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News Release

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Sunovion Announces Utibron™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder Now Available in the United States

UTIBRON NEOHALER is a new combination therapy for people with chronic obstructive pulmonary disease (COPD) that addresses unmet patient needs

Marlborough, Mass., April 3, 2017 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder is now available at pharmacies in the United States for the long-term maintenance treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. UTIBRON NEOHALER is not indicated to treat asthma or for the relief of sudden symptoms of COPD.

UTIBRON NEOHALER is a twice-daily combination long-acting beta agonist and long-acting muscarinic antagonist (LABA/LAMA). Sunovion entered into an exclusive license agreement with Novartis for the U.S. commercialization rights to UTIBRON NEOHALER, as well as Seebri™ Neohaler® and Arcapta® Neohaler®, on December 21, 2016. Novartis received approval from the U.S. Food and Drug Administration (FDA) for UTIBRON NEOHALER in October 2015.

“Sunovion is pleased to bring to market UTIBRON NEOHALER, an important dual-bronchodilator handheld inhaler, that is a new combination therapy now available for the millions of people with COPD in the United States,” said David Frawley, Executive Vice President and Chief Commercial Officer at Sunovion. “As part of our commitment to people living with COPD, Sunovion has built a broad COPD portfolio including nebulized and handheld treatment options for patients at various stages of COPD.”

In clinical studies, UTIBRON NEOHALER demonstrated significantly improved lung function compared to either of its single bronchodilator components (indacaterol 27.5 mcg and glycopyrrolate 15.6 mcg) as well as placebo. Peak improvement in lung function as measured by FEV_1 (forced expiratory volume in one second) within four hours after morning dose from baseline was 290 mL and 260 mL in the two 12 week, Phase 3 pivotal studies. Median time to onset of action as defined as 100 mL improvement in FEV_1 was seen 12 to 16 minutes after the first dose and was maintained throughout the 12 hour dosing interval in the two pivotal studies. 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. UTIBRON NEOHALER's safety profile was similar to its individual components and placebo in clinical trials. The most common adverse reactions (≥2% and higher than placebo) were nasopharyngitis and hypertension.

"UTIBRON NEOHALER is well aligned with the recently updated global treatment strategy for COPD, which emphasizes the use of a LAMA/LABA combination for maintenance treatment in the majority of symptomatic COPD patients," said Gary Ferguson, M.D., Pulmonary Research Institute of Southeast Michigan, Livonia, Michigan. "Additionally, the NEOHALER device allows patients to visualize whether their dose was administered 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 their health care providers."

Additional medical information, patient assistance and other information about UTIBRON NEOHALER is available through Sunovion Answers at www.utibron.com or by calling 1-844-276-8262 Monday through Friday from 8 a.m. to 8 p.m. ET.

Sunovion 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 LAMAs and LABAs

Long-acting bronchodilators currently are the first-line standard of care maintenance therapy for symptomatic patients with COPD.[1] Within that class there are long-acting muscarinic antagonists (LAMAs) and long-acting beta agonists (LABAs), both of which are widely used and important therapeutic approaches. LAMA and LABA medicines dilate, or open, the airways in the lungs to reduce symptoms such as wheezing, cough, chest tightness and shortness of breath. Combining a LAMA and a LABA may offer additive benefits, including increased efficacy, compared with the LAMA or LABA alone. As a result, patients with increasing severity are often treated with both a LAMA and LABA.

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 alveolar abnormalities usually caused by significant exposure to noxious particles or gases. The main risk factor for COPD is tobacco smoking, but other environmental exposures may contribute.[1] Approximately 15.7 million adults in the U.S. report that they have been diagnosed with COPD.[2] It is estimated that several million more adults have undiagnosed COPD.[3] COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the U.S.[3] COPD develops slowly and the symptoms often worsen over time, potentially limiting the ability to perform routine activities.[2] 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.[3] The symptoms of COPD can be most severe during the night and early morning.[4] Morning symptoms can be associated with limitation of activities during the day, impaired health status and increased risk of exacerbation.[5] 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.[6]

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 (≥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$_2$-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$_2$-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$_2$-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 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 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.

Expanding Sunovion's Respiratory 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). The company offers the broadest COPD portfolio in the U.S., providing treatment options for people at all 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), LATUDA® (lurasidone HCI) 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, www.sunovion.eu and 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.

For a copy of this release, visit Sunovion's web site at www.sunovion.com

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