Availability of UTIBRON™ NEOHALER® (indacaterol/glycopyrrolate) Inhalation Powder in the United States

UTIBRON™ NEOHALER® is the latest combination therapy for people with chronic obstructive pulmonary disease (COPD) that addresses unmet patient and physician needs

Tokyo, Japan – 4 April 2017: Sosei Group Corporation ("Sosei"; TSE Mothers Index:4565) is pleased to confirm that Sunovion Pharmaceuticals Inc. (Marlborough, Mass.,) announced the availability of Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder 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 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).

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Notes to Editors

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.

Glycopyrronium and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei and Vectura.

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 Sosei
Sosei Group Corporation is an international biopharmaceutical company originating from Japan that discovers and develops innovative biopharmaceuticals for the treatment of Alzheimer's disease, schizophrenia, cancer, migraine, addiction, metabolic disease, and other indications. By utilizing its GPCR structure-based drug design platform technology, Sosei have established a product pipeline with first/best in class potential. Through development and commercialization partnerships, Sosei have already delivered two bronchodilators for COPD which generate significant and stable revenue streams that enable further growth. Sosei partners include Novartis, Allergan, AstraZeneca, MedImmune, MorphoSys, Teva, and Pfizer and we are actively looking for new partnerships to enhance the development of our products and help us deliver them to patients worldwide.

For further information about Sosei, please visit http://www.sosei.com/en/.

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References

1. GOLD Guidelines 2017. http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html. Accessed: March 16, 2017.
2. 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/
3. 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
4. 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.
5. 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.
6. 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.

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Sosei Group Corporate Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development and commercialisation of products. Various risks may cause Sosei's actual results to differ materially from those expressed or implied by the forward-looking statements, including: adverse results in clinical development programmes; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialise products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialisation activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.