First in class once-daily dual bronchodilator Ultibro® Breezhaler® (QVA149) approved for the treatment of COPD in Europe

- Ultibro® Breezhaler® (QVA149) is the first once-daily dual bronchodilator to gain European Commission approval as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD

- Pivotal Phase III IGNITE data showed QVA149 significantly improved lung function and patient-reported outcomes including breathlessness and rescue medication use, compared to current standards of care

- COPD is a progressive disease affecting up to 10% of adults across Europe and is projected to be the third leading cause of death by 2020

Tokyo, Japan – 23 September 2013: Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms the information released today by Novartis announcing that the European Commission approved once-daily Ultibro® Breezhaler® (indacaterol 85 mcg / glycopyrronium 43 mcg) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Ultibro® Breezhaler® was developed under the name QVA149. The approval triggers a $10m milestone payment to Sosei.

Dual bronchodilation with QVA149 is expected to set a new standard of care in COPD by combining the proven efficacy and safety benefits of two established Novartis COPD treatments, the LABA*, Onbrez® Breezhaler® (indacaterol), and the LAMA**, Seebri® Breezhaler® (glycopyrronium bromide). Both these components are delivered through the Breezhaler® inhalation device, as is QVA149, and are widely available in many countries around the world.

Last week, QVA149 was approved also in Japan and US submission is anticipated at the end of 2014.

The approval of QVA149 was based on the comprehensive IGNITE Phase III clinical trial program, one of the largest international trial programs in COPD comprising 11 studies in total with more than 10,000 patients from 52 countries. From the eight IGNITE studies which completed in 2012, data showed that QVA149 significantly improved lung function versus several current standard treatments and showed significant symptomatic improvements versus placebo in breathlessness, exercise tolerance, rescue medication use and health-related quality of life. QVA149 also demonstrated statistically significant symptomatic improvements in breathlessness, rescue medication use and health-related quality of life compared to open-label (OL) tiotropium 18 mcg. The rate of all COPD exacerbations (mild, moderate and severe) was significantly improved with QVA149 compared to glycopyrronium 50 mcg and OL tiotropium 18 mcg.

* a long-acting beta2-adrenergic agonist, ** a long-acting muscarinic antagonist
In clinical studies, QVA149 demonstrated an acceptable safety profile with no meaningful differences between the treatment groups (placebo, indacaterol 150 mcg, glycopyrronium 50 mcg, OL tiotropium 18 mcg, salmeterol / fluticasone (SFC) 50 mcg / 500 mcg) in the incidence of adverse and serious adverse events. The safety profile was characterized by typical anticholinergic and beta-adrenergic effects related to the individual components of the combination.

Ultibro®, Seebri®, Onbrez® and Breezhaler® are registered trademarks of Novartis AG.

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About Ultibro®

Ultibro® Breezhaler® (indacaterol / glycopyrronium) is an inhaled, once-daily, fixed-dose combination of the LAMA, glycopyrronium bromide and the LABA, indacaterol maleate and was developed under the name QVA149. QVA149 was investigated for the treatment of COPD in the Phase III IGNITE clinical trial program. IGNITE was one of the largest international clinical trial programs in COPD comprising 11 studies in total (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON, RADIATE, LANTERN, FLAME) with more than 10,000 patients across 52 countries. The first eight studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON) completed in 2012. The studies were designed to investigate efficacy (lung function, exercise endurance, exacerbations, shortness of breath and quality of life), safety and tolerability of patients treated with Ultibro® Breezhaler.

Results from the Phase III IGNITE trials have demonstrated statistically significant improvements in bronchodilation with QVA149 versus several treatments widely used as current standards of care. Data showed that QVA149 significantly improved lung function compared to OL tiotropium 18 mcg, fixed dose combination SFC 50 mcg / 500 mcg, indacaterol maleate 150 mcg, glycopyrronium 50 mcg and placebo providing a rapid onset of action within five minutes, and sustained bronchodilation during a 24 hour period which was maintained for up to 26 weeks. In the IGNITE phase III trial program, QVA149 also showed symptomatic improvements versus placebo in COPD patients. These symptomatic improvements included breathlessness, exercise tolerance, rescue medication use and health-related quality of life. QVA149 also significantly improved the rate of all COPD exacerbations (mild, moderate and severe) compared to glycopyrronium 50 mcg and OL tiotropium 18 mcg.

* Total refers to all 11 IGNITE studies.
About Seebri® Breezhaler®
Seebri® Breezhaler® (glycopyrronium bromide) is a once-daily inhaled long-acting muscarinic antagonist (LAMA; also referred to as a long-acting anticholinergic) indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD16. Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei. In Phase III studies (GLOW 1, 2 and 3), once-daily glycopyrronium 50 mcg demonstrated rapid improvements in lung function after first dose on Day 1 which were sustained for 24 hours and maintained over the 52 week study period compared with placebo17-19. Glycopyrronium bromide 50 mcg also significantly improved shortness of breath, health-related quality of life, exacerbation risk, and exercise endurance versus placebo17-19. Seebri® Breezhaler® is approved in the EU, Japan, Switzerland, Canada, Australia and a number of other countries.

All Novartis inhaled COPD portfolio products are being developed for delivery via a single-dose dry powder inhaler (SDDPI) called the Breezhaler® device which has low air flow resistance, making it suitable for patients with airflow limitation20. The Breezhaler® device allows patients to hear, feel and see that they have taken the full dose correctly16.

About COPD
COPD is a progressive life-threatening disease that makes it hard to breathe, with symptoms that have a destructive impact on patients’ function and quality of life21. It affects an estimated 210 million people worldwide5 and is projected to be the third leading cause of death by 202021. COPD is often considered to be a disease of later years, but estimates suggest that 50% of those with COPD are now less than 65 years old, resulting in increases in absenteeism, premature retirement22 and reductions in workforce participation22,23.

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:
8. Mahler D et al. Superior lung function with once-daily QVA149 translates into improvements in patient reported breathlessness compared with placebo and tiotropium in COPD patients: the BLAZE study. [ATS abstract 45308; Session C20; Date: May 21, 2013 Time: 8:15-10:45].