



## **Sosei and Vectura Announce Start of Phase II Clinical Study with NVA237 in the USA**

**Tokyo, Japan and Chippenham, UK – 6 August 2007:** Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) and Vectura Group plc (“Vectura”; LSE: VEC) announce the commencement of a Phase II clinical study in the USA, by Novartis, with NVA237, a once daily long acting muscarinic antagonist for the treatment of chronic obstructive pulmonary disease (COPD). This follows the publication on the ClinicalTrials.gov website of a study being undertaken under a US IND regulatory authorisation to support the safety of NVA237 in a Novartis proprietary Single Dose Dry Powder Inhaler (SDDPI).

The trial, a randomised, double-blind, placebo-controlled, parallel group, multi-centre study will assess the safety of 28 days treatment of NVA237 in patients with moderate to severe COPD.

NVA237 was licensed to Novartis by Sosei and Vectura in 2005 in a deal in which the two companies could receive up to US\$ 375 million in milestones as well as royalties on product sales. NDA submissions are expected to be filed in 2010 for both NVA237 and the combination product with indacaterol known as QVA149.

Mr Shinichi Tamura, President & CEO of Sosei, said: "I am pleased that clinical development of NVA237 has now commenced in the USA and that work in support of Phase III studies is progressing to plan."

Dr Chris Blackwell, Chief Executive of Vectura added: "Continued good progress on NVA237 with a study under a US IND provides additional confidence that the development of both NVA237 and QVA149 by Novartis is on track."

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**Notes for Editors:****About the NVA237 licence agreement with Novartis**

Sosei and its co-development partner Vectura Group plc concluded a global development and commercialisation agreement with Novartis in April 2005 for their collaborative product NVA237. Novartis is responsible for developing and commercializing NVA237 both as a monotherapy and in combination with indacaterol, its once daily, long acting beta 2 agonist, as QVA149.

Under the terms of the agreement, Sosei and Vectura have already received \$15 million each and will receive up to \$172.5 million each for achieving pre-agreed clinical, regulatory and commercialisation targets for both the monotherapy and combination product. These potential milestones thus total up to \$375 million. In addition, royalties on product sales will be paid for the monotherapy and the combination product. If a third combination product is developed by Novartis, using NVA237, further milestones and royalties may be payable.

**About COPD**

COPD is a chronic obstruction of the airways which in the developed world is caused primarily by smoking. Symptoms include chronic bronchitis and/or emphysema which slowly progress and eventually lead to a largely irreversible loss of lung function. COPD is currently the fourth most common cause of death and by 2020 is predicted to become the third most common cause of death and the fourth most important disability causing illness. The total financial burden of lung disease in Europe amounts to nearly €102 billion with COPD contributing almost one half of this figure. Around three-quarters of patients with advanced COPD are unable to perform normal everyday activities. The current market for COPD drug therapy is estimated to be worth around \$5.5 billion per annum and is predicted to double to over \$11 billion by 2011 as a result of increasing diagnosis and treatment and the growth of high value new products.

**About Sosei**

Sosei is a leading international biopharmaceutical company with significant expertise in product discovery and development. It has established a reduced risk business model primarily upon identifying new uses for established drugs and exploiting its unique position within Japanese, European and North American pharmaceutical markets by acquiring compounds from, and bringing compounds into, Japan.

For further information about Sosei, please visit [www.osei.com](http://www.osei.com)