pertains to disruption of the bronchial epithelial layer in asthma and tumor invasion in breast cancer.

His team was the first to show that cells comprising an epithelial collective can jam or can unjam and migrate, invade, and spread. Together, this body of work illuminates relevant but poorly understood physical processes that underlie asthma, wound healing, development, and cancer.

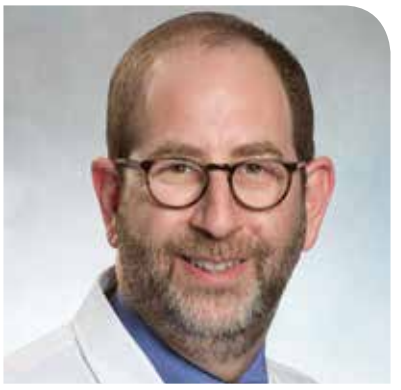


Darrell N. Kotton, MD

David Seldin Professor of Medicine
Director, Center for Regenerative Medicine (CreM)
Boston University and Boston Medical Center

Dr. Kotton will present Pluripotent Stem Cells for Lung Regeneration. Dr. Kotton is a pulmonary physician-scientist whose laboratory research program has focused on lung stem cells in lung injury and repair.

He has pioneered the development of pluripotent stem cell models to define the genetic landscapes of lung cell fate, the mechanisms that establish those fates, and the approaches by which foregut endodermal lineages, such as lung, thyroid, and liver, can be derived *de novo* for disease modeling or engineering novel therapies.



Bruce Levy, MD, MS

Parker B. Francis Professor of Medicine
Harvard Medical School
Chief, Division of Pulmonary and Critical Care Medicine
Brigham and Women's Hospital

Dr. Levy will present Specialized Pro-Resolving Mediators for Lung Catabasis. Dr. Levy and his laboratory were the first to report several aspects of resolution lung biology in health and disease. The thinking about the pathogenesis of airway disease before his pivotal experiments was centered on pro-inflammatory mechanisms and, to a great extent, protein-based mediators.

Dr. Levy focused on the other side of the coin—pathways that resolve inflammation. His studies defined the complex braking signals for the inflammatory response, which is triggered largely by lipid-based moieties, and then found them to be defective in human airway disease. These findings defined new fundamental paradigms in inflammation biology and, in so doing, turned the field on its head. ■

Fluid Administration in Sepsis

It's time to question what we're doing

Administration of intravenous fluid is one of the key therapies in the ICU for treating one of our most common and lethal diseases—sepsis. There's been a large reduction in sepsis mortality, which is partially attributable to early and aggressive fluid administration. However, several recent investigations have raised questions about the appropriateness of current fluid practice.

These questions will be addressed during the Monday session Six Controversies in Fluid Administration in Sepsis. The session covers the latest research and the edge of evidence for sepsis fluid administration.

"These are questions every intensivist grapples with," says session chair Michael J. Lanspa, MD, ATSF, of Intermountain Medical Center in Salt Lake City, Utah. "Many of them don't have a simple answer."

The questions that will be covered by session panelists include:

What target are we striving for when we administer fluid? How do we know the fluid challenge worked? Traditionally, we would assess increases in stroke volume, or delivery of oxygen. However, perhaps an increase in blood pressure or the improvement of lactate might be better goals.

How do we predict response to fluid? Some novel technologies are supposedly better at predicting fluid, but they have limitations as well.

When should we administer fluid? There may be big differences in early versus later administration, and strategies that work well early on may not fare as well six hours later.

What type of fluid should be administered? There is growing evidence about the harms of saline. Different populations may respond differently to certain types of fluid.

What harms are associated with excess fluid administration? Many studies suggest harm, but is this real or simply confounding by indication?

Six Controversies in Fluid Administration in Sepsis (B84)

2:15-4:15 p.m.

Monday

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

When it is appropriate to diurese or dialyze patients in sepsis? This is a common question asked by perhaps every intensivist and is one of the most exciting.

"Although fluid therapy is over a century old, there is still a lot of uncertainty on how best to administer fluid," Dr. Lanspa says. "This session is important for ATS attendees because experts in the field will not only discuss the most recent science, but will offer insights for the bedside clinician and the researcher. After this session, we expect that attendees will not only be aware of all the recent scientific developments in this field, but will also walk away with a conceptual framework of how to deal with these controversies." ■

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.

