

## News Release

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### **Sunovion to Present Clinical Efficacy, Safety and Health-Related Quality of Life Outcomes Data from Its Respiratory Franchise at the American Thoracic Society 2017 International Conference**

- Seven presentations include data from Phase 3 studies of SUN-101/eFlow<sup>®</sup> as a potential maintenance treatment for moderate-to-very-severe chronic obstructive pulmonary disease (COPD) –
- Additional ATS 2017 presentations include data on Brovana<sup>®</sup> (arformoterol tartrate) inhalation solution, as well as data on Utibron<sup>™</sup> Neohaler<sup>®</sup> (indacaterol/glycopyrrolate) inhalation powder –

**Marlborough, Mass., May 15, 2017** – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) will present data on multiple products from its broad chronic obstructive pulmonary disease (COPD) portfolio, including data from Phase 3 efficacy and safety studies of SUN-101/eFlow<sup>®</sup> in patients with moderate-to-very-severe COPD, at the American Thoracic Society 2017 International Conference (ATS 2017) to be held May 19-24, 2017, in Washington, D.C.

The seven poster presentations from SUN-101/eFlow<sup>®</sup> clinical studies include data that demonstrate the safety and efficacy of SUN-101/eFlow<sup>®</sup>, a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the proprietary, investigational eFlow<sup>®</sup> closed system nebulizer, developed by PARI Pharma GmbH, as well as data from a patient survey showing patient satisfaction with the eFlow<sup>®</sup> device. Sunovion will also present data from two health economics and outcomes research (HEOR) studies investigating the factors that influence the use of nebulized long-acting beta agonists (LABAs) in COPD treatment and the effect of long-acting versus short-acting bronchodilators on COPD-related re-hospitalizations.

“These presentations demonstrate our commitment to improving the lives of patients with COPD by better understanding the treatment landscape and advancing innovative treatment options, including nebulized and handheld products, for patients at various stages of the disease,” said Thomas H. Goodin, Ph.D., Senior Director, Clinical Development at Sunovion. “We look forward to presenting data from our portfolio of COPD products that highlight our mission to address unmet needs for people living with COPD.”

In October last year, Sunovion [announced](#) that the U.S. Food and Drug Administration (FDA) accepted its New Drug Application (NDA) for SUN-101/eFlow<sup>®</sup> as a long-term, maintenance treatment of airflow obstruction in patients with moderate-to-very-severe COPD. If approved, this will be the first nebulized LAMA approved for the treatment of COPD in the U.S.

Sunovion presentations at ATS 2017 include:

#### SUN-101/eFlow<sup>®</sup>

- Poster #1105: Health-Related Quality of Life (HRQOL) in Moderate-to-Very-Severe Chronic Obstructive Pulmonary Disease (COPD) Patients Treated with SUN-101 (glycopyrrolate/eFlow<sup>®</sup>): Findings from the Phase 3 GOLDEN Studies (Sunday, May 21, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1119: Patient Device Satisfaction with eFlow<sup>®</sup> Closed System Nebulizer: Results from the GOLDEN-5 Study in Patients with Moderate-to-Very-Severe Chronic Obstructive Pulmonary Disease (COPD) (Sunday, May 21, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #355: Long-Term Safety of SUN-101/eFlow<sup>®</sup> in Moderate-to-Very-Severe COPD: Results from the Glycopyrrolate for Obstructive Lung Disease Via Electronic Nebulizer (GOLDEN) 5 Study (Monday, May 22, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #358: Dose Selection for SUN-101/eFlow<sup>®</sup> Phase 3 Clinical Studies: Results from GOLDEN (Glycopyrrolate for Obstructive Lung Disease Via Electronic Nebulizer) Phase 2 Dose-Finding Studies (Monday, May 22, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1080: Efficacy and Safety of SUN-101/eFlow<sup>®</sup> (Nebulized Glycopyrrolate) in Moderate-To-Very-Severe COPD: Results from the Glycopyrrolate for Obstructive Lung Disease Via Electronic Nebulizer (GOLDEN 3 and 4 Studies) (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1088: In-Vitro Characterization of the eFlow<sup>®</sup> Closed-System (eFlow<sup>®</sup> CS) Nebulizer with Glycopyrrolate Inhalation Solution (SUN-101) (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1167: Severity of Respiratory Symptoms in Moderate-to-Very-Severe Chronic Obstructive Pulmonary Disease (COPD) Patients Treated with SUN-101 (glycopyrrolate/eFlow<sup>®</sup>): Findings from the Phase 3 GOLDEN Studies (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)

