

## News Release

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### **Sunovion Announces Utibron™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder Data Showing Lung Function and Health-Related Quality of Life Improvement in Patients with Moderate-to-Severe Chronic Obstructive Pulmonary Disease**

*– Presentations at the American Thoracic Society 2017 International Conference (ATS 2017) also included long-term safety data and pooled analyses of pivotal studies –*

**Marlborough, Mass., May 23, 2017** – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) announced that multiple data analyses from two Phase 3 studies demonstrating that Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder improved lung function, health-related quality of life (HRQL), dyspnea and night-time symptoms compared to placebo in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD), were presented at the 2017 American Thoracic Society International Conference (ATS 2017) held May 19-24, 2017, in Washington, D.C. Findings from the FLIGHT1 and FLIGHT2 pivotal efficacy and safety studies, as well as from the FLIGHT3 long-term safety study, were included in nine posters for UTIBRON NEOHALER presented at the meeting.

UTIBRON NEOHALER is a twice-daily combination long-acting beta<sub>2</sub> agonist (indacaterol) and long-acting muscarinic antagonist (glycopyrrolate) (LABA/LAMA) for the long-term maintenance treatment of airflow obstruction in people with COPD, including chronic bronchitis and/or emphysema. UTIBRON NEOHALER is not indicated to treat asthma or for the relief of sudden symptoms of COPD.

“Improvement in health related quality of life, including reduction of difficult or labored breathing, is a key therapeutic goal for patients with COPD that is reflected in the updated 2017 Global Initiative for Chronic Obstructive Lung Disease (GOLD) report,” said lead investigator of FLIGHT1 and FLIGHT2 studies Donald A. Mahler, M.D., Emeritus Professor of Medicine, Geisel School of Medicine at Dartmouth, Lebanon, N.H. “These UTIBRON NEOHALER data show that the dual bronchodilator

significantly improves and sustains bronchodilation and may improve health status and COPD symptoms in moderate-to-severe patients.”

“UTIBRON NEOHALER has demonstrated the value of dual bronchodilation treatment for people living with COPD,” said Thomas H. Goodin, Ph.D., Senior Director, Clinical Development at Sunovion. “The data presented at ATS indicate that UTIBRON NEOHALER was associated with statistically significant and clinically important improvements in lung function as well as a reduction in the number of sleep disturbances and in the use of rescue medication, which may have a positive impact on patients’ quality of life.”

Key data presented at ATS 2017 include:

- A pooled analysis of efficacy results from FLIGHT1 and FLIGHT2 studies, which showed that UTIBRON NEOHALER demonstrated significant and sustained improvement in lung function compared to placebo, as measured by time-weighted mean forced expiratory volume in 1 second (FEV<sub>1</sub>). Treatment differences between UTIBRON NEOHALER and placebo ranged from 0.159 to 0.179 L on Day 1 and from 0.223 to 0.281 L at Week 12 (all p-values <0.001). These results are consistent with [previously reported](#) findings from the FLIGHT studies.
- Results from a pooled analysis of HRQL data from FLIGHT1 and FLIGHT2 studies showed that patients treated with UTIBRON NEOHALER for moderate-to-severe COPD had statistically and clinically significant improvements in disease specific health related quality of life, as measured by the St. George's Respiratory Questionnaire (SGRQ) and dyspnea, as measured by the Transition Dyspnea Index (TDI), compared to placebo treated patients after 12 weeks of treatment. These improvements were seen in all patients, irrespective of age, gender, severity of disease, smoking status or baseline use of drugs like corticosteroids.
- Two pooled analyses of FLIGHT1 and FLIGHT2 trials evaluated the effect of UTIBRON NEOHALER on patient-reported daily total COPD symptoms, night-time use of rescue medication and sleep disturbance.
  - One of these presentations showed that patients treated with UTIBRON NEOHALER reported significant reduction in their total night-time COPD symptoms score versus placebo over the 12-week treatment period.
  - A separate pooled analysis showed that 12 weeks of treatment with UTIBRON NEOHALER significantly reduced the use of rescue medications at night and significantly increased the number of nights with no awakenings, compared to placebo. Specifically, a significant reduction in the number of night-time rescue medication puffs use (treatment difference: -0.50; standard error (SE): +/- 0.06; p < 0.001) and significant increases in the percentage of nights with no awakenings (treatment difference: 7.7; SE: +/- 1.58; p < 0.001) compared to placebo, were seen after 12 weeks of treatment.

## 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>2</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>

#### **About FLIGHT1 and FLIGHT2 Studies<sup>8</sup>**

FLIGHT1 and FLIGHT2 were Phase 3, replicate, multicenter, double-blind, parallel group, placebo- and active-controlled studies that randomized (1:1:1:1) patients with moderate-to-severe COPD to receive indacaterol/glycopyrrolate 27.5/15.6 mcg, indacaterol 27.5 mcg, glycopyrrolate 15.6 mcg or placebo (all given twice daily) over a 12-week treatment period. All treatments were delivered via the Neohaler<sup>®</sup> device. The studies were funded by Novartis Pharmaceuticals Corporation.

#### **About Utibron<sup>™</sup> Neohaler<sup>®</sup> (indacaterol/glycopyrrolate) Inhalation Powder<sup>9</sup>**

UTIBRON NEOHALER (indacaterol/glycopyrrolate) inhalation powder is a combination bronchodilator indicated for the long-term maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is not indicated to treat acute deteriorations of COPD or to treat asthma. UTIBRON NEOHALER combines two medicines in one twice-daily fixed-dose combination: indacaterol 27.5 mcg, a long-acting beta<sub>2</sub>-adrenergic agonist (LABA), and the long-acting muscarinic antagonist (LAMA) glycopyrrolate 15.6 mcg.

Sunovion entered into an [exclusive license agreement](#) with Novartis for the U.S. commercialization rights to UTIBRON NEOHALER, as well as Seebri<sup>™</sup> Neohaler<sup>®</sup> (glycopyrrolate) inhalation solution and Arcapta<sup>®</sup> Neohaler<sup>®</sup> (indacaterol) inhalation solution, on December 21, 2016. Novartis received approval from the U.S. Food and Drug Administration (FDA) for UTIBRON NEOHALER in October 2015.

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

##### **INDICATION**

UTIBRON<sup>™</sup> NEOHALER<sup>®</sup> (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, acclidinium, 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 [www.UTIBRON.com](http://www.UTIBRON.com).**

### **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 to choose handheld or nebulized delivery based on individual 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.

<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.

<sup>8</sup> Mahler DA, Kerwin E, Ayers T, et al. FLIGHT1 and FLIGHT2: Efficacy and Safety of QVA149 (Indacaterol/Glycopyrrolate) versus its Monocomponents and Placebo and Patients with Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med.* 2015;192(9):1068-1079.

<sup>9</sup> Utibron™ Neohaler® Full Prescribing Information. Novartis Pharmaceuticals Corporation. January 2017.