

News Release

Contact: Patrick Gaffey
Executive Director, Corporate Communications
Sunovion Pharmaceuticals Inc.
508-357-7740
patrick.gaffey@sunovion.com

Sunovion Enters into License Agreement for Three Approved Treatment Options for People with COPD in the U.S.

– Agreement includes U.S. rights to Utibron™ Neohaler®, Seebri™ Neohaler® and Arcapta® Neohaler® –

– Expanded portfolio provides treatment options for people with all stages of COPD –

MARLBOROUGH, Mass., December 21, 2016 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) today announced that it has entered into an exclusive license agreement with Novartis for the U.S. commercialization rights to three approved medicines, Utibron™ Neohaler® (indacaterol and glycopyrrolate) inhalation powder (27.5 mcg/15.6 mcg), Seebri™ Neohaler® (glycopyrrolate) inhalation powder (15.6 mcg) and Arcapta® Neohaler® (indacaterol) inhalation powder (75 mcg), which are indicated for the long-term, maintenance treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD). With this transaction, Sunovion now has the broadest COPD portfolio in the U.S., providing handheld and nebulized treatment options for people with all stages of COPD.

Under terms of the agreement, Sunovion has the exclusive rights to market Utibron™ Neohaler®, Seebri™ Neohaler® and Arcapta® Neohaler® in the U.S. Utibron™ Neohaler® and Seebri™ Neohaler® were approved by the U.S. Food and Drug Administration (FDA) in 2015, and Sunovion plans to bring them to market in 2017. Arcapta® Neohaler® was approved in the U.S. in 2011 and made available to people with COPD in 2012. Novartis will continue to manufacture these three medicines under the terms of the agreement. Novartis and its affiliates will continue to retain the commercialization rights for Ultibro® Breezhaler® (indacaterol/glycopyrronium), Seebri® Breezhaler® (glycopyrronium) and Onbrez® Breezhaler® (indacaterol) outside of the U.S.

“Sunovion has a long-standing commitment to advancing respiratory health and to providing new treatment options for people with COPD,” said David Frawley, Executive Vice President and Chief Commercial Officer, Sunovion. “We are pleased to add Utibron™ Neohaler®, Seebri™ Neohaler® and Arcapta® Neohaler® to our respiratory portfolio as these will complement our existing products and allow us to provide a wide range of treatment options for people with COPD.”

Sunovion’s COPD portfolio includes Brovana® (arformoterol tartrate), an FDA approved twice-daily nebulized long-acting beta agonist (LABA), and SUN-101/eFlow® (glycopyrrolate), an investigational

nebulized long-acting muscarinic antagonist (LAMA), for which Sunovion submitted a New Drug Application (NDA) to the FDA in July 2016.

Utibron™ Neohaler®, Seebri™ Neohaler®, and Arcapta® Neohaler® are delivered by the Neohaler®, a handheld dry powder inhaler device.

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 prevent 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 a 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, also known as COPD, includes chronic bronchitis and emphysema, and is a progressive respiratory disease that causes worsening obstruction to airflow in the lungs over time.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.³ COPD develops slowly and the symptoms often worsen over time, potentially limiting the ability to perform routine activities.¹ 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.⁵ Morning symptoms can be associated with limitation of activities during the day, impaired health status and increased risk of exacerbation.⁶ 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.⁷

About Utibron™ Neohaler® (indacaterol and glycopyrrolate) Inhalation Powder

Utibron™ Neohaler® (indacaterol and 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® offers the additive benefits of the LABA indacaterol and the LAMA glycopyrrolate compared to each component alone. Utibron™ Neohaler® also showed clinically meaningful improvements in health-related quality of life and reduced use of rescue medication compared to placebo in the trials. Health status was assessed using the St. George's Respiratory Questionnaire (SGRQ)⁸ total score, which is a composite of 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 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%).

For additional information, please see Utibron™ Neohaler® Full Prescribing Information including **Box Warning** and Medication Guide at <http://utibron.sunovion.com>.

About Seebri™ Neohaler® (glycopyrrolate) Inhalation Powder

Seebri™ Neohaler® (glycopyrrolate) Inhalation Powder is a twice-daily 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 a well-documented safety and efficacy profile. In clinical trials, Seebri™ Neohaler® showed clinically meaningful improvements in health-related quality of life and reduced use of rescue medication compared to placebo. Health status was assessed using the St. George's Respiratory Questionnaire (SGRQ) total score, which is a composite of symptoms, activities and impact on daily living.

The most common adverse reactions ($\geq 1\%$ 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>.

About Arcapta® Neohaler® (indacaterol) Inhalation Powder

Arcapta® Neohaler® (indacaterol) Inhalation Powder is a once-daily long-acting beta agonist (LABA) approved for the long-term, maintenance bronchodilator treatment of airflow obstruction in patients with COPD, and has been available in the U.S. since 2012. The product provides proven efficacy with once daily dosing and 24-hour bronchodilation.