#### Health Economics and Outcomes Research (HEOR) Studies

- Poster #1115: Continuing Care with Nebulized Bronchodilators After Hospital Discharge and Impact on Readmissions: Analysis of Medicare COPD Beneficiaries Receiving Arformoterol vs. Nebulized Short-Acting Agents (Sunday, May 21, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1154: Predictors of Treatment with Nebulized Long-Acting Beta<sub>2</sub> Agonists Among Medicare Beneficiaries with Chronic Obstructive Pulmonary Disease (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)

Additional clinical data presentations on products in Sunovion's COPD portfolio include nine posters on Utibron™ Neohaler<sup>®</sup> (indacaterol/glycopyrrolate) inhalation powder:

- Poster #353: Improvement in Trough FEV<sub>1</sub> with Indacaterol/Glycopyrrolate in Patients with Moderate-to-Severe COPD: A Pooled Subgroup Analysis of the FLIGHT1 and FLIGHT2 Studies (Monday, May 22, 9:15 a.m. – 4:15 p.m. EDT)

- Poster #356: Indacaterol/Glycopyrrolate Reduces Night-Time Symptoms in Patients With Moderate-to-Severe COPD: Pooled Analysis of the FLIGHT1 and FLIGHT2 Studies (Monday, May 22, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #376: Proportion of Patients with Superior Improvement in Health Status with Indacaterol/Glycopyrrolate Versus Placebo in Patients with Moderate-to-Severe COPD: A Pooled Analysis of FLIGHT1 and FLIGHT2 Studies (Monday, May 22, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1077: Indacaterol/Glycopyrrolate Significantly Reduces Nocturnal Rescue Medication Use and Awakenings in Patients With Moderate-to-Severe COPD: Results from a Pooled Analysis of FLIGHT1 and FLIGHT2 Studies (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1078: Significant and Sustained Bronchodilation with Indacaterol/Glycopyrrolate Versus Placebo: Pooled Analysis of FLIGHT1 and FLIGHT2 Studies (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1079: Indacaterol/Glycopyrrolate Is More Effective than Placebo in Improving FEV<sub>1</sub> by ≥200 mL from Baseline in Patients with Moderate-to-Severe COPD: FLIGHT1/FLIGHT2 Pooled (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1083: Indacaterol/Glycopyrrolate Significantly Improves HealthStatus and Dyspnea in Different Subgroups of Patients with Moderate-to-Severe COPD: Pooled Analysis of FLIGHT1 and FLIGHT2 Studies (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1084: Improvement in Lung Function with Twice-Daily Indacaterol/Glycopyrrolate Versus Once-Daily Indacaterol in Patients with Moderate-to-Severe COPD: Results from the FLIGHT3 Study (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)
- Poster #1091: Safety of Indacaterol/Glycopyrrolate 27.5/15.6 µg Twice Daily in Patients with Moderate-to-Severe COPD: Analysis from the FLIGHT Studies (Tuesday, May 23, 9:15 a.m. – 4:15 p.m. EDT)

Sunovion received U.S. commercial rights for UTIBRON NEOHALER, along with Seebri™ Neohaler® (glycopyrrolate) inhalation powder and Arcapta® Neohaler® (indacaterol) inhalation powder, in December 2016. Sunovion [announced on April 3, 2017](#) that UTIBRON NEOHALER is now available at pharmacies in the U.S. The Company expects to launch SEEBRI NEOHALER, which was approved by the FDA in 2015, and begin promotion of ARCAPTA NEOHALER, which was launched in the U.S. in 2012, in the U.S. during fiscal year 2017 (April 2017-March 2018).

### **About SUN-101/eFlow®**

SUN-101 (glycopyrrolate) is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the proprietary investigational eFlow® closed system nebulizer. SUN-101/eFlow® is currently in development as a nebulized treatment for patients with moderate-to-very-severe chronic obstructive pulmonary disease (COPD). The investigational combined product, consisting of SUN-101 and the eFlow® closed system nebulizer, which has been optimized for SUN-101 delivery, has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of COPD.

