



**NVA237 Phase II results presented at the European Respiratory Society Annual Meeting show promising efficacy and tolerability with potentially faster onset than tiotropium.**

**Tokyo, Japan and Chippenham, UK** – 7 October 2008: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) and Vectura Group plc (“Vectura”; LSE: VEC), announce results of two Phase II studies evaluating the efficacy, safety and tolerability of NVA237 presented at the annual congress of the European Respiratory Society (ERS) in Berlin, Germany. The new data show that NVA237 (glycopyrronium bromide), a novel inhaled long-acting muscarinic antagonist (LAMA), provides sustained 24-hour bronchodilation in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD).

NVA237 showed similar efficacy and duration of action to tiotropium with potentially a more rapid onset of action. In addition, studies lasting up to 28 days showed that NVA237 was safe and well tolerated with no clinically relevant cardiovascular findings.

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.

COPD 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 progress and eventually lead to a largely irreversible loss of lung function. While there is no cure, bronchodilators such as LAMAs make breathing easier by enlarging the patient’s airways, and are recognized in international guidelines as first-line treatment for COPD.

One of the randomized, double-blind, placebo-controlled studies compared NVA237 (12.5, 25, 50 and 100µg once-daily) with placebo and open-label tiotropium. In the study involving 83 patients, all doses of NVA237 showed rapid onset of action and sustained 24-hour bronchodilation over the seven-day treatment period.

Clinically relevant improvements (i.e. >120mL more than placebo) in forced expiratory volume in one second (FEV<sub>1</sub>), a standard measure of lung function, were observed with both the 50 and 100µg doses of NVA237. Early post-dose spirometry data suggested a more rapid onset of action than tiotropium. During the study, NVA237 was well tolerated with a good overall safety profile.

The other study evaluated the safety and tolerability of NVA237 (100 and 200µg once-daily) in 250 patients during 28 days of treatment. In this study, both doses were safe and well tolerated, with no clinically significant changes seen in vital signs or on other cardiac monitoring. NVA237 provided sustained 24-hour bronchodilation

over the study period. The authors concluded that NVA237 should be further evaluated for the treatment of COPD.

The results of the latest studies are consistent with previous clinical studies with NVA237 which demonstrated a potentially faster onset of action than tiotropium (five minutes versus 20-30 minutes) and a good overall safety and tolerability profile.

Mr Shinichi Tamura, President & CEO of Sosei, said: "I am pleased that these two trials have further confirmed the clinical profile of NVA237 in terms of low side effects and fast onset of action and that the drug has been deemed worthy of further study."

Dr Chris Blackwell, Chief Executive of Vectura commented: "On the back of these encouraging results, we now look forward to the continued progress of NVA237, and the combination therapy, QVA149."

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**Enquiries:**

**Sosei Group Corporation**

Ichiban-cho FS Bldg., 8 Ichiban-cho, Chiyoda-ku, Tokyo 102-0082 Japan  
Hiroki MAEKAWA, Representative Executive Officer,  
E-mail: hmaekawa@sosei.com Tel: +81-3-5210-3399 Fax: +81-3-5210-3291

1F London BioScience Innovation Centre  
2 Royal College Street, London NW1 0NH  
Tina HARBIGE, PA to CEO  
E-mail: tharbige@sosei.com Tel: +44-20-7691-2081 Fax: +44-20-7209-2484

**Vectura Group plc Tel: + 44 (0) 1249 667700**

Chris Blackwell, Chief Executive  
Anne Hyland, Chief Financial Officer  
Julia Wilson, Director of Investor Relations

**Financial Dynamics Tel: + 44 (0) 207 831 3113** David Yates / Ben Atwell

**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 a third combination product is 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 development company focused on the development of a range of inhaled therapies principally for the treatment of respiratory diseases. Vectura develops products to treat respiratory diseases such as asthma, chronic obstructive pulmonary disease (COPD) and cystic fibrosis, a market which is forecast to double over the next ten years from \$23 billion in 2007 to \$46 billion by 2017. Vectura also develops products for non-respiratory diseases where optimised delivery via the lungs could provide significant benefits, such as a rapid onset of action, improved efficacy and improved tolerability compared with current therapies.

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. The Company seeks to develop certain programmes further through development to optimise value through licensing at a later stage.

Vectura also offers its formulation and inhalation technologies to other pharmaceutical companies on a licensing basis where this complements Vectura's business strategy.

Vectura has development collaborations with several pharmaceutical companies including Boehringer Ingelheim, Novartis and Sandoz. The acquisition of Innovata in January 2007 brought established alliances with a number of additional companies, such as Baxter, GlaxoSmithKline (GSK), Merck Generics (part of Mylan Inc), UCB and Otsuka, as well as providing revenue streams, complementary products and critical mass. 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 Sosei's or Vectura'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 statement. 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.*