First in class once-daily dual bronchodilator Ultibro® Breezhaler® (QVA149) gains positive CHMP opinion for the treatment of COPD

- *QVA149 (indacaterol/glycopyrronium) is the first once-daily fixed-dose combination of both a LABA and a LAMA bronchodilator to gain positive CHMP opinion*
- *Pivotal Phase III IGNITE data showed QVA149 significantly improved lung function and patient-reported outcomes including breathlessness and rescue medication use, compared to current standard of care*[1]
- *QVA149 demonstrated significantly reduced rates of COPD exacerbations and improved health-related quality of life compared to open-label tiotropium 18 mcg and glycopyrronium 50 mcg*[2,3]

Tokyo, Japan – 27 July 2013: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) confirms the information released by Novartis that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for approval of once-daily Ultibro® Breezhaler® (indacaterol 85 mcg/glycopyrronium 43 mcg delivered dose, equivalent to 110 mcg/50 mcg metered dose per capsule), as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Ultibro Breezhaler was developed under the name of QVA149.

QVA149 is an investigational fixed dose combination of two bronchodilators, indacaterol, a long-acting beta$_2$-adrenergic agonist (LABA) and glycopyrronium, a long-acting muscarinic antagonist (LAMA).

QVA149 significantly improved the rate of all exacerbations compared to open-label (OL) tiotropium 18 mcg, glycopyrronium 50 mcg[3]. The rate of moderate or severe exacerbations was significantly lower compared to glycopyrronium 50 mcg and numerically lower compared to OL tiotropium 18 mcg[2,3].

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, SFC 50 mcg/500 mcg) in the incidence of adverse and serious adverse events[2,4,5].

The European Commission generally follows the recommendations of the CHMP and normally grants a marketing authorization within three months of the opinion. Worldwide submissions and reviews of QVA149 are ongoing with US filing expected at the end of 2014.

About the IGNITE clinical trial program
In the Phase III IGNITE clinical trial program, QVA149 is being investigated for the treatment of COPD patients as an inhaled, once-daily, fixed-dose combination of indacaterol maleate and glycopyrronium bromide. 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[3,6-17]. The first eight studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON) completed in 2012. The studies were designed to investigate the efficacy, safety and tolerability, lung function, exercise endurance, exacerbations, shortness of breath and quality of life in patients treated with QVA149.

Results from five of the Phase III IGNITE trials[3,6-9] supported the CHMP's positive opinion for QVA149 which demonstrated statistically significant improvements in bronchodilation versus treatments widely used as current standards of care[1]. Data showed that QVA149 significantly improved bronchodilation compared to OL tiotropium 18 mcg, 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, along with symptomatic improvements[1,3,7,8]. These symptomatic improvements included breathlessness, exercise tolerance, rescue medication use and health-related quality of life[3-6].

**Total refers to all 11 IGNITE studies.*

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About Seebri® Breezhaler®
NVA237 (glycopyrronium bromide; brand name: Seebri® Breezhaler® (EU), Seebri® Inhalation Capsules (Japan); ("glycopyrronium")) is 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[18]. Glycopyrronium 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) glycopyrronium 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. Glycopyrronium 50 mcg also significantly improved shortness of breath, health-related quality of life, exacerbation risk, and exercise endurance versus

placebo[19-21]. 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[22], making it suitable for patients with airflow limitation[23]. The Breezhaler® device allows patients to hear, feel and see that they have taken the full dose correctly[18].

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

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 life[24,25]. It affects an estimated 210 million people worldwide and is projected to be the third leading cause of death by 2020[25,26]. 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 retirement and reductions in workforce participation[27].

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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