### **About Long Acting Muscarinic Antagonists (LAMAs)**

A long-acting muscarinic antagonist (LAMA) is a type of long-acting bronchodilator, along with long-acting beta agonists (LABAs). According to the GOLD report, these are currently the first-line standard of care maintenance therapy for symptomatic patients with COPD and help the muscles around the airways in lungs stay relaxed to prevent symptoms such as wheezing, coughing, chest tightness, and shortness of breath.<sup>1</sup> LAMAs and LABAs are widely used and important therapeutic approaches for people with COPD.

### **About the Phase 3 GOLDEN Clinical Trials**

GOLDEN-3 and GOLDEN-4 were pivotal Phase 3, 12-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter, efficacy and safety trials comparing SUN-101/eFlow<sup>®</sup> with placebo in adults with moderate-to-very severe COPD. The GOLDEN-3 trial enrolled 653 people who were at least 40 years old at 45 sites in the United States. The GOLDEN-4 trial enrolled 641 people who were at least 40 years old at 49 sites in the United States. SUN-101/eFlow<sup>®</sup> 25 mcg, SUN-101/eFlow<sup>®</sup> 50 mcg or placebo was administered twice daily in these studies. The primary endpoint was the change from baseline in trough FEV<sub>1</sub> at Week 12. Secondary endpoints included standardized change from baseline at Week 12 in FEV<sub>1</sub> area under the curve (AUC), change from baseline in trough forced vital capacity (FVC) at Week 12, change from baseline in health status measured by St. George's Respiratory Questionnaire and change in rescue medication use. Safety was assessed by the number of treatment-emergent adverse events (TEAE), serious adverse events (SAE) or major adverse cardiac events (MACE) and the number and percentage of study participants who discontinued the study due to TEAE. Both GOLDEN-3 and GOLDEN-4 studies included not only patients who were taking effective background long-acting bronchodilator therapy but also patients with very severe disease and co-existing significant cardiovascular illness. Approximately 10 percent of the population were elderly (>75 years), 65 percent were classified as being high-risk cardiovascular patients and more than 30 percent were taking long-acting bronchodilator therapy [NCT02347761 and NCT02347774].

GOLDEN-5 was a Phase 3, 48-week, randomized, open-label, active-controlled, parallel-group, multicenter safety trial designed to evaluate the long-term safety and tolerability of SUN-101/eFlow<sup>®</sup> in adults with moderate-to-very severe COPD. The study enrolled 1,087 patients at 111 investigational sites in the United States and Europe. The study evaluated 50 mcg of SUN-101/eFlow<sup>®</sup> delivered twice-daily and active comparator 18 mcg of Spiriva<sup>®</sup> (tiotropium bromide) delivered once-daily by the HandiHaler<sup>®</sup> device. The primary safety endpoints were: the number and percentage of study participants with treatment-emergent adverse events (TEAE), the number and percentage of study participants with treatment-emergent serious adverse events (SAE) and the number and percentage of study participants who discontinued the study due to TEAEs. The secondary endpoints were the number and percentage of subjects with MACE and the mean change from baseline over 48 weeks in trough FEV<sub>1</sub> for all subjects and. The study included not only patients who were taking effective background long acting bronchodilator therapy but also patients with very severe disease and co-existing significant cardiovascular illness. Approximately 10 percent of the population were elderly

(>75 years), 65 percent were classified as being high-risk cardiovascular patients and more than 40 percent were taking long-acting bronchodilator therapy [NCT02276222].

### **About Utibron™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder**

UTIBRON NEOHALER (indacaterol/glycopyrrolate) inhalation powder is a twice-daily combination long-acting beta agonist and long-acting muscarinic antagonist (LABA/LAMA) approved in the U.S. for the long-term maintenance treatment of airflow obstruction in people with COPD, including chronic bronchitis and/or emphysema. Phase 3 clinical trials demonstrated that UTIBRON NEOHALER has the additive benefits of the LABA indacaterol and the LAMA glycopyrrolate compared to each component alone. UTIBRON NEOHALER also improved overall quality of life as measured by the St. George's Respiratory Questionnaire (SGRQ) total score, reduced COPD rescue medication use and improved breathlessness as measured by the Transitional Dyspnea Index (TDI) total score in patients as compared to placebo.

The most common adverse reactions ( $\geq 1\%$  and more common than placebo) reported in two 12-week clinical trials with UTIBRON NEOHALER (and placebo) were: nasopharyngitis, 4.1% (1.8%); hypertension, 2.0% (1.4%); back pain, 1.8% (0.6%); oropharyngeal pain, 1.6% (1.2%).

