Seebri® Breezhaler® receives European Commission approval as once-daily maintenance treatment for COPD in the EU

- Approval triggers $10m milestone payment to Sosei
- Seebri® Breezhaler® 44 mcg delivered dose approved for maintenance treatment of COPD will be available to patients and physicians in some EU markets by year-end
- In GLOW trials, Seebri® Breezhaler® improved lung function, reduced shortness of breath, reduced exacerbations, and improved quality of life up to 52 weeks versus placebo\textsuperscript{1,2,3}
- GLOW2 study showed Seebri® Breezhaler® provided 24-hour bronchodilation and is superior to placebo and similar to open-label tiotropium in improving lung function\textsuperscript{2}

Tokyo, Japan – 1 October 2012: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms the information released today by Novartis that the European Commission has approved Seebri® Breezhaler® (glycopyrronium bromide) 44 mcg delivered dose (equivalent to 50 mcg glycopyrronium measured dose per capsule), as a once-daily inhaled maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). This approval triggers a $10m milestone payment to Sosei.

The European Commission approved Seebri® Breezhaler® based on data from the Novartis Phase III GLOW trials which demonstrated the safety and efficacy of glycopyrronium 44 mcg and involved 1,996 COPD patients who required maintenance treatment from around the world, with many in EU countries\textsuperscript{1,2,3}.

The GLOW trials showed that glycopyrronium, when compared to placebo, significantly improved lung function over the first four hours after morning dosing and that this benefit was sustained for 24 hours over a 52-week period\textsuperscript{2}. Patients on glycopyrronium demonstrated improved lung function, reduced shortness of breath, reduced exacerbations, reduced use of rescue medication, improved quality of life and improved exercise tolerance compared to placebo\textsuperscript{1,2,3}.

GLOW1 was a 26-week, randomized, double-blind, placebo-controlled study. The study demonstrated the clinically significant superiority of glycopyrronium versus placebo for lung function improvements at 12 weeks (primary endpoint) measured by trough FEV\textsubscript{1} (p<0.01)\textsuperscript{1}.

GLOW2 demonstrated a similar magnitude of effect and also showed that glycopyrronium was similar to open-label (OL) tiotropium over 52 weeks measured by improvements in trough FEV\textsubscript{1} compared to placebo. In addition to demonstrating benefits in terms of lung function, glycopyrronium exhibited a rapid onset of action within five minutes at first dose and reduced exacerbations. Significant benefits in both breathlessness and health-related quality of life (HRQL), as measured by the Transition Dyspnea Index (TDI) and St. George’s Respiratory Questionnaire (SGRQ) compared to placebo, were also demonstrated. GLOW2 was a 52-week, randomized, double-blind, placebo-controlled study with OL tiotropium 18 mcg as an active exploratory arm.\textsuperscript{2}

The GLOW3 study showed that after glycopyrronium was administered in the morning, patients experienced improved exercise tolerance from the first dose onward. Overall,
patients treated with glycopyrronium 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, glycopyrronium was shown to have an overall safety profile similar to placebo.

CEO of Sosei, Shinichi Tamura commented:

“We are delighted with the EU approval of Seebri Breezhaler which marks an important milestone in the evolution of the Sosei business. The latest Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend long-acting muscarinic antagonists as first-line therapy for a broad range of COPD patients with moderate to very severe symptoms. Seebri Breezhaler will provide an important once-daily treatment option for this serious disease”.

– Ends –

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Notes for editors

About Seebri® Breezhaler®:
Seebri® Breezhaler® (glycopyrronium bromide) is a long-acting muscarinic antagonist (LAMA) developed as a once-daily inhaled maintenance therapy for the treatment of COPD. Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura. Phase III data from the GLOW 1, 2 and 3 studies demonstrated that glycopyrronium increased patients’ lung function over a 24-hour period compared to placebo with a fast onset of action at first dose, and improved exercise endurance versus placebo. Seebri® also received MHLW approval as once-daily maintenance treatment for COPD in Japan on 28 September 2012, under the brand name Seebri® Inhalation Capsules 50mcg. The US filing for Seebri® Breezhaler® is expected in 2014.

About QVA149:
QVA149 is an investigational inhaled, once-daily, fixed-dose combination of indacaterol maleate and glycopyrronium bromide. QVA149 is being investigated for the maintenance treatment of COPD in the Phase III IGNITE clinical trial program. IGNITE is one of the largest international clinical trial programs in COPD comprising 10 studies in total with more than 7,000 patients across 42 countries. The first five studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK) have already completed in 2012 with three additional studies (BLAZE, ARISE, BEACON) expected to complete by the end of the year. The studies are designed to investigate efficacy, safety and tolerability, lung function, exercise endurance, exacerbations, breathlessness and quality of life. Initial filings for regulatory approval are expected in Q4 2012 for Europe and Japan. US filing is expected at the end of 2014.

All Novartis inhaled COPD portfolio products are being developed for delivery via the Breezhaler® device, a single-dose dry powder inhaler (SDDPI), which has low air flow resistance, making it suitable for patients with airflow limitation, such as COPD patients.
The Breezhaler® device allows patients to hear, feel and see that they have taken the drug correctly4.

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 worldwide17 and is predicted to be the third leading cause of death by 202018. 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 responsibilities19.

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.

References


