Sunovion Announces Lonhala™ Magnair™ (glycopyrrolate) Inhalation Solution Now Available in the U.S. for the Treatment of COPD

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- LONHALA MAGNAIR is the first nebulized long-acting muscarinic antagonist (LAMA) available for the treatment of COPD in the U.S. -

MARLBOROUGH, Mass.—(BUSINESS WIRE)—Sunovion Pharmaceuticals Inc. today announced that Lonhala™ Magnair™ (glycopyrrolate) Inhalation Solution (25 mcg twice daily) is now available at pharmacies in the U.S. for the long-term, maintenance treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

LONHALA MAGNAIR is the first nebulized long-acting muscarinic antagonist (LAMA) approved for the treatment of COPD in the U.S. LONHALA is delivered by oral inhalation exclusively through the MAGNAIR Nebulizer System, which uses eFlow® technology developed by PARI Pharma GmbH. The MAGNAIR Nebulizer System is a virtually silent, portable, closed system nebulizer that is designed to deliver the medication in two to three minutes, allowing people to breathe normally as they use the device. Sunovion received approval from the U.S. Food and Drug Administration (FDA) for LONHALA MAGNAIR in December 2017.

“Sunovion is pleased that LONHALA MAGNAIR is now available as a treatment option for people in the U.S. living with COPD,” said David Frawley, Executive Vice President and Chief Commercial Officer at Sunovion. “COPD is a chronic, progressive respiratory disease affecting millions of Americans. Bringing this product to market exemplifies Sunovion’s commitment to advancing new therapeutic options for people with COPD, especially those seeking nebulized solutions to manage their COPD symptoms.”

In clinical studies, LONHALA MAGNAIR demonstrated statistically significant and clinically important changes from baseline in forced exhalation (throug forced expiratory volume in one second, FEV1) at Week 12 versus placebo. LONHALA MAGNAIR was generally well-tolerated by study participants, with the most common side effects being dyspepsia and urinary tract infection.

“Despite the availability of several therapies for COPD, many people still struggle with their disease, a challenge that may, in part, be related to the delivery method used to administer their medications,” said Gary Ferguson, M.D., Pulmonary Research Institute of Southeast Michigan, Farmington Hills, Michigan. “For people with moderate-to-severe COPD, nebulization is a delivery option that may be preferable for patients, especially patients who may have difficulties using handheld devices, as it allows patients to breathe normally while taking their medication. LONHALA MAGNAIR offers such an option, providing a long-acting bronchodilator with a nebulizer that is virtually silent, portable and designed to deliver the drug in two to three minutes.”

Additional product information, patient assistance and other information about LONHALA MAGNAIR is available through Sunovion Answers at lonhalamagnair.com or by calling 1-844-276-8262 Monday through Friday from 8:00 a.m. to 8:00 p.m. ET.

Sunovion is committed to providing treatment options for people at various stages of COPD to help improve the lives of the 15.7 million people in the U.S. living with this serious respiratory condition. Driven by this commitment, we seek to offer health care providers and patients with the flexibility to choose handheld or nebulized products based on their individual treatment needs. Our portfolio of approved products for COPD includes Lonhala™ Magnair™ (glycopyrrolate) Inhalation Solution, Utribron™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder, Seebri™ Neohaler® (glycopyrrolate) Inhalation Powder, Arcapta® Neohaler® (indacaterol) Inhalation Powder and Brovana® (arformoterol tartrate) Inhalation Solution.

About Lonhala™ Magnair™ (glycopyrrolate) Inhalation Solution

LONHALA MAGNAIR (glycopyrrolate) Inhalation Solution, also known as SUN-101eFlow®, is the first long-acting muscarinic antagonist (LAMA) bronchodilator approved for the treatment of COPD in the U.S. delivered by oral inhalation exclusively through the MAGNAIR Nebulizer System, which is based on eFlow® technology developed by PARI Pharma GmbH. The MAGNAIR Nebulizer System is a virtually silent, portable, closed system nebulizer that is designed to deliver the medication in two to three minutes, allowing people to breathe normally as they use the device. LONHALA MAGNAIR is approved for the long-term, maintenance treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Important Safety Information for LONHALA MAGNAIR (glycopyrrolate) Inhalation Solution

INDICATION

LONHALA™ MAGNAIR™ (glycopyrrolate) is a medicine called an anticholinergic. LONHALA MAGNAIR is used long term, twice each day (morning and evening), for maintenance treatment of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

IMPORTANT SAFETY INFORMATION

LONHALA MAGNAIR does not relieve sudden symptoms of COPD and should not be used more than twice daily. Always have a short-acting beta-agonist with you to treat sudden symptoms.

Do not use LONHALA MAGNAIR unless your health care provider has taught you how to use the device and you understand how to use it correctly. Use LONHALA MAGNAIR exactly as your health care provider tells you to use it.

Do not use LONHALA MAGNAIR more often than is prescribed for you. Do not stop using LONHALA MAGNAIR or other medicines to control or treat your COPD unless told to do so by your health care provider because your symptoms might get worse. Your health care provider will change your medicines as needed.

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 LONHALA MAGNAIR if you are allergic to glycopyrrolate or to any of the ingredients in LONHALA MAGNAIR. 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 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 LONHALA MAGNAIR or any of its ingredients, or to any other medicines or food products.

Tell your health care provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. LONHALA MAGNAIR 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).

LONHALA MAGNAIR can cause serious side effects, including:

- sudden shortness of breath (that may be life-threatening) immediately after use of LONHALA MAGNAIR.
- serious allergic reactions, including: rash; hives; swelling of the tongue, lips, and face; and difficulty 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).

Common side effects of LONHALA MAGNAIR include shortness of breath and urinary tract infection.

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

LONHALA solution is for oral inhalation only and should not be injected or swallowed. LONHALA vials should only be administered with MAGNAIR.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch [4] or call 1-800-FDA-1088.

This information is not comprehensive.

How to get more information:

- Talk to your health care provider.
- Call 1-888-394-7377

For additional information, please see full Prescribing Information [6] and Patient Information for LONHALA MAGNAIR at www.LonhalaMagnair.com [7].

About Long-Acting Muscarinic Antagonists (LAMAs)

A long-acting muscarinic antagonist (LAMA) is a type of long-acting bronchodilator, along with long-acting beta₂-agonists (LABAs). According to the GOLD 2017 report, these bronchodilators are currently the first-line standard of care maintenance therapy for symptomatic individuals 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.¹ ² LAMAs are widely used and an important therapeutic approach for people with COPD.

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.² Approximately 15.7 million adults in the U.S. report that they have been diagnosed with COPD.³ It is estimated that several million more adults have undiagnosed COPD.⁴ COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the U.S.⁵ 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.¹ The symptoms of COPD can be most severe during the night and early morning.¹ Morning symptoms can be associated with limitation of activities during the day, impaired health status and increased risk of exacerbation.⁴ 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.⁵

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.


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 [15].