Phase III data show NVA237 significantly improves lung function with good safety profile in COPD patients

- *Data from the Novartis Pivotal GLOW1 study show once-daily NVA237 met its primary endpoint, demonstrating superior bronchodilation (trough FEV_1) relative to placebo ($p<0.001$) at 12 weeks*

- *NVA237 significantly improved lung function while demonstrating a good safety profile in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD)*

- *Detailed results to be presented at a scientific congress in H2 2011*

Tokyo, Japan – 19 April 2011: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) announces that NVA237, a long-acting muscarinic antagonist (LAMA) being investigated as a once daily treatment for chronic obstructive pulmonary disease (COPD), achieved its primary end point in a Phase III study. As part of its first quarter earnings release today, Novartis confirmed results from the first Phase III clinical trial with once-daily NVA237 (glycopyrronium bromide) show that it significantly improved lung function while demonstrating a good safety profile in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD).

The pivotal double-blind 26-week GLOW1 study met its primary endpoint by demonstrating superior bronchodilation to placebo at 12 weeks measured by trough FEV_1 (i.e. forced expiratory volume in one second), a standard measure of lung function ($p<0.001$).

The incidence of adverse events was similar in the NVA237 treated patients and in those receiving placebo. Detailed data will be presented at a scientific congress in H2 2011.

Mr Shinichi Tamura, CEO of Sosei, said:

"We are very encouraged that results from the initial pivotal GLOW1 trial, showing significantly increased lung function with a positive safety profile, have provided further confirmation of the clinical potential of NVA237 as a novel once-daily LAMA therapy for COPD patients."

NVA237 was licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura. Novartis intends to launch NVA237 in 2012 as a once-daily monotherapy for COPD. The first launch for QVA149; the combination of NVA237 with Novartis' once-daily, long-acting beta2-agonist (LABA), indacaterol, is planned for 2013. Indacaterol is now approved in more than 50 countries and available in more than 20, with US approval dependent on an FDA decision expected in July 2011.

– Ends

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Notes for Editors:

About COPD

COPD is a chronic obstruction of the airways which affects 210 million people worldwide[1] and is projected to be the third leading cause of death by 2020[2]. It is a progressive lung disease with symptoms including chronic bronchitis and/or emphysema, which slowly progresses and eventually leads to a largely

irreversible loss of lung function. While there is no cure, bronchodilators such as LAMAs and LABAs make breathing easier by enlarging the patient's airways, and are recognised in international guidelines as an integral part of the treatment for COPD.

About Sosei

Sosei is an international biopharmaceutical company anchored in Japan with a global reach. It practises a reduced risk business model by acquiring compounds from, and bringing compounds into, Japan through exploitation of its unique position within global markets.
For further information about Sosei, please visit www.sosei.com.

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.

References:

1. WHO. Factsheet No 315: Chronic obstructive pulmonary disease (COPD), Available at: www.who.int/mediacentre/factsheets/fs315/en/index.html.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2009. Available at: http://www.goldcopd.com/Guidelineitem.asp?l1=2&l2=1&intId=2003.