### **UTIBRON™ NEOHALER® (indacaterol/glycopyrrolate) Inhalation Powder**

#### **INDICATION**

UTIBRON™ NEOHALER® (indacaterol and glycopyrrolate) is a combination of a long-acting beta<sub>2</sub>-agonist, or LABA, medicine (indacaterol) and an anticholinergic medicine (glycopyrrolate). UTIBRON NEOHALER is used long term, twice each day (morning and evening), to treat the symptoms of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

#### **IMPORTANT SAFETY INFORMATION**

**UTIBRON NEOHALER has been approved for COPD only and is NOT indicated for the treatment of asthma. People with asthma who take long-acting beta<sub>2</sub>-adrenergic agonist (LABA) medicines, such as indacaterol (one of the medicines in UTIBRON NEOHALER), have an increased risk of death from asthma problems. It is not known if LABA medicines, such as indacaterol, increase the risk of death in people with COPD.**

UTIBRON NEOHALER does not relieve sudden symptoms of COPD and should not be used more than twice daily. Always have a short-acting beta<sub>2</sub>-agonist with you to treat sudden symptoms.

Use UTIBRON NEOHALER exactly as your health care provider tells you to use it. Do not use UTIBRON NEOHALER more often than it is prescribed for you.

Get emergency medical care if your breathing problems worsen quickly, you need to use your rescue medication more often than usual, or your rescue medication does not work as well to relieve your symptoms.

Do not use UTIBRON NEOHALER if you are allergic to indacaterol, glycopyrrolate, or any of the ingredients in UTIBRON NEOHALER. Ask your health care provider if you are not sure.

Tell your health care provider about all of your health conditions, including if you:

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- have liver problems
- have kidney problems
- have eye problems such as glaucoma
- have prostate or bladder problems, or problems passing urine
- have any other medical conditions
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed
- are allergic to UTIBRON NEOHALER or any of its ingredients, any other medicines, or food products. UTIBRON NEOHALER contains lactose (milk sugar) and a small amount of milk proteins. It is possible that allergic reactions may happen in people who have a severe milk protein allergy

Tell your health care provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. UTIBRON NEOHALER and certain other medicines may interact with each other. This may cause serious side effects.

Especially tell your health care provider if you take:

- anticholinergics (including umeclidinium, tiotropium, ipratropium, aclidinium, glycopyrrolate)
- LABA medicines (including formoterol, salmeterol, vilanterol, indacaterol, olodaterol)

UTIBRON NEOHALER can cause serious side effects, including:

- sudden shortness of breath (that may be life-threatening) immediately after use of UTIBRON NEOHALER

- increased blood pressure
- fast or irregular heartbeat (palpitations)
- chest pain
- serious allergic reactions, including rash; hives; swelling of the tongue, lips, and face; and difficulties breathing or swallowing. Call your health care provider or get emergency medical care if you get any symptoms of a serious allergic reaction
- new or worsened eye problems, including acute narrow-angle glaucoma (symptoms may include eye pain or discomfort, blurred vision, red eyes, nausea or vomiting, seeing halos or bright colors around lights)
- new or worsened urinary retention (symptoms may include difficulty urinating, urinating frequently, painful urination, urination in a weak stream or drips)
- changes in laboratory blood levels, including high levels of blood sugar (hyperglycemia) and low levels of potassium (hypokalemia), which may cause symptoms of muscle spasm, muscle weakness, or abnormal heart rhythm

Common side effects of UTIBRON NEOHALER include sore throat and runny nose, high blood pressure, and back pain.

These are not all of the possible side effects with UTIBRON NEOHALER. Tell your health care provider about any side effect that bothers you or that does not go away.

Do not swallow UTIBRON capsules. UTIBRON capsules are for inhalation only with the NEOHALER device. Never place a capsule in the mouthpiece of the NEOHALER device.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

This information is not comprehensive.

How to get more information:

- Talk to your health care provider
- Visit [www.UTIBRON.com](http://www.UTIBRON.com) to obtain the FDA-approved product labeling
- Call 1-888-394-7377

**For additional information, please see full [Prescribing Information](#), including **BOXED WARNING** and [Medication Guide](#), for UTIBRON NEOHALER, or visit <http://www.UTIBRON.com>.**

**About NEOHALER® Inhaler**

The NEOHALER inhaler is a handheld device designed to deliver UTIBRON, SEEBRI and ARCAPTA. The NEOHALER inhaler offers several feedback mechanisms that allow patients to see whether or not the capsules are empty, while giving them the flexibility to inhale any remaining dose not fully administered. The ability to provide dosing feedback is an important feature for patients and physicians. The NEOHALER inhaler is also small enough to carry easily in a pocket, bag or purse.

