



## Update on NVA237 and QVA149 for Chronic Obstructive Pulmonary Disease

**Tokyo, Japan** – 22 October 2009: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565), announces that the Phase III trials with NVA237, which commenced in June 2009, are proceeding to plan. Initiation of Phase III studies with QVA149 is now expected to occur during 2010. Receipt of the associated milestone payment of \$7.5m is therefore expected during the financial year to 31 March 2011.

QVA149 is a novel once-daily, dry powder, fixed dose, bronchodilator combination of the once-daily beta2-agonist indacaterol and the long-acting muscarinic antagonist NVA237 (glycopyrronium bromide), in development for the treatment of chronic obstructive pulmonary disease (COPD). Novartis announced on 25 September 2009 that indacaterol was recommended for approval in European Union to treat patients with COPD following its regulatory submission in late 2008. Furthermore, Novartis received a Complete Response letter from the FDA on 16<sup>th</sup> October requesting additional information on the dosing proposed for indacaterol.

Mr Shinichi Tamura, President and CEO of Sosei said: “Progress with Phase III studies evaluating NVA237, and the rapid review and recommendation for approval of indacaterol in Europe, are both encouraging with regard to the development of QVA149. We were impressed with the positive data at the European Respiratory Society meeting, and it continues to be our belief that QVA149 has the potential to be the first once-daily LAMA/LABA combination available to patients.”

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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 intends to launch NVA237 as a once-daily, long-acting muscarinic antagonist (LAMA) monotherapy for COPD and also in combination with their once-daily, long-acting beta2-agonist (LABA) indacaterol (QAB149). The combination of NVA237 and indacaterol is known as QVA149.

NVA237 entered Phase III trials in June 2009 which triggered a \$7.5million milestone payment to both Sosei and Vectura. Under the terms of the agreement, Sosei and Vectura will each receive up to \$172.5 million for achieving pre-agreed clinical, regulatory and commercialisation targets for both the monotherapy and combination product. These milestones total up to \$375 million. 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. Commonly caused by cigarette smoke and other harmful fumes COPD 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 LABAs and LAMAs 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 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.sosei.com](http://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.*