Major report recommends broad use of dual bronchodilators to treat COPD

- *2017 GOLD report recommends the first-line use of dual bronchodilators, such as Ultibro® Breezhaler®, in the treatment of the majority of symptomatic COPD patients*

- *Bronchodilation regarded as the foundation treatment for COPD patients prior to the use of inhaled steroid-containing therapies, as supported by Novartis' FLAME study evidence*

- *Today's recommendations expected to translate to health care professionals moving away from the historical reliance on inhaled corticosteroid combinations for the treatment of COPD*

Tokyo, Japan –22 November 2016: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) confirms the announcement by Novartis welcoming the publication of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017 report. For the first time, GOLD has recommended the first-line use of dual bronchodilators, such as Ultibro® Breezhaler® (indacaterol/glycopyrronium) 110/50 mcg, in the treatment of the majority of symptomatic chronic obstructive pulmonary disease (COPD) patients, regardless of their exacerbation risk[1].

The GOLD 2017 report is a tool to help health care professionals worldwide implement effective COPD management programs. Significantly, the use of inhaled steroid-containing combination therapies is now only recommended in a minority of patients (those with a history of two or more exacerbations in the previous year, or one hospitalization), following dual bronchodilator (LABA/LAMA*) treatment[1].

Today's new recommendations may translate to health care professionals moving away from the historical reliance on inhaled corticosteroid (ICS)/LABA combinations as first line therapy for the prevention of exacerbations[1]. The GOLD 2017 report clearly identifies the elevated risk of adverse effects (including pneumonia) when using these treatments and references evidence showing no significant harm from withdrawing this medication in many patients when used as part of a triple regimen[1].

Ultibro Breezhaler is currently the only steroid-free treatment to offer prescribers clinically proven superiority over the most prescribed ICS/LABA combination** in preventing COPD exacerbations[2]. The head-to-head FLAME study[2] was considered significant enough to be included as a reference for the first-line use of dual bronchodilators in symptomatic patients with high exacerbation risk.

About GOLD
The Global Initiative for Chronic Obstructive Lung Disease (GOLD) is an independent organization that was launched in 1997. It collaborates with health care professionals

and public health officials worldwide to raise awareness of COPD and improve disease prevention and treatment[3].

Through the development of evidence-based strategy documents for COPD management, GOLD works to improve the lives of people with COPD in every corner of the globe[1].

About Ultibro Breezhaler
Ultibro Breezhaler (indacaterol/glycopyrronium bromide) 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 COPD4. 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 [5-7] 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 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[8]. The Breezhaler device allows patients to hear, feel and see that they have taken the full dose correctly [4,8].

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

About COPD
Chronic obstructive pulmonary disease (COPD) affects an estimated 210 million people worldwide[9] and is the third leading cause of death[10]. It is progressive (usually gets worse over time), and can be a life-threatening disease [1,9]. 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[1,9].

About Sosei
Sosei Group Corporation is an international biopharmaceutical company originating from Japan that discovers and develops innovative biopharmaceuticals for the treatment of Atlhzeimer's disease, schizophrenia, cancer, migraine, addiction, metabolic disease and other indications. By utilizing its platform technologies-GPCR structure-based drug design technology platform, peptide platform technologies and nanotechnology-Sosei has established a product pipeline with first/best in class potential.

Through development and commercialization partnerships, Sosei has already delivered 3 medicines to the market (two COPD bronchodilators and an emergency contraceptive), which generate significant and stable revenue stream that enable further growth. Sosei partners include Novartis, Pfizer, Allergan, AstraZeneca, MedImmune, MorphoSys, Teva and we are actively looking for new partners 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.

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Notes

* Long-acting beta2-adrenergic agonist/Long-acting muscarinic antagonist
** Seretide® Accuhaler® (salmeterol/fluticasone) 50 microgram /500 microgram /dose inhalation powder. Seretide and Accuhaler are registered trademarks of the GlaxoSmithKline group of companies

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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.