



Novartis files NDA for NVA237 as a treatment for chronic obstructive pulmonary disease (COPD) in Japan

Tokyo, Japan – 25 November 2011: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565), announces that Novartis Pharma K.K. filed an application today for sales and marketing approval of NVA237 (glycopyrronium bromide) for the treatment of adult patients with chronic obstructive pulmonary disease (COPD) in Japan.

NVA237 is a long-acting muscarinic antagonist (LAMA) submitted for approval in the European Union in September as a once-daily treatment for COPD under the brand name Seebri[®] Breezhaler[®].

Mr. Shinichi Tamura, CEO of Sosei, said: *“Filing of NVA237 in Japan represents an important milestone for us, and we are very happy to see that development of NVA237 is progressing to plan. It is estimated that over 5 million people in Japan suffer from COPD and we are looking forward to seeing this drug being delivered to patients in the near future.”*

Furthermore, Novartis Pharma K.K. announced on 18 November that it had reached an agreement with Eisai Co. Ltd. regarding a co-promotion contract for up to three therapies for chronic obstructive pulmonary disease (COPD). These include Onbrez[®] 150 mcg Capsules for Inhalation (indacaterol maleate), and, if approved, NVA237 and QVA149 (a fixed-dose combination of indacaterol and NVA237).

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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. The dual activity of a muscarinic antagonist and a beta-adrenergic agonist promises to be a potent bronchodilator and Sosei believes that QVA149 could be the first once-daily LAMA/LABA combination to come to market for COPD.

Novartis received European regulatory approval for indacaterol 150 mcg and 300 mcg once-daily doses, under the brand name Onbrez[®] Breezhaler[®] in November 2009. In July 2011, Novartis announced approval of the 75 mcg once-daily dose of indacaterol 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 \$35m from Novartis and, under the terms of the licence, could receive up to an additional \$152.5m 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 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.