Health-related quality of life was measured using the St. George's Respiratory Questionnaire (SGRQ) in the confirmatory COPD clinical trials. SGRQ is a disease-specific patient reported instrument which measures symptoms, activities, and its impact on daily life. At week 12, pooled data from these trials demonstrated an improvement over placebo in SGRQ total score of -3.8 with a 95% confidence interval (CI) of (-5.3, -2.3) for the ARCAPTA NEOHALER 75 mcg dose.

Most common adverse reactions ($>2\%$ and more common than placebo) associated with Arcapta Neohaler® 75 mcg use in the three month pivotal studies were cough (6.5%), oropharyngeal pain (2.2%), nasopharyngitis (5.3%), headache (5.1%) and nausea (2.4%).

For additional information, please see Arcapta® Neohaler® Full Prescribing Information including **Box Warning** and Medication Guide at <http://arcapta.sunovion.com>.

About Brovana® (arformoterol tartrate) Inhalation Solution

Brovana® (arformoterol tartrate) Inhalation Solution is indicated for the long-term, twice-daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. BROVANA is for use by nebulization only.

Important Safety Information for BROVANA

WARNING: ASTHMA-RELATED DEATH

Long-acting beta₂-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta₂-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including arformoterol, the active ingredient in BROVANA (see WARNINGS). The safety and efficacy of BROVANA in patients with asthma have not been established. All LABA, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS).

BROVANA is not indicated for the treatment of acute episodes of bronchospasm, i.e., rescue therapy, and does not replace fast-acting rescue inhalers. BROVANA should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition.

BROVANA should not be used in conjunction with other inhaled, long-acting beta₂-agonists. BROVANA should not be used with other medications containing long-acting beta₂-agonists. Patients who have been taking inhaled short-acting beta₂-agonists on a regular basis should be instructed to discontinue their regular use and to use them only for symptomatic relief for acute respiratory symptoms.

All LABAs, including BROVANA, are contraindicated in patients with asthma without use of a long-term asthma control medication.

As with other inhaled beta₂-agonists, BROVANA can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, BROVANA should be discontinued immediately and alternative therapy instituted.

BROVANA, like other beta₂-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms.

BROVANA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines.

BROVANA, as with other beta₂-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the corrected QT interval (QTc) because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents.

Overall efficacy of BROVANA was maintained throughout the 12-week trial duration. Some tolerance to the bronchodilator effect of BROVANA was observed after 6 weeks of dosing (at the end of the dosing interval), although the trough forced expiratory volume in 1 second (FEV₁) improvement remained statistically significant. This was not accompanied by other clinical manifestations of tolerance.

The five most common adverse events reported with frequency $\geq 2\%$ in patients taking BROVANA, and occurring more frequently than in patients taking placebo, were pain (8% vs 5%), chest pain (7% vs 6%), back pain (6% vs 2%), diarrhea (6% vs 4%), and sinusitis (5% vs 4%). For more information, please see the full Prescribing Information and Medication Guide for BROVANA.

For additional information, please see the full Prescribing Information and Medication Guide for BROVANA (arformoterol tartrate) Inhalation Solution.

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.

About SUN-101/eFlow[®]

SUN-101 (glycopyrrolate) is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the innovative, proprietary investigational eFlow[®] closed system nebulizer. SUN-101/eFlow[®] is currently in development as a nebulized treatment for patients with moderate-to-very severe chronic obstructive pulmonary disease (COPD). The investigational combined product, consisting of SUN-101 and the eFlow[®] closed system nebulizer which has been optimized for SUN-101 delivery, has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of COPD.

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, the Company 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 Brovana[®] (arformoterol tartrate), Latuda[®] (lurasidone HCl), and most recently 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, and 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 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

UTIBRON is a trademark of Novartis AG

SEEBRI is a trademark of Novartis AG

ARCAPTA is a registered trademark of Novartis AG
NEOHALER is a registered trademark of Novartis AG
ULTIBRO is a registered trademark of Novartis AG
ONBREZ is a registered trademark of Novartis AG
BREEZHALER is a registered trademark of Novartis AG
BROVANA is a registered trademark of Sunovion Pharmaceuticals Inc.
LATUDA is a registered trademark of Sumitomo Dainippon Pharma Co., Ltd.
APTIOM is used under license from BIAL.
eFlow[®] is a registered trademark of PARI GmbH.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.
© 2016 Sunovion Pharmaceuticals Inc.

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

References

¹ GOLD Guidelines 2016. <http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html>. Accessed: April 20, 2016

² National Heart, Lung and Blood Institute. What Is COPD? Available at <http://www.nhlbi.nih.gov/health/health-topics/topics/copd/>. Accessed: March 2, 2016

³ 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/>

⁴ 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

⁵ 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.

⁶ 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.

⁷ 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.

⁸ Utibron[™] Neohaler[®] (indacaterol and glycopyrrolate) inhalation powder. East Hanover, NJ: Novartis Pharmaceuticals Corporation, October 2015.