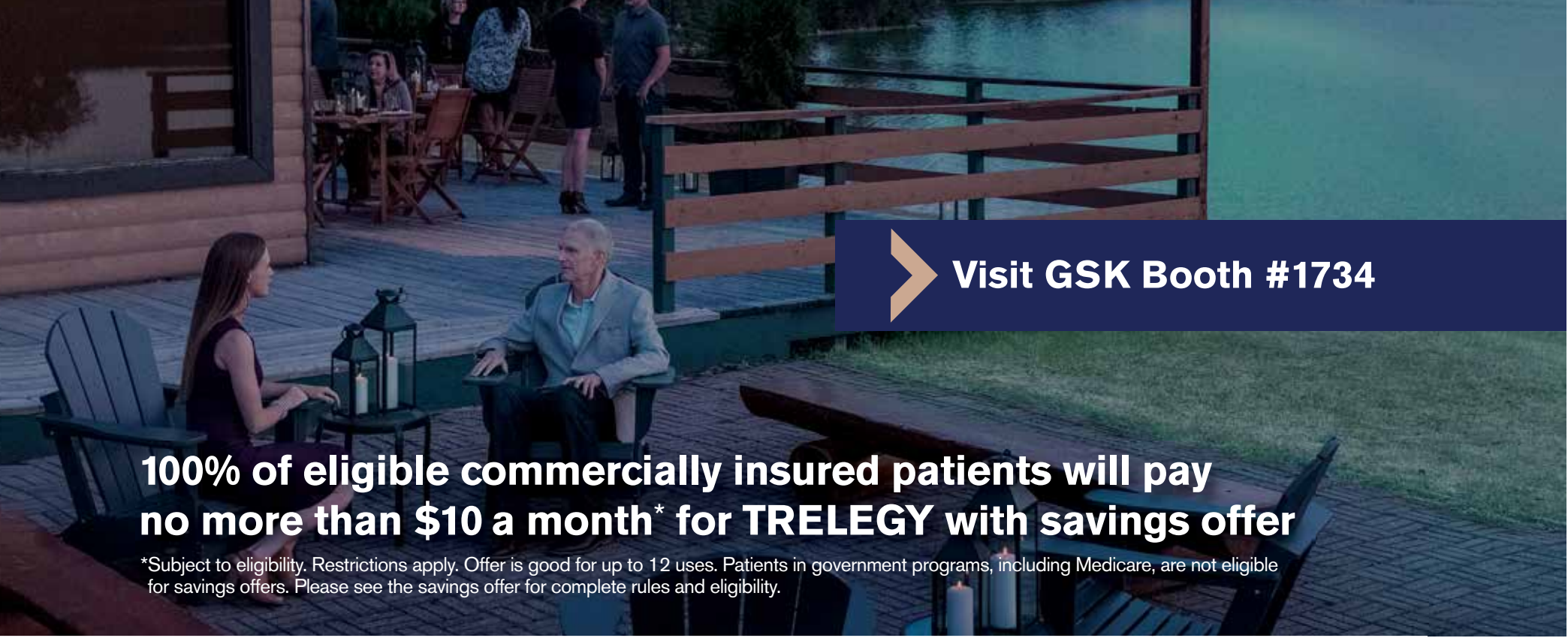
IMPORTANT SAFETY INFORMATION (cont'd)

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)

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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.

Should There Be a Global Approach to Sleep Medicine?

Although the global burden of sleep disorders remains unknown, it is estimated that obstructive sleep apnea affects nearly 1 billion people worldwide—and that's a conservative number, according to Atul Malhotra, MD, of the University of California at San Diego.

Global Care for Sleep Disorders: Toward Universal Access (B12)

9:15-11:15 a.m.

Monday

Room 7 A-B (Upper Level), San Diego Convention Center

Dr. Malhotra will describe how researchers calculated that number as he introduces today's session about global care for sleep disorders, chaired by members of the International Health Committee (Drs. Sonia Buist and Mihaela Teodorescu) and of the Assembly on Sleep and Respiratory Neurobiology (Drs. ChingLi Chai-Coezer and Bharati Prasad).

