Ultibro® Breezhaler® improved lung function and COPD symptoms after direct switch from previous treatment

- Ultibro® Breezhaler® improved lung function and breathlessness after direct switch from long-acting bronchodilators or steroid-containing combination therapies

- Results further support the 2017 GOLD recommendations that dual bronchodilation should be the foundation treatment for the majority of symptomatic COPD patients

- Data from the pragmatic CRYSTAL study showcased for the first time at the 2016 British Thoracic Society Winter Meeting in London, UK

Tokyo, Japan – 9 December 2016: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms the announcement by Novartis of positive results from the first large-scale study exploring the effects of directly switching symptomatic, non-frequently-exacerbating patients with moderate COPD from their current treatments, including steroid-containing combinations and long-acting bronchodilators, to the dual bronchodilator Ultibro® Breezhaler® (indacaterol/glycopyrronium) 110/50 mcg.

In the CRYSTAL study, patients with moderate COPD who were switched to Ultibro Breezhaler from their previous therapy (LABA+ICS or LABA or LAMA†) experienced superior improvements in lung function (trough FEV1) and breathlessnessǂ at week 12 (p<0.0001). Significantly, CRYSTAL is the first LABA/LAMA pragmatic trial, designed to mimic clinical practice, so treatment switching occurred without a washout period1.

Ultibro Breezhaler was also well tolerated in the CRYSTAL study1.

About CRYSTAL
CRYSTAL was a prospective, multicenter, 12-week, randomized, pragmatic, open-label trial. Patients were recruited into four groups according to previous medication and symptoms, and randomized to a direct switch to Seebri® Breezhaler® (glycopyrronium) 50 mcg or Ultibro® Breezhaler® (indacaterol/glycopyrronium)110/50 mcg once daily vs. continuation of previous treatment. The study enrolled a total of 4,389 symptomatic, non-frequently-exacerbating (up to one exacerbation in the previous year) patients with moderate COPD and 2,159 patients received Ultibro Breezhaler or continued their baseline therapy. The Seebri Breezhaler treatment arms of the study were underpowered due to sample size.

Co-primary objectives of the study were:
- Superiority of Ultibro Breezhaler vs. LABA, LAMA and LABA+ICS in terms of improvement of lung function (trough FEV1) and breathlessness (transition dyspnoea index) at week 12.
- Superiority of Seebri Breezhaler vs. previous SABA and/or SAMA§ treatment in terms of improvement of lung function (trough FEV1) and breathlessness (transition dyspnoea index) at week 12
• Non-inferiority of Seebri Breezhaler vs. previous LABA or LAMA treatment in terms of improvement of lung function (trough FEV1) and breathlessness (transition dyspnoea index) at week 12.

About Ultibro Breezhaler
Ultibro Breezhaler (indacaterol/glycopyrronium) 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 also currently the only steroid-free treatment to offer prescribers clinically proven superiority over the most prescribed ICS/LABA combination** in preventing COPD exacerbations. 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 Seebri Breezhaler
Seebri Breezhaler (glycopyrronium) 50 mcg is a once-daily LAMA bronchodilator approved in the European Union (EU) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. Seebri Breezhaler is approved for use in over 90 countries, including countries within the EU and Latin America, Japan, Canada, Switzerland and Australia.

Glycopyrronium 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.

Ultibro®, Seebri® 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.

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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Notes
1 Long-acting beta2-adrenergic agonist + inhaled corticosteroid (free or fixed-dose combinations)
† Long-acting muscarinic antagonist
§ Transition dyspnea index (TDI)
** Seretide® Accuhaler® (salmeterol/fluticasone) 50 microgram /500 microgram /dose inhalation powder. Seretide and Accuhaler are registered trademarks of the GlaxoSmithKline group of companies

References
3. 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].
4. 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].
5. 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 851368; Session 346; Date: September 10, 2013 Time: 8:30-10:30].
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.