QVA149 ILLUMINATE Phase III COPD study meets primary endpoint and clarification of anticipated timing of US filings for NVA237 and QVA149

- Superior lung function with once-daily QVA149 compared with twice-daily Seretide®
- Study is part of IGNITE Phase III clinical trial program intended to form the basis of regulatory filings in COPD
- US filings for NVA237 and QVA149 expected in 2014

Tokyo, Japan – 24 April 2012: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms the information released today by Novartis that a fourth study in the IGNITE programme, has met its primary endpoint. All four QVA149 Phase III studies have now met their primary endpoints, including the latest, ILLUMINATE, a head-to-head study against Seretide®, demonstrating its strong potential to address the unmet needs of patients with chronic obstructive pulmonary disease (COPD).

The ILLUMINATE study in more than 500 patients demonstrated that superior lung function (measured by FEV\textsubscript{1} AUC\textsubscript{0-12h} with a p value <0.001) was achieved with once-daily QVA149 compared with twice-daily Seretide® (fluticasone 500mcg / salmeterol 50mcg) in patients with moderate to severe COPD.

After discussions with the Food and Drug Administration (FDA), Novartis also confirmed today that they have agreed on the Phase III trial design for QVA149 as well as NVA237 for the US and that they expect the filing for NVA237 to take place at the beginning of 2014 with QVA149 following at the end of 2014.

CEO of Sosei, Shinichi Tamura commented:
“The ILLUMINATE study will be an important part of the regulatory submission for QVA149 and achieving superior lung function given once daily versus twice-daily Seretide® gives us more confidence in the potential of QVA149 in the treatment of patients with COPD. We now have clarity on US filing timelines for both NVA237 and QVA149 and we look forward to a decision from the EU regulators on NVA237 in the near future”

Data from three other studies in the IGNITE program were announced recently. SHINE, with an enrolment of more than 2,100 patients, demonstrated the superiority in trough FEV1 (p<0.001) of once-daily QVA149 compared to once-daily indacaterol or once-daily NVA237 in patients with moderate to severe COPD. In addition, QVA149 showed superiority in trough FEV1 (p<0.001) compared to placebo and open-label tiotropium (18 mcg). The results of BRIGHT showed that patients experienced significantly better exercise endurance versus placebo (p=0.006). ENLIGHTEN demonstrated that QVA149 was well tolerated with a safety and tolerability profile similar to placebo.

The studies, ILLUMINATE, SHINE, BRIGHT and ENLIGHTEN, are part of the IGNITE clinical trial program intended to form the basis of filing QVA149 in COPD in the EU, Japan and other countries. IGNITE is one of the largest international patient registration programs in COPD, comprising 10 studies in total, and including more than 5,700 patients across 42 countries. These studies are designed to investigate efficacy, safety and tolerability, lung function, exercise endurance, exacerbations, dyspnoea and quality of life. Three more QVA149 Phase III studies (SPARK, BLAZE and ARISE) are expected to complete in 2012.

QVA149 (indacaterol 110 mcg / glycopyrronium bromide 50 mcg) is an investigational inhaled, once-daily, fixed dose combination of the long acting beta_2-agonist (LABA)
indacaterol, and the long-acting muscarinic antagonist (LAMA) glycopyrronium bromide (NVA237). Data from the IGNITE clinical trial program, examining QVA149 in a number of settings, will be submitted for presentation to a major medical congress later this year.

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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. It was submitted for regulatory approval in Europe in Q3 2011 and Japan in Q4 2011.

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.

About the QVA149 Phase III Studies

ILLUMINATE is a 26-week, multi-center, randomized, double-blind, double-dummy, parallel-group study to assess the efficacy, safety and tolerability of QVA149 compared to fluticasone 500mcg/ salmeterol 50mcg (Seretide® ) in patients with moderate to severe stable COPD.

SHINE is a 26-week, multicenter, randomized, double-blind, parallel-group, placebo and active controlled pivotal trial of 2,144 patients with moderate to severe COPD to assess efficacy in terms of trough FEV1.

BRIGHT is a three-week, randomized, blinded, double-dummy, multi-center, placebo controlled, three-period crossover pivotal trial of 85 patients with moderate or severe COPD to assess the effect on exercise tolerance of QVA149.

ENLIGHTEN is a 52-week, multicenter, randomized, double-blind, parallel-group, placebo controlled pivotal trial of 339 patients with moderate or severe COPD to assess the safety and tolerability of QVA149.
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 worldwide\(^2\) and is predicted to be the third leading cause of death by 2020\(^3\). 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 responsibilities\(^4\).

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
1. Seratide\(^\circ\) is a registered trademark of GSK.

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.