During this session, doctors from around the world (Georg Nilius, MD, Germany; Manuel Sanchez De La Torre, PhD, Spain; Yuksel Peker, MD, PhD, Turkey; Oana Claudia Deleanu, MD, Romania; Gustavo A. Moreira, MD, Brazil; and Sanjeev Sinha, MD, India) will discuss the models of care for sleep disorders/OSA used in their countries. Experts also will present the various methods used for diagnosing and treating sleep disorders/OSA, while exploring how a global standard could raise the level of care throughout the world if the sleep health service provision can be extended to reach under-resourced areas.

To address the growing problem of sleep disorders/OSA globally, increasing attention has turned toward the involvement of primary care physicians and specialist nurses for diagnosis and treatment.

"One-third of patients who visit their primary care physician have a high pre-test probability of OSA, yet the disease frequently remains undiagnosed and undertreated," says Ching Li Chai-Coetzer, MBBS, PhD, of the Adelaide Institute for Sleep Health in Australia. "With the appropriate training of GPs and practice nurses, primary care-based management has significant potential to improve patient access to sleep service provision."

In the past, OSA diagnosis rested on the performance of a full night attended polysomnography. Over the last decade, there has been increased interest in the use of home sleep apnea testing. Bringing ambulatory management into the treatment of OSA could make initial diagnosis less expensive and more attainable.

"Recent randomized trials have shown that in selected patients, HSAT can be just as effective as PSG as an initial test to diagnose patients with suspected obstructive sleep apnea, and likely should play a role in the management of selected patients," says Najib Ayas, MD, MPH, of the University of British Columbia in Vancouver, Canada. "However, the use of HSAT varies considerably among and within countries."

Another possible bridge for extending the reach of sleep services globally could lie in wearable technologies and telemedicine. Anita V. Shelgikar, MD, of the University of Michigan, says that cloud-based systems can provide new ways for patient and providers to collaboratively communicate in the management of chronic diseases, including sleep disorders.

"Patient-driven use of wearable devices, associated mobile apps, and cloud-based technologies can be used not only for individual patient care, but also for participation in crowdsourced research endeavors," she says. "This may allow previously understudied populations to participate in research that may ultimately improve care for all patients."

Even if these ideas guide sleep medicine toward a global approach, should this be a focus of sleep medicine? This team of experts offers arguments for and against having a global approach to sleep disorders. (See "The Pros and Cons of a Global Approach to Sleep Disorders" below.) ■

> "Patient-driven use of wearable devices, associated mobile apps, and cloud-based technologies can be used not only for individual patient care, but also for participation in crowdsourced research endeavors."
>
> **Anita V. Shelgikar, MD**

The Pros and Cons of a Global Approach to Sleep Disorders

PRO:

- Standardized approach will mean uniformity in international agreements for defining, diagnosing, and treating sleep disorders/OSA.
- It would help to reduce diagnostic uncertainties and facilitate access.
- Templates for formation of national guidelines could be provided based on international recommendations (similar to WHO recommendations with national interpretations and alterations).
- It would foster acquiring evidence for developing appropriate resources for large data collection, funding issues, and homogeneity of methodology in publications.

CON:

Overall differences in population characteristics

- Genetics: predisposition to development of sleep disorders, severity of damage caused, co-occurrence with other comorbidities, response to treatment.
- Environmental factors: affecting baseline health status, risk factors for development of sleep disorders.
- Cultural factors: readiness to seek health care, limited health care access for women, adherence to treatment, native and traditional medical practices.
- Organization of health care: access; limitation in facilities for diagnosis and management, staff and expert availability; monitoring and follow-up limitations. ■

The ATS Center Is Your Resource in the Exhibit Hall

The Exhibit Hall has much to offer, from hands-on learning to cutting-edge technology, and Guru Bars to Industry Theaters. But a trip through the Exhibit Hall isn't complete without stopping at the ATS Center. There is so much valuable information at the Center. You can:

- Use our computer kiosks to access patient information fact sheets. Choose from more than 100 titles in English and Spanish, as well as select titles in six other languages.
- Rediscover our three medical journals, including the special conference issues and the journal apps.
- Learn about ATS education products, including MOC and CME opportunities, many of which are free to ATS members.
- Purchase gift items, including pewter lung key chains, conference T-shirts, San Diego coffee mugs, ATS hats, doctor ducks, and more.
- Obtain copies of Guidelines Pocket Cards, Highlights for Clinicians, Clinical Year in Review, Nursing Year in Review, and Pediatric Year in Review.
- Pick up the Road Map for Early Career Professionals to learn about ATS 2018 sessions most advantageous for your career.
- Learn about grant activities and opportunities.
- Relax while recharging your phone or tablet.

