First in class once-daily dual bronchodilator Ultibro® Inhalation Capsules (QVA149) approved for the treatment of COPD in Japan

- *Once-daily Ultibro® Inhalation Capsules (QVA149) (glycopyrronium / indacaterol), delivered through the Breezhaler® device, approved for relief of various symptoms due to airway obstruction in COPD*

- *IGNITE data showed QVA149 significantly improved lung function and patient-reported outcomes including breathlessness and rescue medication use, compared to current standards of care*[1-3]

- *QVA149 significantly reduced the rate of all COPD exacerbations compared to glycopyrronium 50 mcg and open-label tiotropium 18 mcg*[3]

Tokyo, Japan – 20 September 2013: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) confirms that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved once-daily Ultibro® Inhalation Capsules (glycopyrronium 50 mcg / indacaterol 110 mcg), delivered through the Breezhaler® device, for relief of various symptoms due to airway obstruction in chronic obstructive pulmonary disease (COPD). Ultibro Inhalation Capsules were developed by Novartis under the name of QVA149 and will be available to the 5.3 million Japanese patients who may be living with COPD[4]. The approval triggers a $2.5m 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® Inhalation Capsules (indacaterol), *and the LAMA***,* Seebri® Inhalation Capsules (glycopyrronium bromide). Both these components are delivered through the Breezhaler® device, as is QVA149, and are widely available in many countries around the world including Japan.

The efficacy and safety of QVA149 is supported by 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[1-3,5-14].

From the eight IGNITE studies which completed in 2012[1-3,5-9], data showed that QVA149 significantly improved lung function versus several current standard treatments[1,3,5] and showed significant symptomatic improvements versus placebo in breathlessness, exercise tolerance, rescue medication use and health-related quality of life[1,2,5]. 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[1]. 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[3].

** a long-acting beta$_2$-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[1-3,5]. The safety profile was characterized by typical anticholinergic and beta-adrenergic effects related to the individual components of the combination[1-3,5-9].

In July, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for approval of QVA149. US submission is anticipated at the end of 2014.

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

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About QVA149

QVA149 is an inhaled, once-daily, fixed-dose combination of glycopyrronium bromide and indacaterol maleate. QVA149 was investigated for the treatment of COPD in the Phase III IGNITE clinical trial program. IGNITE is 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[1-3,5-14]. The first eight studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON) completed in 2012[1-3,5-9]. The studies are designed to investigate the efficacy (lung function, exercise endurance, exacerbations, shortness of breath and quality of life), safety and tolerability, in patients treated with QVA149[1-3,5-12].

Results from the Phase III IGNITE trials demonstrated statistically significant improvements in bronchodilation with QVA149 versus comparator treatments[1,3,5] widely used as current standards of care. Data showed that QVA149 significantly improved bronchodilation 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 within five minutes, and sustained bronchodilation during a 24 hour period which was maintained for up to 26 weeks[2,5]. In the IGNITE Phase III trial program, QVA149 also showed symptomatic improvements versus placebo in COPD patients[1,2,5]. These symptomatic improvements included shortness of breath, exercise tolerance, rescue medication use and health-related quality of life[1,2,5]. QVA149 aslo significantly improved the rate of all COPD exacerbations (mild, moderate and severe) compared to glycopyrronium 50 mcg and OL tiotropium 18 mcg[3].

** Total refers to all 11 IGNITE studies.*

About Seebri® Breezhaler®

Once-daily Seebri® Breezhaler® / Seebri® Inhalation Capsules (glycopyrronium bromide) are a novel 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 COPD[15]. Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura. 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 was sustained for 24 hours and maintained over the 52 week study period compared with placebo[16-18]. Glycopyrronium 50 mcg also significantly improved shortness of breath, health-related quality of life, exacerbation risk, and exercise endurance versus placebo[16-18]. Glycopyrronium 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 limitation[19]. The Breezhaler® device allows patients to hear, feel and see that they have taken the full dose correctly[15].

About COPD

COPD is a chronic, progressive lung disease that is commonly caused by tobacco smoking, air pollution or occupational exposure, and results in airflow obstruction and debilitating bouts of breathlessness[20]. Although the latest figures show only 173,000 people have been diagnosed with COPD in Japan[21], epidemiological data suggest that the total number of patients could be as high as 5.3 million[4]. There are concerns that the number of patients could grow in Japan where smoking rates are high and many people are starting to smoke at an increasingly early age.

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.

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