Phase III study shows once-daily NVA237 is superior to placebo and similar to tiotropium in improving lung function in COPD

- *GLOW2 study shows NVA237 provides superior 24-hour bronchodilation to placebo ($p < 0.001$) with comparable efficacy to open-label tiotropium at 12 weeks*

- *NVA237 shown to be well-tolerated in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD)*

- *Phase III data support first regulatory submission by Novartis for NVA237 by end of 2011*

Tokyo, Japan – 30 June 2011: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565), announces that results reported today by Novartis from the pivotal Phase III GLOW2 clinical trial show that once-daily NVA237 (glycopyrronium bromide) 50 mcg significantly improved lung function in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) relative to placebo ($p < 0.001$), with similar efficacy to open-label tiotropium.

Further efficacy and safety results from GLOW2 will be presented at a scientific congress in 2012, and the data will be used to support an application for regulatory approval to be filed before the end of 2011.

Mr Shinichi Tamura, CEO of Sosei, said: *"GLOW2 is the second NVA237 Phase III study to meet its primary end point and further endorses the benefit of NVA237 in COPD patients. We look forward to Novartis filing the product in 2011, followed by the filing of QVA149, the fixed-dose combination of NVA237 and indacaterol, expected to occur in 2012."*

In an exploratory arm of the study, NVA237 was compared with open-label tiotropium (Spiriva® HandiHaler®*) 18 mcg, another once-daily long-acting muscarinic antagonist (LAMA) indicated for the treatment of COPD. Results show that NVA237 produced similar improvements in lung function to tiotropium.

The study met its primary endpoint by demonstrating superior 24-hour 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[1]. NVA237 was delivered using the Concept1® device, a single-dose dry-powder inhaler.

Key secondary endpoints were improvement in breathlessness assessed using the Transition Dyspnea Index (TDI) at 26 weeks, and improved quality of life as measured by the St George's Respiratory Questionnaire (SGRQ) at 52 weeks. Important secondary endpoints were time to first COPD exacerbation and use of rescue medication during 52 weeks of treatment. The study met all of these endpoints.

The GLOW2 study also showed that NVA237 was well-tolerated with a similar incidence of adverse events for patients treated with NVA237, placebo and open-label tiotropium.

GLOW2 was a 52-week double-blind, placebo-controlled, parallel-group study involving 1,066 patients to assess the efficacy, safety and tolerability of NVA237 in patients with COPD. Patients were randomized into three treatment arms receiving either once-daily NVA237 50 mcg, placebo, or once-daily open-label tiotropium 18 mcg. They were also permitted to use COPD background therapy and rescue medication.

In April 2011 Novartis announced results from the first Phase III clinical trial with NVA237. The pivotal double-blind 26-week GLOW1 study met its primary endpoint by demonstrating superior bronchodilation to placebo at 12 weeks measured by trough FEV1 ($p<0.001$). The incidence of adverse events was similar in NVA237-treated patients and in those receiving placebo. Further data

* Spiriva® and HandiHaler® are registered trademarks of Boehringer Ingelheim Pharma GmbH & Co. KG.

from GLOW1 will be presented at the European Respiratory Society congress in Amsterdam in September 2011.

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.

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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:

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