Once-daily Seebri® Breezhaler® receives positive CHMP opinion to treat COPD patients in the EU

- COPD patients in Phase III GLOW trials experienced improved lung function, reduced shortness of breath, reduced exacerbations, and improved quality of life\(^1,2,3,4\)

- GLOW2 study showed Seebri Breezhaler provided 24-hour bronchodilation and was superior to placebo and similar to open-label tiotropium in improving lung function\(^2\)

Tokyo, Japan – 23 June 2012: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms the information released today by Novartis that the European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Seebri® Breezhaler\(^\circledR\) (glycopyrronium/NVA237) 44 mcg delivered dose (50 mcg glycopyrronium per capsule), as a once-daily inhaled maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Seebri Breezhaler is a long-acting muscarinic antagonist (LAMA), a type of bronchodilator that is recommended in COPD global treatment strategies as maintenance therapy administered either alone or in combination with other treatments\(^5\).

Data from three of the Novartis Phase III GLOW trials informed the CHMP’s positive opinion for Seebri Breezhaler and included 1,996 COPD patients from around the world with many in EU countries\(^1,2,3,4,6\).

GLOW1 demonstrated the clinically significant superiority of Seebri versus placebo for lung function improvements at 12 weeks measured by trough FEV\(_1\) \((p<0.01)\). GLOW2 demonstrated a similar magnitude of effect and also showed that Seebri was similar to open-label (OL) tiotropium over 52 weeks measured by improvements in trough FEV\(_1\) compared to placebo\(^2\). In addition to demonstrating benefits in terms of lung function, Seebri Breezhaler exhibited a rapid onset of action within five minutes at first dose\(^2\) and reduced exacerbations\(^4\). Significant benefits in both breathlessness and health-related quality of life, as measured by the Transition Dyspnea Index (TDI) and St. George’s Respiratory Questionnaire (SGRQ) compared to placebo, were also demonstrated\(^3\).

The GLOW3 study showed that after Seebri Breezhaler was administered in the morning, patients experienced improved exercise tolerance from the first dose onward\(^6\). Overall, patients treated with Seebri Breezhaler experienced a significant 21% improvement in exercise endurance versus placebo at the end of the study (day 21), with a significant 10% increase from day one (both \(p<0.001)\).

In all studies, Seebri Breezhaler was well tolerated with an incidence of adverse events similar to placebo\(^1,2,3,4,6\).

The European Commission generally follows the recommendations of the CHMP and usually delivers its final decision within three months of the CHMP recommendation.
Worldwide submissions and reviews of Seebri® Breezhaler® (glycopyrronium bromide/NVA237) are ongoing. The US filing for Seebri Breezhaler is expected in 2014.

CEO of Sosei, Shinichi Tamura commented:

“This positive opinion for Seebri Breezhaler is a value enhancing milestone for both Sosei and its co-development partner Vectura. The drug was developed to Phase II proof-of-principle by the two companies before being licensed to Novartis and, when approved, will be the second once-daily inhaled treatment in the LAMA class for COPD patients. This innovative therapy has the potential to reduce breathlessness, increase the capacity to exercise and help improve quality of life. We look forward also to key Phase III QVA149 data with filing in Europe expected in 2012”.

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Notes for editors:

About Seebri Breezhaler

Seebri® Breezhaler® (glycopyrronium bromide/NVA237) is an investigational LAMA developed as a once-daily inhaled maintenance therapy for the treatment of COPD. Glycopyrronium bromide was licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura. It was submitted for regulatory approval in Europe in Q3 2011 and Japan in Q4 2011.

In addition to Seebri Breezhaler, also under development is QVA149 (indacaterol maleate 110 mcg/glycopyrronium bromide 50 mcg), an investigational inhaled, once-daily, fixed dose combination of glycopyrronium bromide and the LABA indacaterol maleate.

The first four Novartis QVA149 Phase III studies in the treatment of COPD all met their primary endpoints7,8,9,10. 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 COPD7,8,9,10.
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 worldwide11 and is predicted to be the third leading cause of death by 20205. 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 responsibilities12.

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.

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.

Reference:

2 Kerwin E, et al. NVA237 once daily provides rapid and sustained bronchodilation in COPD patients, with efficacy similar to tiotropium: The GLOW2 trial. [Abstract A2920: Thematic poster session B41: Monday, 21 May, 2012; 08:15–16:30].
4 Kerwin E, et al. NVA237 once daily reduces COPD exacerbations with similar rates to tiotropium: The GLOW2 trial. [Abstract A2255: Poster discussion session A101: Sunday, 20 May, 2012; 14:00–16:30].
7 QVA149 A2303 (SHINE). Data on file, Novartis Pharma AG. ClinicalTrials.gov identifier: NCT01202188.
8 QVA149 A2307 (ENLIGHTEN). Data on file, Novartis Pharma AG. ClinicalTrials.gov identifier: NCT01120717.
9 QVA149 2305 (BRIGHT). Data on file, Novartis Pharma AG. ClinicalTrials.gov identifier: NCT01294787.
QVA149 2313 (ILLUMINATE). Data on file, Novartis Pharma AG. ClinicalTrials.gov identifier: NCT01315249.
