New findings confirm Ultibro® Breezhaler® is consistently more effective than Seretide® in reducing COPD flare-ups across different patient groups

- Ultibro® Breezhaler® reduced the rate of all COPD exacerbations across different patient sub-groups vs Seretide in new results from the FLAME study

- Ultibro Breezhaler also lowered patients’ need for rescue medication and had an improved benefit-risk profile compared to Seretide, with less evidence of systemic effects

- Sub-group analyses of FLAME and a large-scale study showing inhaled corticosteroid use and pneumonia risk interrelationship to be shared at ERS 2016

Tokyo, Japan – 5 September 2016: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms the announcement by Novartis that new analyses from the head-to-head FLAME study confirmed that Ultibro® Breezhaler® is a more effective option for patients at risk of chronic obstructive pulmonary disease (COPD) flare-ups (exacerbations) than Seretide®, across different patient sub-groups. These findings will be presented to the scientific community at the 2016 European Respiratory Society (ERS) International Congress, September 3-7, 2016 in London, UK.

In the new analyses, once-daily Ultibro Breezhaler (indacaterol/glycopyrronium bromide) 110/50 mcg demonstrated consistent reductions in the rate of all exacerbations (mild, moderate and severe), regardless of age, smoking status, exacerbation history, disease severity and previous inhaled corticosteroid (ICS) use, versus twice-daily Seretide (salmeterol/fluticasone [SFC]) 50/500 mcg. Specifically, among patients with the severest forms of COPD, Ultibro Breezhaler significantly reduced the rate of exacerbations and improved their health status versus the commonly used inhaled corticosteroid (ICS)/LABA combination. Furthermore, patients using Ultibro Breezhaler needed less rescue medication during the day.

Data to be presented at ERS 2016 also showed that, compared to Seretide, Ultibro Breezhaler was associated with fewer systemic effects, namely impairment of adrenal function, which regulates the natural production of hormones. Ultibro Breezhaler use has previously shown to be associated with significantly fewer cases of pneumonia than the ICS/LABA combination.

Adding weight to the need to reduce inappropriate use of ICS therapy, results of a large observational study involving >87,000 participants (with and without COPD) from Sweden will also be shared at ERS 2016. The ARCTIC study found that COPD patients were at higher risk of pneumonia than those without the disease, but that this risk was more acute for those taking an ICS (whether at a low or high dose). In fact, even people without COPD that took an ICS increased their risk of pneumonia, further demonstrating their interrelationship.

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* GOLD Group D
† a long-acting beta2-adrenergic agonist
Novartis is presenting over 35 abstracts from across its broad respiratory portfolio at ERS 2016. The company is committed to continual clinical and patient-led research to address the evolving unmet needs of people living with respiratory diseases.

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**About FLAME**

FLAME is a randomized, double-blind, double-dummy, parallel-group, non-inferiority, active-controlled 52-week study involving 3,362 COPD patients and conducted at 356 sites across 43 countries.

Results published in the New England Journal of Medicine confirmed that Ultibro Breezhaler 110/50 mcg met its primary endpoint (non-inferiority) and furthermore demonstrated superiority to Seretide 50/500 mcg on the rate of all COPD exacerbations (mild/moderate/severe) over one year of treatment in COPD patients with a history of at least one exacerbation in the previous year. Against further secondary endpoints, Ultibro Breezhaler was also superior compared to SFC in reducing or improving the following:

- Rate and time to first moderate or severe COPD exacerbation
- Time to first COPD exacerbation (mild/moderate/severe)
- Time to first severe COPD exacerbation
- Lung function (trough FEV1)
- Health-related quality of life (St. George’s Respiratory Questionnaire)

FLAME is part of the IGNITE Phase III clinical trial program exploring Ultibro Breezhaler for the treatment of COPD.

**About Ultibro Breezhaler**

Ultibro Breezhaler 110/50 mcg is a once-daily LABA/LAMA dual bronchodilator approved in the European Union (EU) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. Clinical trials have shown that it offers statistically significant improvements in bronchodilation compared to treatments widely used as current standards of care, including SFC 50/500 mcg and open-label tiotropium (18 mcg). Ultibro Breezhaler is currently approved for use in over 90 countries worldwide, including countries within the EU and Latin America, Japan, Canada, Switzerland and Australia.

Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura.

Ultibro® and Breezhaler® are registered trademarks of Novartis AG.

**About COPD**

Chronic obstructive pulmonary disease (COPD) affects an estimated 210 million people worldwide and is the third leading cause of death. It is progressive (usually gets worse over time), and can be a life-threatening disease. COPD makes it difficult to breathe, with symptoms that have a destructive impact on patients’ function (i.e. activity limitation, decreased mobility) and quality of life.
Exacerbations (disease flare-ups) are a sudden worsening of COPD symptoms that can be "frightening" for patients, causing distress, anxiety and the deterioration of quality of life. COPD exacerbations are also associated with significant healthcare resource burden and costs, particularly due to the frequent need for hospitalization. Consequently, the prevention of exacerbations is an important goal in COPD management to improve long-term health status and conserve healthcare resources.

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 platform technologies - GPCR structure-based drug design platform technology, peptide platform technologies and nanotechnology - Sosei have established a product pipeline with first/best in class potential.

Through development and commercialization partnerships Sosei have already delivered three medicines to the market (two COPD bronchodilators and an emergency contraceptive), which generate significant and stable revenue streams that enable further growth. Sosei partners include Novartis, Pfizer, Allergan, AstraZeneca, MedImmune, MorphoSys, Teva 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 www.sosei.com/en.

References

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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.