New analyses of FLAME study data reinforce the potential of Ultibro® Breezhaler® for COPD patients historically treated with steroids

- *New analyses from the FLAME study suggest dual bronchodilator Ultibro® Breezhaler® provides similar or better efficacy versus steroid-containing therapies, regardless of blood eosinophil (a type of white blood cell) counts*

- *Data was published in the centenary issue of the American Thoracic Society's 'American Journal of Respiratory and Critical Care Medicine'*

- *Together with the International Primary Care Respiratory Group, Novartis is launching physician guidance to support a deeper evaluation of inhaled steroid use in COPD patients*

Tokyo, Japan –24 May, 2017: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) has confirmed the announcement by Novartis that further analyses of the head-to-head FLAME study suggest that inhaled corticosteroids (ICS) may not be needed in some chronic obstructive pulmonary disease (COPD) patients with high blood eosinophil (a type of white blood cell) counts. The new data showed that Ultibro® Breezhaler® consistently provided superior or similar benefits over Seretide®* in COPD patients regardless of the eosinophil count[1]. These results contrast with data suggesting better clinical outcomes with ICS therapies for patients with high eosinophil counts[2-5]. The data was published in the centenary issue of the American Thoracic Society's 'Blue Journal'**[1] and solidifies the need for individualized risk-benefit assessments when considering ICS treatments.

The potential for high blood eosinophil counts to be considered as a biomarker to direct the use of a LABA***/ICS combination over dual bronchodilation (LABA/LAMA****) in some patients, has been referenced in the 2017 GOLD (Global Initiative for Chronic Obstructive Lung Disease) report[6]. FLAME was the first trial to prospectively study the influence of blood eosinophils on the efficacy of ICS-containing therapies versus a LABA/LAMA. The new analyses showed that once-daily Ultibro Breezhaler (indacaterol/glycopyrronium) 110/50 mcg was superior to twice-daily Seretide (salmeterol/fluticasone [SFC]) 50/500 mcg in reducing exacerbations (flare-ups), independent of a blood eosinophil count above or below 2%[1]. In addition, at no cut-off was Seretide more effective than Ultibro Breezhaler[1].

With funding support from Novartis, the International Primary Care Respiratory Group (IPCRG) is addressing the appropriate use and safe withdrawal of ICS in COPD patients with the launch of a primary care physician guide. The guide was launched at the recent IPCRG conference in Slovenia and aims to ensure the latest evidence based treatment guidance from the 2017 GOLD report is translated into daily clinical practice. The guide is accessible on the IPCRG website here: https://goo.gl/FlSVck

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Note to edit

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[7].

Results published in the New England Journal of Medicine[7] confirmed that Ultibro Breezhaler (indacaterol/glycopyrronium) 110/50 mcg met its primary endpoint (non-inferiority) and furthermore demonstrated superiority to Seretide (salmeterol/fluticasone [SFC]) 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[7]:

- 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)

The pre-specified analyses of data from the FLAME study compared treatment efficacy according to blood eosinophil percentage (<2% and ≥2%, <3% and ≥3%, and <5% and ≥5%) and absolute blood eosinophil count (≤150 cells/µl, 150 to <300 cells/µl, and ≥300cells/µl)[1].

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

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[8]. The Breezhaler device allows patients to hear, feel and see that they have taken the full dose correctly[8,9].

Seebri®, Ultibro® and Breezhaler® are registered trademarks of Novartis AG

About COPD

Chronic obstructive pulmonary disease (COPD) affects an estimated 210 million people worldwide[10] and is the third leading cause of death[11]. It is progressive (usually gets worse over time) and can be a life-threatening disease[10,12]. 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[10,12].

Exacerbations are a sudden worsening of COPD symptoms that can be frightening for patients, causing distress, anxiety and quality of life deterioration[13]. COPD exacerbations are also associated with significant healthcare resource burden and costs[14], 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[15].

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.

Notes

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

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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.