Join the ATS or renew your membership at the ATS Center, and you'll receive a FREE gift pack. Your membership will give you reduced prices on ATS products and services, and on next year's International Conference registration fees. ■

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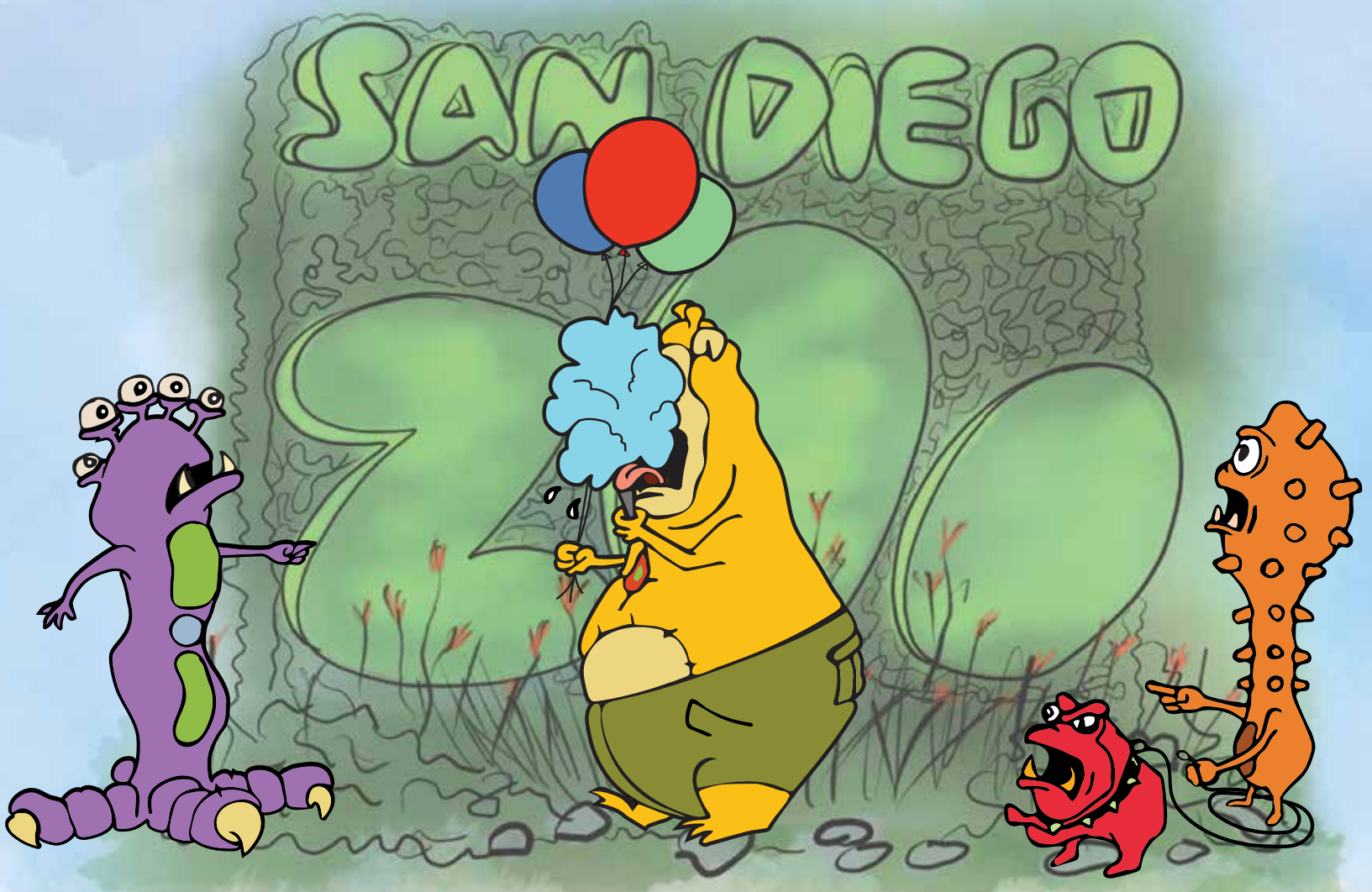

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Promoting Pulmonary Rehab Program

Pulmonary rehabilitation is known to improve quality of life for patients with COPD and other lung diseases. The problem? Not enough patients, or their doctors, know about this treatment option.

