Chronic obstructive pulmonary disease (COPD) is a serious, progressive respiratory disease that should have a personalized approach to choose a therapy and delivery method, and these terms as a need for additional treatment options for newly diagnosed patients as well as those managing uncontrolled symptoms," said Edward Kerwin, M.D., Medical Director of the Clinical Research Institute of Southern Oregon. “SEEBRI NEOHALER is a long-acting muscarinic antagonist delivered through a small, handheld inhaler that provides important audiovisual feedback to patients, caregivers and health care providers.”

Additional medical information, patient assistance and other information about SEEBRI NEOHALER is available through Sunovion Answers at https://www.seebri.us/sunovion-answers.html [4] or by calling 1-844-726-8262 Monday through Friday from 8 a.m. to 8 p.m. ET.

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.3 LAMAs and LABAs are widely used and important therapeutic approaches 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.3 Approximately 15.7 million adults in the U.S. report that they have been diagnosed with COPD.4 It is estimated that several million more adults have undiagnosed COPD.5 COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the U.S.4 COPD develops slowly and the symptoms often worsen over time, potentially limiting the ability to perform routine activities.4 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.6 The symptoms of COPD can be most severe during the night and early morning.7 Morning symptoms can be associated with limitation of activities during the day, impaired health status and increased risk of exacerbation.8 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.9

About Seebri® Neohaler® (glycopyrrolate) Inhalation Powder
Seebri® Neohaler® (glycopyrrolate) Inhalation Powder, 15.6 mcg twice daily, is a long-acting muscarinic antagonist (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. SEEBRI NEOHALER is delivered by a dry powder inhaler (DPI), and its active ingredient, glycopyrrolate, has an established safety and efficacy profile. In clinical trials, SEEBRI NEOHALER improved lung function and showed reduced use of rescue medication and improvements in health-related quality of life, as measured by the St. George’s Respiratory Questionnaire (SGRQ) total score, which is a composite of patient-reported symptoms, activities and impact on daily living.

The most common adverse reactions (≥1% and more common than placebo) reported in two 12-week clinical trials with SEEBRI NEOHALER (and placebo) were: upper respiratory tract infection, 3.4% (2.3%); nasopharyngitis, 2.1% (1.9%); urinary tract infection, 1.4% (1.3%); sinusitis, 1.4% (0.7%); oropharyngeal pain, 1.8% (1.2%).

Please see full Prescribing Information for SEEBRI NEOHALER at http://seebri.sunovion.com [5].

SEEBRI NEOHALER® (glycopyrrolate) Inhalation Powder
INDICATION
SEEBRI® NEOHALER® (glycopyrrolate) is a medicine called an anticholinergic. SEEBRI NEOHALER 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

SEEBRI 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.

Do not use SEEBRI NEOHALER unless your health care provider has taught you how to use the inhaler and you understand how to use it correctly. Use SEEBRI NEOHALER exactly as your health care provider tells you to use it.

Do not use SEEBRI NEOHALER more often than it is prescribed for you. Do not stop using SEEBRI NEOHALER 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 SEEBRI NEOHALER if you are allergic to glycopyrrolate or any of the ingredients in SEEBRI 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 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 SEEBRI NEOHALER or any of its ingredients, any other medicines, or food products
- SEEBRI 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. SEEBRI 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).

SEEBRI NEOHALER can cause serious side effects, including:

- sudden shortness of breath (that may be life-threatening) immediately after use of SEEBRI NEOHALER
- 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, eye redness, swelling, eye discomfort, vision changes, eye irritation, or 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 SEEBRI NEOHALER include upper respiratory tract infection, sore throat, and runny nose.

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

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

SEEBRI capsules should always be stored in the blister strip and only removed immediately before use.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov medwatch [6] or call 1-800-FDA-1088.

This information is not comprehensive.

How to get more information:

- Talk to your health care provider
- Visit www.SEEBRI.us [7] to obtain the FDA-approved product labeling
- Call 1-888-394-7377

For additional information, please see full Prescribing Information [8] and Patient Information [9] for SEEBRI NEOHALER, or visit www.SEEBRI.us [10].

About the NEOHALER® Inhaler

The NEOHALER inhaler is a handheld device designed to deliver UTIBRON, SEEBRI and ARCAPTA capsules, which should not be stored or pre-loaded into the inhaler. The NEOHALER inhaler offers a feedback mechanism that allows patients to see whether or not there is any medication left in the capsules, while giving them the flexibility to inhale any remaining dose. 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 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. Patients with 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 Ulbrin® (neohaler® (indacaterol/glycopyrrolate) Inhalation Powder, Brovana® (arformoterol tartrate) Inhalation Solution, Latuda® (lurasidone HCl) and Aipton® (eslicarbazepine acetate).


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., 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 web sites: www.sunovion.com [11], www.sunovion.eu [12] and www.sunovion.ca [13]. Connect with Sunovion on Twitter [14], LinkedIn [15], Facebook [16] and YouTube [17].

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For a copy of this release, visit Sunovion’s web site at www.sunovion.com [19]

References

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Links: