



NEWS RELEASE

Sunovion to Present Data on LONHALA® MAGNAIR® Inhalation Solution and COPD at the American Thoracic Society International Conference 2019

5/1/2019

- Post hoc analyses of LONHALA MAGNAIR evaluated lung function in patients with common COPD comorbidities -

MARLBOROUGH, Mass.--**(BUSINESS WIRE)**--**Sunovion Pharmaceuticals Inc.** (Sunovion) will present data from its portfolio of treatments for chronic obstructive pulmonary disease (COPD) at the American Thoracic Society International Conference 2019 (ATS 2019), taking place May 17-22, 2019 in Dallas, Texas.

"Several of Sunovion's presentations at ATS 2019 focus on the importance of comorbidities, including anxiety and depressive symptoms and metabolic syndrome, on physiological and symptomatic responses in patients with moderate-to-very severe COPD who participated in the LONHALA MAGNAIR clinical program," said Thomas H. Goodin, Ph.D., Senior Director of Clinical Development at Sunovion. "COPD is a serious and complex medical condition that affects millions of Americans. Patients with COPD often present in the clinic with significant medical and psychiatric comorbidities. Therefore, it is important to provide these data from post hoc analyses to healthcare practitioners that evaluate the effectiveness and tolerability of a COPD therapy in the presence of other relevant medical conditions to help support individualized patient care."

Lonhala® Magnair® (glycopyrrolate) Inhalation Solution (25 mcg twice daily) was the first nebulized long-acting muscarinic antagonist (LAMA) approved for the treatment of COPD in the U.S. LONHALA is administered 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 administer the medication in two to three minutes, as people breathe normally. Sunovion received approval from the U.S. Food and Drug Administration (FDA) for LONHALA MAGNAIR in December 2017, and it

became available to patients in April 2018.

Sunovion presentations at ATS 2019 include:

- Poster #P624: Improvement in Lung Function and Patient-Reported Outcomes in Patients with COPD with Comorbid Anxiety and Depression Receiving Nebulized Glycopyrrolate in the GOLDEN 3 and 4 Studies (Monday, May 20, 11:15 a.m. – 1:00 p.m. CDT, Area D, (Hall F, Level 2))
- Poster #P620: Effect of Metabolic Syndrome Status on Lung Function and Patient-Reported Outcomes in Patients with COPD Receiving Nebulized Glycopyrrolate in the GOLDEN 3 and 4 Studies (Monday, May 20, 11:15 a.m. – 1:00 p.m. CDT, Area D, (Hall F, Level 2))
- Poster #P621: Use of a Comorbidity Count to Assess the Prevalence of Comorbidities in the GOLDEN 3 and 4 Randomized Clinical Trials in Patients with Moderate-to-Very-Severe COPD (Monday, May 20, 11:15 a.m. – 1:00 p.m. CDT, Area D, (Hall F, Level 2))
- Poster #P625: The Impact of Missing Spirometry Data in the GOLDEN 3 and 4 Studies of Patients with Moderate-to-Very-Severe COPD Treated with Nebulized Glycopyrrolate (Monday, May 20, 11:15 a.m. – 1:00 p.m. CDT, Area D, (Hall F, Level 2))
- Poster #P623: Lung Function and Patient-reported Outcomes with Nebulized Glycopyrrolate in Patients with COPD by Baseline Rescue Medication Use in the Phase 3 GOLDEN 3 and 4 Studies (Monday, May 20, 11:15 a.m. – 1:00 p.m. CDT, Area D, (Hall F, Level 2))
- Poster #P619: Effect of Gender on Lung Function and Patient-Reported Outcomes in Patients with COPD Receiving Nebulized Glycopyrrolate in the GOLDEN 3 and 4 Studies (Monday, May 20, 11:15 a.m. – 1:00 p.m. CDT, Area D, (Hall F, Level 2))
- Poster #P815: Clinically Important Deterioration Among Patients with Chronic Obstructive Pulmonary Disease (COPD) Treated with Glycopyrrolate eFlow® Closed System (CS) (Nebulized Glycopyrrolate) in Pooled Data from Two Randomized, Double Blind, Placebo-Controlled Studies (Tuesday, May 21, 11:15 a.m. – 1:00 p.m. CDT, Area F (Hall F, Level 2))
- Poster #P522: Overuse of Short-Acting Bronchodilators and the Risk of Exacerbation Among Patients with Chronic Obstructive Pulmonary Disease (COPD) Treated with Nebulized Short-Acting Bronchodilators (Wednesday, May 22, 1:30 p.m. – 3:30 p.m. CDT, Room D222-D224 (Level 2))

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 beta2-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 or call 1-800-FDA-1088.

This information is not comprehensive.

How to get more information:

- Talk to your health care provider
- Visit www.lonhalamagnair.com to obtain the FDA-approved product labeling
- Call 1-888-394-7377

For additional information, please see full **Prescribing Information** and Patient Information for LONHALA MAGNAIR at www.LonhalaMagnair.com .

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 2018 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.¹ It is estimated that several million more adults have undiagnosed COPD.² COPD is responsible for over 120,000 deaths per year, making it the fourth leading cause of death in the U.S.¹ 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.³ 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.

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, and Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's websites: 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 and 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 6,200 employees worldwide. Additional information about

Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

LONHALA is a registered trademark of Sunovion Pharmaceuticals Inc. MAGNAIR is a registered trademark of PARI Pharma GmbH, used under license. eFlow is a registered trademark of PARI Pharma GmbH.

SUNOVION is a registered trademark of Sumitomo Dainippon Pharma Co. Ltd.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

© 2019 Sunovion Pharmaceuticals Inc. All rights reserved.

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

References

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

2 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.

3 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.

4 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.

5 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.

Kirsten Fallon

Senior Manager, Portfolio Communications

Sunovion Pharmaceuticals Inc.

774-369-7116

kirsten.fallon@sunovion.com