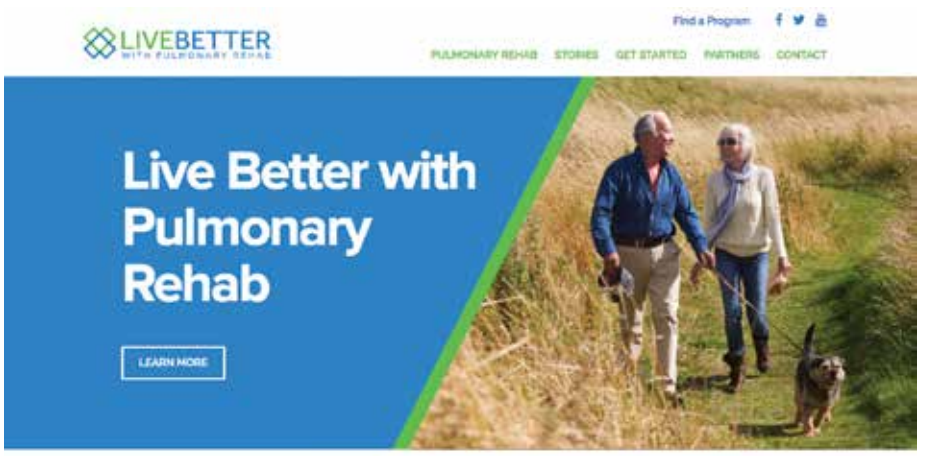
To help address that knowledge gap, the ATS is partnering with the Gawlicki Family Foundation to launch a pilot program to increase public awareness of pulmonary rehab. At the center of the campaign is a new, patient-friendly website: **www.livebetter.org**.

On the website, visitors will find a number of resources to help patients (and their families, friends, caregivers, and doctors) answer an important question: Is pulmonary rehab right for me?

The website also features:

- Resources explaining what pulmonary rehab is and its benefits
- Directory of pulmonary rehab programs across the United States
- Criteria for selecting a PR program and the enrollment process
- Patient stories
- Frequently asked questions

Visit **www.livebetter.org** to learn more. ■



Step It Up for Research

Are you getting your steps in? Make them count! You still have time to participate in the ATS Walking Challenge. The ATS Walking Challenge Mobile App supports attendees who are using their own FitBit, Jawbone, or iPhone/Android smartphone to count steps.

You can watch the results unfold in real-time on leaderboards in the Teva Respiratory booth #2735, or at the ATS Walking Challenge booth. The top five overall steppers win a prize, which is awarded Wednesday morning at 9 a.m. at the Walking Challenge booth in Lobby A.

Don't forget, the ATS Walking Challenge also supports the ATS Foundation Research Program. For every participant who walks 30,000 steps during ATS 2018, Teva Respiratory makes a donation of $100 to the ATS Foundation, with a total maximum donation of $50,000 to fund new research awards in pulmonary, critical care, and sleep medicine. ■

Explore the Clinical Trial Awareness Area

The Clinical Trials Awareness area is your on-site resource for finding a clinical connection. If you are looking for opportunities to be an investigator for clinical trials or ongoing trials for your patients, visit with these companies, located in Lobby E outside the Exhibit Hall.

BELLEROPHON THERAPEUTICS

Bellerophon Therapeutics is a clinical-stage biotherapeutics company that develops innovative therapies to address significant unmet medical need in the treatment of cardiopulmonary diseases. Bellerophon's pipeline programs are researching potential indications with INOpulse, a delivery system for inhaled nitric oxide for pulmonary arterial hypertension, pulmonary hypertension in interstitial lung disease, and pulmonary hypertension associated with chronic obstructive pulmonary disease.