### **About COPD**

Chronic obstructive pulmonary disease (COPD) is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or lung abnormalities usually caused by significant exposure to toxic particles or gases. The main risk factor for COPD is tobacco smoking, but other environmental exposures may contribute.<sup>1</sup> Approximately 15.7 million adults in the U.S. report that they have been diagnosed with COPD.<sup>2</sup> It is estimated that several million more adults have undiagnosed COPD.<sup>3</sup> COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the U.S.<sup>3</sup> COPD develops slowly and the symptoms often worsen over time, potentially limiting the ability to perform routine activities.<sup>2</sup> Symptoms of COPD include coughing, wheezing, shortness of breath, excess production of mucus in the lungs, the inability to breathe deeply and the feeling of being unable to breathe.<sup>4</sup> The symptoms of COPD can be most severe during the night and early morning.<sup>5</sup> Morning symptoms can be associated with limitation of activities during the day, impaired health status and increased risk of exacerbation.<sup>6</sup> Night-time symptoms disturb sleep, reduce sleep quality and, in the long term, may be associated with development or worsening of cardiovascular diseases, cognition, depression and increased mortality.<sup>7</sup>

### **Expanding Sunovion's Heritage in COPD**

Sunovion is committed to expanding its heritage of advancing new treatments for serious respiratory medical conditions, including the 15.7 million people in the U.S. who are living with chronic obstructive pulmonary disease (COPD).<sup>2</sup> The company offers the broadest COPD portfolio in the U.S., providing treatment options for people at various stages of COPD, as well as the flexibility for health care providers and patients to choose handheld or nebulized products based on individual treatment needs. Sunovion goes beyond treatment offerings to support awareness and understanding with the entire COPD community – health care providers, patients and caregivers – and to advancing disease state education through its partnerships with various organizations.

### **About Sunovion Pharmaceuticals Inc. (Sunovion)**

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments

that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological and respiratory conditions. Sunovion's track record of discovery, development and commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, Brovana® (arformoterol tartrate) inhalation solution, Latuda® (lurasidone HCl) and Aptiom® (eslicarbazepine acetate).

Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, and Sunovion CNS Development Canada ULC, based in Toronto, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's web sites: [www.sunovion.com](http://www.sunovion.com), [www.sunovion.eu](http://www.sunovion.eu) and [www.sunovion.ca](http://www.sunovion.ca). Connect with Sunovion on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

### **About Sumitomo Dainippon Pharma Co., Ltd.**

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan operating globally in major pharmaceutical markets, including Japan, the United States, China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 6,500 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at [www.ds-pharma.com](http://www.ds-pharma.com).

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<sup>1</sup> GOLD Guidelines 2017. <http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html>. Accessed: March 16, 2017.

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<sup>2</sup> MMWR: Morbidity and Mortality Weekly Report. Employment and Activity Limitations Among Adults with Chronic Obstructive Pulmonary Disease — United States, 2013. March 27, 2015; 64(11). Available at <http://www.cdc.gov/mmwr/>

<sup>3</sup> National Heart, Lung, and Blood Institute. "What is COPD?" Available at: <http://www.nhlbi.nih.gov/health/educational/copd/what-is-copd/index.htm>. Accessed: March 2, 2016

<sup>4</sup> National Heart, Lung and Blood Institute. (2013). What Are the Signs and Symptoms of COPD? Retrieved from <https://www.nhlbi.nih.gov/health/health-topics/topics/copd/signs>.

<sup>5</sup> Partridge MR, Karlsson N, Small IR. Patient insight into the impact of chronic obstructive pulmonary disease in the morning: an internet survey. *Curr Med Res Opin.* 2009;25:2043–8.

<sup>6</sup> Roche N, Small M, Broomfield S, Higgins V, Pollard R. Real world COPD: association of morning symptoms with clinical and patient reported outcomes. *COPD.* 2013;10:679–86.

<sup>7</sup> Agusti A, Hedner J, Marin JM, Barbé F, Cazzola M, Rennard S. Night-time symptoms: a forgotten dimension of COPD. *Eur Respir Rev.* 2011;20:183–94.