New data showed Ultibro® Breezhaler® significantly improved COPD patients’ lung function after direct switch from Seretide®

- New data showed switching moderate-to-severe, symptomatic COPD patients to Ultibro® Breezhaler® from Seretide® improved lung function and was well tolerated.

- The FLASH study is the first randomized controlled trial to investigate the direct switch of patients to the dual bronchodilator Ultibro® Breezhaler from the steroid-containing Seretide®.

- Data presented at the Asian Pacific Society of Respirology (APSR) Congress in Sydney, Australia.

Tokyo, Japan – 27 November, 2017: Sosei Group Corporation (“Sosei”; TSE: 4565) has confirmed the announcement by Novartis of positive results from the FLASH* study examining the safety and efficacy of directly switching moderate-to-severe symptomatic and non-frequently exacerbating† chronic obstructive pulmonary disease (COPD) patients to Ultibro® Breezhaler® (indacaterol/glycopyrronium) 110/50 mcg from Seretide® (salmeterol/fluticasone) 50/500 mcg. The study met the primary endpoint demonstrating that switching patients to Ultibro® Breezhaler® resulted in significantly improved lung function (trough FEV1)†.

The FLASH study is the first randomized controlled trial to confirm the benefits of directly switching patients to Ultibro® Breezhaler®† from this widely-used steroid-containing therapy, therefore avoiding the side effects of the long-term use of inhaled corticosteroids. Critically, patients were switched without a wash-out period‡ to mimic clinical practice†. The superiority of once-daily Ultibro® Breezhaler® over twice-daily salmeterol/fluticasone in improving lung function²-³ and reducing the rate of COPD exacerbations⁴ has been established in previous studies.

The results of the FLASH study further reinforce the latest GOLD recommendations, which support the use of dual bronchodilation for the majority of symptomatic COPD patients and limit the use of steroid-containing therapies to specific patient types⁵.

Importantly, the data released today also indicated that the safety and tolerability profiles of the two treatments were similar.

The FLASH study results were presented at the Asian Pacific Society of Respirology (APSR) Congress in Sydney, Australia (23-26 November 2017).

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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 has established a product pipeline with first/best in class potential. Through development and commercialization partnerships, Sosei has already delivered two bronchodilators for COPD, which generate significant and stable revenue streams that enable further growth. Sosei partners include Novartis, Allergan, AstraZeneca, Daiichi Sankyo, 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 www.sosei.com/en.

About the FLASH study
The FLASH study is a randomized, multicenter, double-blind, double-dummy, parallel-group, 12-week treatment trial. It involved a total of 502 moderate-to-severe, symptomatic and non-frequently exacerbating† patients with COPD†.

The primary objective of the study was to demonstrate the superiority of once-daily Ultibro® Breezhaler® 110/50 mcg compared with twice-daily salmeterol/fluticasone (50/500 mcg) in terms of improving lung function (trough pre-dose FEV1 at Week 12)†.

Secondary objectives of the study were to investigate the effect of Ultibro Breezhaler compared with salmeterol/fluticasone on†:
- Transition Dyspnea Index (TDI) focal score at Week 12
- Trough pre-dose forced expiratory vital capacity (FVC) at Week 12
- COPD symptoms at Week 12 as measured by the COPD Assessment Test (CAT)
- Mean rescue medication use (puffs/day) and percentage of days without rescue medication use over 12 weeks

The study also assessed the safety and tolerability over 12 weeks (including adverse events, serious adverse events and COPD exacerbations)†.

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 salmeterol/fluticasone 50/500 mcg and open-label tiotropium (18 mcg)⁸-¹⁰. 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.
About the Novartis COPD portfolio
Novartis is committed to addressing the unmet medical needs of COPD patients and improving their quality of life by providing innovative medicines and devices. The Novartis COPD portfolio includes Ultibro® Breezhaler® (indacaterol/glycopyrronium bromide) and Seebri® Breezhaler® (glycopyrronium bromide), which are both indicated as maintenance treatments for COPD patients.

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

Novartis continues development of respiratory products for delivery via the low resistance Breezhaler inhalation device, which makes it suitable for patients with different severities of airflow limitation. The Breezhaler device allows patients to hear, feel and see that they have taken the full dose correctly.

Seebri®, 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 fourth 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.

References
8. Vogelmeier C, et al. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes versus placebo, indacaterol, glycopyrronium, tiotropium and salmeterol/fluticasone in patients with COPD. [ATS abstract 40759; Session C45; Date: May 21, 2013 Time: 8:15 -10:45].
9. Vogelmeier C, et al. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes. [ERS 2013 abstract 851178; Session 82; Date: September 8, 2013 Time: 12:50-14:40].
10. Banerji D, et al. Dual bronchodilation with once-daily QVA149 improves dyspnea and health status and reduces symptoms and rescue medication use in patients with COPD: the IGNITE trials. [ERS 2013 abstract 851388; Session 346; Date: September 10, 2013 Time: 8:30-10:30].

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Forward-looking statements
This press release may contain 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.