REATA PHARMACEUTICALS

Reata Pharmaceuticals is a clinical-stage biopharmaceutical company that develops novel therapeutics by targeting molecular pathways involved in the regulation of cellular metabolism and inflammation. Reata's two most advanced clinical candidates (bardoxolone methyl and omaveloxolone) target an important transcription factor, called Nrf2, to restore mitochondrial function, reduce oxidative stress, and resolve inflammation. Reata is enrolling patients in the Phase 3 CATALYST trial of bardoxolone methyl in patients with CTD-PAH.

SHIONOGI INC.

Shionogi & Co., Ltd., is a research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and well-being of the patients we serve." Shionogi's research and development currently target infectious diseases and pain/CNS disorders. For over 50 years, Shionogi has developed and commercialized innovative oral and parenteral anti-infectives.

VIVUS

VIVUS is a biopharmaceutical company developing and commercializing innovative, next-generation therapies to address unmet medical needs. Qsymia® (phentermine and topiramate extended release) is approved by the FDA for chronic weight management. STENDRA® (avanafil) is approved for erectile dysfunction by the FDA and by the EC under the trade name SPEDRA. Tacrolimus is in clinical development for the treatment of patients with pulmonary arterial hypertension. ■

MECOR Looks To Recuit Faculty, Mentors

Since it began, MECOR has grown tremendously, with more than 1,800 graduates around the world.

Loyal to its tagline, "We help the world breathe," the ATS has been working to build research capacity in low- and middle-income countries through its Methods in Epidemiologic, Clinical, and Operations Research (MECOR) program for 25 years. This intensive course for physicians and related health care professionals increases leadership in pulmonary, critical care, and sleep medicine research around the world.

The ATS recently launched MECOR 2.0. The updated program utilizes a "flipped classroom" teaching model with seminar-style classroom sessions and a focus on one-to-one instruction.

Since it began, MECOR has grown tremendously, with more than 1,800 graduates. Courses and partners include in Africa, the Pan African Thoracic; in China, the Chinese Thoracic Society; in India, the U.S. Centers for Disease Control and Prevention and the Indian Council for Medical Research; in Indonesia, the Indonesian Society for Respirology; in the Mediterranean, the Turkish Thoracic Society; in Latin America the Latin American Thoracic Society; and in Southeast Asia, the Vietnamese National TB Program and the University of Sydney.

To join the ATS MECOR program as a faculty member or mentor, please use the link below to complete an application. To learn more about MECOR, please go to the ATS website at: **thoracic.org/about/global-public-health/mecor-courses/mecor-faculty-application.php**. ■

New at ATS 2018: Educational Consulting Office

Are you planning on submitting a proposal for programming at the 2019 International Conference but don't know where to start?

Do you want to maximize your chances of having your Postgraduate Course Proposal programmed in 2019?

Would you like to review feedback you received on a 2018 proposal that wasn't programmed?

Would you like feedback on slides for a talk you're giving at this year's International Conference?

If you answered yes to any of the above, be sure to check out the Education Committee's Educational Consulting Office hours during the 2018 International Conference. Members of the Education Committee will be available for consulting in the Science and Innovation Center during the following times:

Monday, May 21: 10-11 a.m., 12-1 p.m., 3-4 p.m.

Tuesday, May 22: 10-11 a.m., 12-1 p.m., 3-4 p.m.

Wednesday, May 23: 10-11 a.m., 12-1 p.m. ■

Broad Support for Stubbing Out Tobacco Use

ATS members strongly support the Society's efforts to advocate against tobacco use and educate the public on the dangers of tobacco.

That's the result of a completely unscientific poll conducted outside Hall G and the ATS smoking information poster. Most respondents, but not all, said they were aware that tobacco manufacturers are required to publish statements admitting their complicity in hiding the truth about the deleterious health effects of tobacco.

Not all were aware of the role ATS played in bringing tobacco producers to account. But all were supportive of the advocacy and educational positions the ATS has taken.

"I think it's having a big impact. Anything ATS can do with the resources they have would be beneficial to everybody, not just in pulmonary medicine but in general medicine, cardiology, oncology, everything else that tobacco use impacts."

Robert Burkes, MD
Chapel Hill, North Carolina

"Advocacy and public education is our responsibility. I don't care if we are talking about cigarette smoking, asthma, allergy, and pulmonary problems that we have. We need education. The role of ATS has always been wonderful to educate our public as well as the docs."

