

NVA237 Phase III GLOW2 data at American Thoracic Society (ATS) International Conference and Phase II clinical trial update

- *GLOW2 study showed NVA237 superior to placebo and similar to OL tiotropium in increasing lung function, improving COPD symptoms and reducing exacerbations*
- *Results demonstrated that once-daily NVA237 had rapid onset of action at first dose, sustained 24-hour bronchodilation, and was well tolerated over 52 weeks*
- *NVA237 submitted for EU approval under proposed brand name Seebri[®] Breezhaler[®]. CHMP decision anticipated in 2012. In Japan, NDA submitted in November 2011. US filing expected in 2014*

Tokyo, Japan – 17 May 2012: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms the information released today by Novartis that results from the pivotal Phase III GLOW2 study demonstrated that once-daily (QD) 50 mcg NVA237 (glycopyrronium bromide) was superior to placebo in improving lung function, symptom relief and quality of life, and reducing exacerbations over a one-year period. The data will be presented at the 2012 American Thoracic Society (ATS) International Conference May 18-23, 2012 in San Francisco, CA, USA.

GLOW2 met its primary endpoint by demonstrating NVA237 provided superior 24-hour bronchodilation compared to placebo at 12 weeks measured by mean trough FEV₁ (97 mL; p<0.001). At this same time point, trough FEV₁ for open-label (OL) tiotropium was 83 mL versus placebo (p<0.001). In addition, NVA237 showed similar efficacy to OL tiotropium (Spiriva[®] HandiHaler[®]*/18 mcg) in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD). NVA237 also demonstrated rapid onset of action (within five minutes at first dose) and sustained 24-hour bronchodilation over 52 weeks.

At Day 1, Week 26 and Week 52 of the GLOW2 study, NVA237 significantly improved lung function (measured by mean trough FEV₁) compared to placebo (all p<0.001) and results were similar to those seen with OL tiotropium. At Day 1 and Week 12, 26 and 52, the FEV₁ area under the curve (AUC) for 0–4 hr, 0–12 hr, 12–24 hr and 0–24 hr for NVA237 was superior to placebo (p<0.05) and numerically greater than OL tiotropium.

Shinichi Tamura, CEO of Sosei:

“GLOW2 data further illustrate the potential benefits of once daily NVA237 for patients with COPD. NVA237 has been submitted for approval in Europe and Japan and we look forward to a decision from EU regulators that is expected in 2012.”

The study also demonstrated that NVA237 improved COPD symptoms, quality of life and reduced exacerbations compared to placebo. NVA237 significantly reduced breathlessness (measured by the transition dyspnea index or TDI, p=0.002), improved health-related quality of life (measured by the St George’s Respiratory Questionnaire or SGRQ, p<0.001), reduced use of rescue medication (p=0.039), and increased the percentage of days with no daytime symptoms (p<0.05) compared to placebo over 52 weeks.

For these symptomatic and quality of life indicators, results were numerically similar to those observed with OL tiotropium over the same time period. NVA237 also significantly prolonged the time to first exacerbation and significantly reduced the rate of moderate/severe

* Spiriva[®] HandiHaler[®] is a registered trademark by Boehringer Ingelheim Pharma GmbH & Co. KG.



exacerbations versus placebo over 52 weeks ($p=0.001$); these effects were similar to OL tiotropium ($p=0.001$).

Throughout the GLOW2 study, NVA237 was well-tolerated with a similar incidence of adverse events to placebo and OL tiotropium. Serious adverse events were reported less frequently with NVA237 (12.6%) than with either placebo (15.4%) or OL tiotropium (15.0%).

GLOW2 was a 52-week double-blind, placebo-controlled, parallel-group study involving 1,066 patients to assess the efficacy, safety and tolerability of NVA237 in patients with COPD. Patients were randomized into three treatment arms receiving either once-daily NVA237 50 mcg or placebo (double-blind), or once-daily OL tiotropium 18 mcg. They were also permitted to use COPD background therapy and rescue medication.

Phase II clinical trial update

Results have recently been submitted for publication from the NVA237 Phase II A2208 study. This study comparing once-daily and twice-daily dosing regimens of NVA237 met its primary endpoint by demonstrating that all treatments (12.5 mcg, 25 mcg and 50 mcg given once or twice daily and 100 mcg once daily) provided statistically significant bronchodilation over the course of the day (measured by mean trough FEV_1 at Day 28) in patients with moderate-to-severe COPD compared to placebo.

Differences in lung function (measured by FEV_1 AUC_{0-24h}) between a single daily dose of NVA237 and the same total amount given twice daily were small and not clinically relevant. However once-daily dosing is known to offer the potential to improve patient adherence, an important consideration when selecting the optimum dosing regimen for a novel bronchodilator. Throughout the study, NVA237 showed an overall good safety profile and was well tolerated compared to placebo. The results of A2208 are consistent with previous NVA237 studies and support once-daily dosing of 50 mcg NVA237 in patients with moderate-to-severe COPD.

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Notes for editors:

NVA237 (glycopyrronium bromide. Seebri[®] Breezhaler[®]) is an investigational long-acting muscarinic antagonist (LAMA) developed as a once-daily inhaled maintenance therapy for the treatment of COPD. Phase III data from the GLOW1, 2 and 3 studies demonstrated that NVA237 increased patients' lung function over a 24-hour period compared to placebo with a fast onset of action at first dose, as well as improving exercise endurance. It was submitted for regulatory approval in Europe in Q3 2011 and Japan in Q4 2011, and expected US filing



is in the beginning of 2014. NVA237 was licensed to Novartis in April 2005 by Sosei and our co-development partner Vectura.

Indacaterol (Onbrez[®] Breezhaler[®]) is Novartis' once daily long acting beta₂-agonist (LABA). Novartis received European regulatory approval for 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 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.

QVA149 (indacaterol 110 mcg/glycopyrronium bromide 50 mcg) is an investigational inhaled, once-daily, fixed dose combination of the long acting beta₂-agonist (LABA) indacaterol, and the long-acting muscarinic antagonist (LAMA) glycopyrronium bromide (NVA237). The first four QVA149 Phase III studies in the treatment of COPD all met their primary endpoints. The results of the SHINE, BRIGHT, ENLIGHTEN and ILLUMINATE studies, which are key components of the IGNITE program, demonstrate the potential of QVA149 in the treatment of COPD. Filing for QVA149 in Europe is expected in Q4 2012.

About COPD

COPD is a progressive disease associated mainly with tobacco smoking, air pollution or occupational exposure, which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. It affects an estimated 210 million people worldwide¹ and is predicted to be the third leading cause of death by 2020². Although COPD is often thought of as a disease of the elderly, 50% of patients are estimated to be within the ages of 50 and 65, which means that half of the COPD population are likely to be impacted at the peak of their earning power and family responsibilities³.

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.

References

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3. Fletcher, M, *et al.* COPD Uncovered: An International survey on the impact of chronic obstructive pulmonary disease (COPD) on a working age population. BMC Public Health 2011, 11:612.

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.