



Sosei Announce Start of Phase III Clinical Study with QVA149

- Study Triggers \$7.5m Milestone Payment -

Tokyo, Japan – 10 May 2010 Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) announce the commencement of the Phase III clinical programme by Novartis, with QVA149, a once-daily, dry powder bronchodilator for inhalation combining a fixed dose of the once-daily beta2-agonist QAB149 (indacaterol) and the long-acting muscarinic antagonist NVA237 (glycopyrronium bromide) for the treatment of chronic obstructive pulmonary disease (COPD). The start of Phase III triggers a \$7.5m milestone payment to Sosei.

The programme commences with two 52 week studies. The first trial, a randomised, double-blind, parallel-group design, will assess as its primary outcome measure the superiority of QVA149 over NVA237 alone in the rate of exacerbations in 1,998 patients with severe or very severe COPD (GOLD stages III or IV) from study centres across the USA, Europe and other territories. Secondary endpoints include time to first exacerbation together with safety and tolerability. The second trial has a randomised, double-blind, parallel-group, placebo controlled design and will assess the long term safety and tolerability of QVA149 in 339 patients with moderate to severe COPD. FEV₁ (forced expiratory volume in one second) is a secondary outcome measure. In both trials patients will be randomised to receive a once-daily dose of either the combination product or the comparator from a single dose dry powder inhaler for a 52-week period.

NVA237 was licensed to Novartis by Sosei and its co-development partner Vectura Group plc in a 2005 deal in which the two companies could receive up to US\$375 million in milestones as well as royalties on product sales. Phase III trials on NVA237 commenced in June 2009 and Novartis has stated that it expects to file for approval in 2011. Novartis received European regulatory approval for indacaterol (Onbrez[®] Breezhaler[®] - indacaterol maleate) in November 2009 and launched the product in Germany in December 2009 and in Ireland and Denmark in March 2010 and have confirmed that they are on track to file the additional data requested by the Food and Drug Administration (FDA) in the second half of 2010.

Mr Shinichi Tamura, President & CEO of Sosei, commented:

"The data from the two Phase II QVA149 studies presented at the annual congress of the European Respiratory Society (ERS) in Vienna in September 2009 were very encouraging and demonstrated the benefit of combining two potent bronchodilators in a convenient once-daily therapy with an attractive efficacy and safety profile. This is the first once daily LAMA/LABA combination product to enter Phase III trials and, with an anticipated filing date of 2012, could provide an important future addition to the available treatment options for COPD."

- Ends -

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Notes for Editors:**About the NVA237 Licence Agreement with Novartis**

Sosei and Vectura concluded a global development and commercialisation agreement with Novartis in April 2005 for their collaborative product NVA237. Novartis is responsible for developing and commercialising NVA237 both as a monotherapy and in combination with QAB149 (indacaterol), its once-daily, long-acting beta2-agonist, as QVA149.

NVA237 entered Phase III trials in June 2009 which triggered an earlier milestone payment of \$7.5m to each company. Novartis received European regulatory approval for indacaterol (Onbrez[®] Breezhaler[®] - indacaterol maleate) in November 2009 and launched the product in Germany in December 2009 and in Ireland and Denmark in March 2010 and have confirmed that they are on track to file the additional data requested by the Food and Drug Administration (FDA) in the second half of 2010.

Under the terms of the agreement, Sosei and Vectura will receive total milestones of up to \$375 million for the achievement of pre-agreed clinical, regulatory and commercialisation targets for both the monotherapy and combination product. In addition, royalties on product sales will be paid for the monotherapy and the combination product. If additional combination products are developed by Novartis using NVA237, further milestones and royalties will be payable.

About COPD

COPD is a chronic obstruction of the airways which affects 210 million people worldwide and is projected to be the third leading cause of death by 2030. 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.osei.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.