



## **Sosei and Vectura Announce Start of Phase III Clinical Study with NVA237**

### **Study triggers \$7.5m milestones for both companies**

Tokyo, Japan and Chippenham, UK – 29 June 2009: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) and Vectura Group plc (“Vectura”; LSE: VEC) announce the commencement of a Phase III clinical study by Novartis, with NVA237, a once-daily, long-acting muscarinic antagonist (LAMA) for the treatment of chronic obstructive pulmonary disease (COPD). NVA237 is a dry powder formulation for oral inhalation of glycopyrronium bromide, a LAMA with a rapid onset of activity. The study has now appeared on [clinicaltrials.gov](http://clinicaltrials.gov) and will be recruiting in the next few weeks when the first patient first visit will trigger a \$7.5 million milestone payment to both Sosei and Vectura.

The trial is a randomised, double-blind, placebo-controlled, parallel-group design, including an open-label tiotropium bromide arm, and will assess efficacy, safety and tolerability of NVA237 in patients with COPD. It will include approximately 1000 patients with moderate to severe COPD from study centres across the USA, Europe and other territories. Each patient will be randomised to receive a once-daily dose of placebo, tiotropium bromide or 50µg of NVA237 for a 52-week period. The primary endpoint of the study will be the change from baseline in FEV<sub>1</sub> (forced expiratory volume in one second) over 12 weeks of treatment. A number of secondary endpoints will also be evaluated.

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 monotherapy for COPD and also in combination with Novartis’ investigational once-daily, long-acting beta2-agonist (LABA) indacaterol (QAB149), which was filed for approval with the regulatory authorities as a monotherapy treatment for COPD at the end of 2008. The combination of NVA237 and indacaterol is known as QVA149. NDA submissions are expected to be filed by Novartis for both NVA237 and QVA149 in 2011.

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

“This represents an important milestone in the clinical development of NVA237 and we look forward also to the anticipated commencement of the Phase III study for QVA149 towards the end of this year.”

Dr Chris Blackwell, Chief Executive of Vectura, added: “The Phase II studies demonstrated that NVA237 provides sustained 24-hour bronchodilation in patients with moderate to severe COPD. As it now enters the final stage of clinical development before market, confidence in the product is at a new high as we anticipate confirmation of such benefit in a large target patient population.”

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**Notes for Editors:**

**About the NVA237 and QVA149 licence agreement with Novartis**

Sosei and 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 to date have each received \$15 million and 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 potential 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 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 2030 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 market for COPD drug therapy was estimated to be worth around \$5.7 billion in 2007 with a compound average growth rate of 19% over the preceding 5 years. Further significant growth can be anticipated as a result of better diagnosis and treatment and the introduction of high value new products.

**About Sosei**

Sosei Group 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)

**About Vectura**

Vectura Group plc is a product-focused Group that develops inhaled therapies principally for the treatment of respiratory diseases. Vectura's main products target diseases such as asthma and chronic obstructive pulmonary disease (COPD); a growing market that is currently estimated to be worth \$20 billion. Vectura also develops products for other lung pathologies and non-respiratory diseases.

Vectura has eight products marketed by its partners and a portfolio of drugs in clinical and pre-clinical development, some of which have been licensed to major pharmaceutical companies. Vectura seeks to develop certain programmes itself where this will optimise value. Vectura's formulation and inhalation technologies are available to other pharmaceutical companies on an out-licensing basis where this complements Vectura's business strategy.

Vectura has development collaborations with several pharmaceutical companies, including Boehringer Ingelheim, Novartis, Sandoz (the generics arm of Novartis), Baxter, GlaxoSmithKline (GSK), Mylan, UCB and Otsuka. Vectura has been included in the FTSE 250 index since 23 March 2009. For further information, please visit Vectura's website at [www.vectura.com](http://www.vectura.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 Vectura's or 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.*