FLAME Study Shows Superiority of Ultibro® Breezhaler® over Seretide® in Reducing COPD Exacerbations

- *Ultibro® Breezhaler® met primary endpoint and demonstrated superiority to Seretide® in reducing COPD exacerbations during 52 weeks of treatment*

- *First large-scale study to confirm Ultibro Breezhaler is an effective steroid-free option that both reduces exacerbations and improves lung function in COPD patients with one or more exacerbations in the past year, compared to Seretide*

- *Full FLAME study results to be shared in 2016*

Tokyo, Japan – 17 November 2015: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) confirms the information released today by Novartis on the positive first results from the Phase III FLAME head-to-head trial examining the rate of chronic obstructive pulmonary disease (COPD) exacerbations. Once-daily Ultibro® Breezhaler® (indacaterol/glycopyrronium) 110/50 mcg met its primary endpoint (non-inferiority) and furthermore demonstrated superiority to twice-daily Seretide® (salmeterol/fluticasone) 50/500 mcg in reducing the rate of all COPD exacerbations (mild/moderate/severe) over one year of treatment.

This finding is consistent with the earlier LANTERN trial and is now expanded to patients with at least one exacerbation in the previous year. The safety profiles of the two treatments were consistent with their known profiles, according to the initial FLAME results.

The full FLAME study results, including data from further secondary endpoints, will be reported at an appropriate scientific forum in due course.

About FLAME

FLAME was a randomized, double-blind, parallel-group, non-inferiority, active-controlled 52-week study involving 3,362 COPD patients and conducted at 356 sites across 43 countries[1]. The primary objective of the study was to demonstrate that Ultibro Breezhaler 110/50 mcg is non-inferior to salmeterol/fluticasone 50/500 mcg (SFC) in terms of rate of all COPD exacerbations (mild/moderate/severe) during 52 weeks of treatment[1].

Secondary endpoints for the study comparing Ultibro Breezhaler to SFC included superiority in terms of rate of all COPD exacerbations over the study duration and efficacy in terms of the following: time to first COPD exacerbation (mild/moderate/severe); rate and time to first moderate-to-severe COPD exacerbation; lung function (trough FEV_1); health-related quality of life (as measured by the shortened version of the St George's Respiratory Questionnaire [SGRQ-C]); rescue medication use and safety[1].

FLAME is the last of 11 studies in 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 [1] /LAMA [2] dual bronchodilator approved in the European Union (EU) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD[2]. 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[3-5] and open-label tiotropium (18 mcg). Ultibro Breezhaler is currently approved for use in over 70 countries worldwide, including countries within the EU and Latin America, Japan, Canada, Switzerland and Australia.

About COPD

COPD affects an estimated 210 million people worldwide[6] and is the third leading cause of death[7]. It is progressive (usually gets worse over time), and can be a life-threatening disease[8,9]. 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[8,9]. It is often considered to be a disease of later years but estimates suggest that 50% of those with COPD are now less than 65 years old, resulting in increases in absenteeism, premature retirement and reductions in workforce participation[10,11].

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[1] *a long-acting beta$_2$-adrenergic agonist*

[2] *a long-acting muscarinic antagonist*

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, AstraZeneca, MedImmune, Cubist, MorphoSys, Takeda 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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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.