Joann Blessing-Moore, MD
Woodside, California

"Absolutely. I think it's obvious that there have been a lot of myths perpetuated by the smoking industry for many decades. ATS is the leader in thoracic medicine; they should be taking the lead in advocacy and education."

Gabriel Lockhart, MD
St. Louis, Missouri

"Tobacco advocacy is not limited to the United States or to the ATS. Lebanon, despite decades of turmoil in the region, has mustered the resources and the political will to take on the tobacco industry.

"For the last 10 years, there was a push by the Ministry of Health to advocate education on smoking cessation. They put laws in place and tried to enforce them, where you can't smoke in restaurants, which was a completely new concept. In Lebanon, we have the hookah, and that became prevalent among youngsters 16 and younger. The government put in laws to crack down on that, so kids are not allowed to smoke, and hookah is not allowed to be smoked in closed environments. You have to be in the open air. They have done a lot of ad campaigns on TV about the impact on health of smoking hookah and smoking cigarettes. NGOs and the Ministry of Health have been very, very active in educating people and advocacy against smoking."

Mustapha El-Amine, MD
Formerly of Lebanon, now Washington, DC ■

> One of the issues with educating patients is bridging the divide. How we communicate with each other versus how we communicate with patients can be very different.
>
> **Garth Garrison, MD**

METACOGNITION

Continued from page 1

that deliberately engages learners.

One teaching style does not fit all situations or all learners, Dr. Garrison says. The key to more effective learning is to tailor the technique to the learner. Tailoring teaching begins with understanding the learner's motivations, needs, and goals.

"This symposium is a one-stop shop to help attendees understand why things stick and why they don't and how we can direct education toward specific populations. We have sessions on how doctors think, sessions on interprofessional education, and sessions on patient education," he says.

"One of the issues with educating patients is bridging the divide," Dr. Garrison adds. "How we communicate with each other versus how we communicate with patients can be very different."

Vocabulary is one major difference in professional communication versus patient communication. Motivation is also different.

"Patients have very different motivations to learn than medical practitioners do," Dr. Garrison says. "Patients are under very different stresses than providers, stresses that can get in the way of understanding and remembering content. There are very different strategies you can use when you are trying to educate residents or medical students as opposed to educating patients."

There are differences in learning across generations, too. Younger learners are generally more resistant to didactic learning and more receptive to active participation. Younger learners also leverage technology in different ways than older learners. And not all learners have access to, or familiarity with, the latest technologies that can facilitate learning.

Metacognition in Medicine: Understanding How the Mind Works to Improve Teaching, Learning, and Patient Care (B13)

9:15-11:15 a.m.

Monday

Room 3 (Upper Level), San Diego Convention Center

"Understanding those differences is crucial," Dr. Garrison says. "You have to be sure that how you teach matches those generational, economic, and motivational needs. When you are teaching, the focus should not be on you, the educator. The focus is on the learners and what you can do to improve their learning." ■

KEYNOTE SERIES

Continued from page 1

Dr. Glass's laboratory investigates transcriptional mechanisms that regulate the development and function of the macrophage, a cell that plays key roles in immunity and inflammatory diseases. Current efforts are to determine the biochemical and biological roles of sequence-specific transcription factors and their associated co-regulators at gene-specific and genome-wide scales.

Reducing Burnout and Promoting Engagement: Individual and Organizational Approaches to Physician Well-Being (K4)

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

Tait D. Shanafelt, MD, chief wellness officer at Stanford Medicine, will discuss what is known regarding satisfaction and burnout among physicians.

Tait D. Shanafelt, MD

Dr. Shanafelt is a nationally recognized expert in physician wellness, who joined Stanford Medicine after serving as director of the Program on Physician Well-being at Mayo Clinic, where he led a successful initiative to counter burnout and improve physicians' sense of fulfillment and well-being. Dr. Shanafelt's studies have found that as physicians suffer, so do patients: Burnout has been found to contribute to physician errors, higher mortality among hospitalized patients, and less compassionate care. It is a trend, he says, that is "eroding the soul of medicine." ■

KEYNOTE SERIES LINEUP

Tuesday: Hypoxemic and Ischemic Protection in Deep-Diving Seals

Bacteriophage Therapy

Wednesday: On Pharma: The Complexity of Innovation

The Pulmonologist as Medical Educator

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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