NVA237 filed in Europe and positive Phase III data at European Respiratory Society Congress

- *NVA237 has been filed for marketing authorisation by Novartis with the European Medicines Agency (EMA) under the brand-name Seebri® Breezhaler®, triggering a $5m milestone payment to Sosei*
- *Studies show investigational once-daily NVA237 provides superior 24-hour bronchodilation and increases exercise endurance relative to placebo*
- *Additional data show NVA237 significantly prolonged time to first moderate/ severe COPD exacerbation and reduced associated hospitalizations compared to placebo*

Tokyo, Japan – 27 September 2011: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565), today announces that NVA237 (glycopyrronium bromide), a long-acting muscarinic antagonist (LAMA) being investigated as a once-daily treatment for chronic obstructive pulmonary disease (COPD), has been filed by Novartis for marketing authorisation with the European Medicines Agency (EMA), under the brand-name Seebri® Breezhaler®, triggering a $5m milestone payment to Sosei.

In addition, Novartis has presented new NVA237 Phase III data at the European Respiratory Society (ERS) congress. The GLOW1 and GLOW3 studies in chronic obstructive pulmonary disease (COPD) patients show that NVA237 (glycopyrronium bromide) significantly increased patients' lung function compared to placebo with a fast onset of action at first dose, as well as improving exercise endurance. NVA237 is a new drug in the long-acting anti-muscarinic (LAMA) class.

The GLOW1 study met its primary endpoint by showing that NVA237 50 mcg once-daily produced a significant improvement in lung function of 108 mL in trough FEV_1 (forced expiratory volume of breath in one second) after 12 weeks in patients with moderate-to-severe COPD compared to placebo ($p<0.001$). Moreover, NVA237 had a rapid onset of action, with a 93 mL improvement in

FEV_1 compared to placebo at five minutes post-dose following the first dose on the first day of treatment ($p<0.001$).

NVA237 also significantly prolonged the time to first moderate/severe COPD exacerbation compared to placebo, and reduced the percentage of associated hospitalizations. Significant improvement in breathlessness was seen at 26 weeks compared to placebo, accompanied by a significant improvement in health-related quality of life and reduction in the use of rescue medication.

The GLOW3 study investigated the effects of NVA237 50 mcg once-daily on exercise endurance in moderate-to-severe COPD patients. The study met its primary endpoint by showing a significant 21% improvement in exercise endurance versus placebo at the end of the study (i.e. day 21), with a significant 10% increase from day one (both $p<0.001$).

Both studies showed that NVA237 was well-tolerated, with a similar incidence of adverse events for patients treated with NVA237 and placebo.

Mr Shinichi Tamura, CEO of Sosei, said: *"The filing of this product originating from Sosei and Vectura is an important milestone for us and is further endorsement of our capabilities. The NVA237 Phase III data at ERS illustrate the potential benefits of NVA237 for patients with COPD; a multi-billion dollar market that is still growing. Novartis has a rich portfolio of once-daily inhaled therapies to help COPD patients and has stated that it expects to file QVA149, the fixed-dose combination of NVA237 and their once-daily LABA, indacaterol, in 2012. The combination of two bronchodilators with complementary modes of action is designed to give COPD patients access to two leading classes of therapy in a single inhaler for the first time."*

– Ends –

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Notes for Editors:

About the NVA237 Licence Agreement with Novartis

NVA237 was licensed to Novartis in April 2005 by Sosei and its co-development partner, Vectura. Novartis has stated that it intends to launch NVA237 in 2012 as a once-daily monotherapy for COPD and as a fixed-dose combination with indacaterol, its once-daily, long-acting beta-agonist (LABA), known as QVA149, in 2013. Sosei believes that it could be the first once-daily LAMA/LABA combination to come to market for COPD. The dual activity of a muscarinic antagonist and a beta-adrenergic agonist promises to be a potent bronchodilator and, with convenient once-daily dosing as a fixed-dose combination, has the potential to improve compliance and address a large and unmet need for COPD sufferers.

Novartis received European regulatory approval for Onbrez® Breezhaler® in November 2009. In July 2011, Novartis announced approval of the 75 mcg once-daily dose in the US under the brand name Arcapta™ Neohaler™, and of the 150 mcg once-daily dose in Japan under the brand name Onbrez® Inhalation Capsules.

To date, Sosei has received $30m from Novartis and, under the terms of the licence, could receive up to an additional $157.5m for achievement of regulatory and commercialisation targets for both the monotherapy and the combination product. In addition, royalties on product sales will be received in the event of successful product launches.

About COPD

COPD is a progressive, life-threatening disease associated with tobacco smoking, air pollution or occupational exposure, which causes obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. COPD affects 210 million people worldwide and is projected to be the third leading cause of death by 2020. Although often considered a disease of the elderly, research has shown that a majority of COPD patients are under the age of 65 when they are likely to be at the peak of their earning power and family responsibilities.

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.