QVA149 filed as a once-daily maintenance treatment for COPD in Europe

Tokyo, Japan – 25 October 2012: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms the information released today by Novartis that QVA149, (indacaterol maleate/glycopyrronium bromide) an investigational drug for chronic obstructive pulmonary disease (COPD) has been filed for marketing authorisation with the European Medicines Agency (EMA), triggering a $5 million milestone payment to Sosei.

The first five studies in the Phase III IGNITE clinical trial program for QVA149 formed the basis of the filing. ILLUMINATE, SHINE, SPARK and BRIGHT met their respective superiority primary endpoints of FEV1 area under the curve (AUC) for 0-12 hours at 26 weeks versus salmeterol/fluticasone, mean trough FEV1 at 26 weeks versus both indacaterol maleate and glycopyrronium bromide, reduction in the rate of exacerbations versus glycopyrronium bromide, and exercise endurance time at 21 days versus placebo. The data from ENLIGHTEN demonstrated that QVA149 has a similar overall adverse event profile to placebo.

CEO of Sosei, Shinichi Tamura commented:

“We are delighted with the EU filing for QVA149.

The IGNITE program is among the largest COPD clinical trials performed, the results from which provide strong support as to the effectiveness and safety of QVA149 and its potential to treat patients suffering from this progressive disease. Today’s news follows the recent approval of Seebri® Breezhaler® in Europe and Canada, and Seebri® Inhalation Capsules in Japan.”

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Notes for editors

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. Further
filings for regulatory approval are expected in Q4 2012 for Japan and at the end of 2014 for the US.

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 correctly.

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 and is predicted to be the third leading cause of death by 2020. 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.

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


10. ClinicalTrials.gov. Comparison of Long-term Safety of the Combination Product QVA149A Against Placebo and Standard of Care Treatment in Chronic Obstructive Pulmonary Disease Patients With Moderate to Severe Airflow Limitation (GLISTEN).

11. ClinicalTrials.gov. The Effect of QVA149 on Health Related Quality of Life in Patients With Chronic Obstructive Pulmonary Disease (COPD) (QUANTIFY). 


