Positive results at ATS for once-daily Ultibro® Breezhaler® versus combination therapy (tiotropium plus formoterol)

- *QUANTIFY study met primary endpoint demonstrating non-inferiority of Ultibro® Breezhaler® vs tiotropium 18 mcg plus formoterol 12 mcg in improving health-related quality of life outcomes*[1,2]
- *QUANTIFY study met secondary endpoint demonstrating superiority of Ultibro® Breezhaler® vs tiotropium plus formoterol by improving lung function*[1,2]
- *Ultibro® Breezhaler® provides the convenience of a once-daily fixed-dose combination in a single inhalation device for the treatment of COPD*
- *Novartis showcases 16 respiratory abstracts at the 2014 American Thoracic Society (ATS) International Conference*

Tokyo, Japan – 21 May 2014: Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) confirms the new data announced today by Novartis from the Phase III QUANTIFY study, which demonstrated the non-inferiority of Ultibro® Breezhaler® (indacaterol/glycopyrronium,("Ultibro")) 110/50 mcg compared to tiotropium 18 mcg plus formoterol 12 mcg in terms of health-related quality of life (HRQoL) outcomes in moderate-to-severe chronic obstructive pulmonary disease (COPD) patients at week 26[1,2]. Positive results from QUANTIFY are part of 16 Novartis respiratory abstracts being presented at the American Thoracic Society (ATS) International Conference, May 16-21, 2014 in San Diego, CA, USA.

In the QUANTIFY study, which included over 900 COPD patients, once-daily Ultibro showed superior improvements in lung function (trough FEV_1) at 26 weeks compared to once-daily tiotropium plus twice-daily formoterol in moderate-to-severe COPD patients. Additionally, patients taking Ultibro were more likely to demonstrate a clinically meaningful improvement in shortness of breath and health-related quality of life (per protocol set) at 26 weeks compared to tiotropium plus formoterol. The safety and tolerability of Ultibro was comparable to the other treatment arm in the study[1,2].

COPD affects an estimated 210 million people worldwide[3] and is projected to be the third leading cause of death by 2020[4]. Symptoms can impose a significant burden on patients and reduce quality of life[5,6], but they are often inadequately managed. Treatments that are easy for patients to take and have reliable dose control whilst effectively managing the symptoms of COPD are important to improve patient outcomes[7-9].

QUANTIFY was a 26-week treatment, multicenter, randomized, parallel group, blinded study to assess the efficacy and safety of once-daily Ultibro Breezhaler in 934 patients with moderate-to-severe COPD, versus the free-combination of tiotropium 18 mcg plus formoterol 12 mcg. The primary objective was to demonstrate non-inferiority of Ultibro Breezhaler in HRQoL as assessed by the St. George's Respiratory Questionnaire-

COPD (SGRQ-C) versus tiotropium plus formoterol after 26 weeks of treatment. Secondary endpoints included transition dyspnea index (TDI) score, trough FEV_1, forced vital capacity (FVC) and safety and tolerability[1,2].

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About Ultibro® Breezhaler®

Once-daily Ultibro® Breezhaler® (EU)/ Ultibro® Inhalation Capsules (Japan) is a novel, once-daily dual bronchodilator approved as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD[10]. Ultibro is a fixed-dose combination of the long acting muscarinic antagonist (LAMA), glycopyrronium bromide (brand name: Seebri® Breezhaler®) and the long acting $beta_2$-agonist (LABA), indacaterol maleate, and was developed by Novartis under development code QVA149. Clinical trials have shown that Ultibro Breezhaler offers statistically significant improvements in bronchodilation compared to treatments widely used as current standards of care, including salmeterol/fluticasone 500/50 mcg, in patients with no history of moderate or severe exacerbations over the last year and open-label tiotropium 18 mcg[11-13]. Ultibro Breezhaler is currently approved for use in over 30 countries, including the EU, Japan, Canada, Mexico and Australia, and has been launched in 7 countries including Germany and Japan.

About Seebri Breezhaler®

Once-daily Seebri® Breezhaler® (EU)/ Seebri® Inhalation Capsules 50 mcg (Japan), (NVA237, glycopyrronium bromide), is a novel inhaled long-acting muscarinic antagonist (LAMA) indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. Seebri has been approved as a maintenance bronchodilator treatment for COPD in over 60 countries across Europe, Japan, Canada, Australia, South America, Middle East and Asia. In addition, Novartis is conducting Phase III trial for Seebri in asthma patients.

Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura.

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[4,14]. 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[5,6].

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. Geßner C *et al*. Once-Daily QVA149 Demonstrates Superior Improvements in Lung Function Compared to Tiotropium plus Formoterol: The QUANTIFY Study. [ATS abstract # 50961; Thematic Poster Session D44; Date: May 21, 2014 Time: 8:15 AM-4:30 PM].
2. Korn S *et al*. Once-Daily QVA149 Improves Dyspnea, Quality of Life and Reduces the Rate of Exacerbations Compared to Tiotropium Plus Formoterol in COPD Patients: The QUANTIFY Study. [ATS abstract # 50965; Thematic Poster Session D44; Date: May 21, 2014 Time: 8:15 AM-4:30 PM].
3. Global Alliance Against Chronic Respiratory Diseases (GARD). Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach. Available at: http://www.who.int/gard/publications/GARD_Manual/en/. [Accessed 13 May 2014].
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2014. http://www.goldcopd.org/uploads/users/files/GOLD_Report2014_Feb07.pdf. [Accessed 13 May 2014].
5. Fletcher MJ *et al*. COPD Uncovered: An International survey on the impact of chronic obstructive pulmonary disease (COPD) on a working age population. *BMC Public Health* 2011;**11**:612.
6. daCosta M *et al*. The burden of chronic obstructive pulmonary disease among employed adults. *Int J Chron Obstruct Pulmon Dis* 2012;**7**:211-219. Published online 2012 March 19. doi: 10.2147/COPD.S29280. [Accessed 13 May 2014].
7. Bryant *et al*. Improving medication adherence in chronic obstructive pulmonary disease: a systematic review. *Respiratory Research* 2013;**14**:109. Available at: http://respiratory-research.com/content/pdf/1465-9921-14-109.pdf. [Accessed 13 May 2014].
8. Chrystyn H *et al*. Impact of patients' satisfaction with their inhalers on treatment compliance and health status in COPD. *Respir Med* 2014;108(2):358-65.
9. Pavkov *et al*. Characteristics of a capsule based dry powder inhaler for the delivery of indacaterol. *CMRO* 2010;**26**; 11:2527-2533. doi:10.1185/03007995.2010.518916. [Accessed 13 May 2014].
10. EMA. 2012. Ultibro Breezhaler EU Summary of Product Characteristics. [Online] 3 October 2013. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002679/WC500151255.pdf [Accessed 13 May 2014].
11. Vogelmeier C *et al*. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes versus placebo, indacaterol, glycopyrronium, tiotropium and salmeterol/fluticasone in patients with COPD. [ATS abstract 40759; Session C45; Date: May 21, 2013 Time: 8:15 -10:45].
12. Vogelmeier C *et al*. Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes. [ERS abstract 851178; Session 82; Date: September 8, 2013 Time: 12:50-14:40].
13. Banerji D *et al*. Dual bronchodilation with once-daily QVA149 improves dyspnea and health status and reduces symptoms and rescue medication use in patients with COPD: the IGNITE trials. [ERS abstract 851388; Session 346; Date: September 10 2013 Time: 8:30-10:30].
14. Joshi A *et al*. Symptom burden in chronic obstructive pulmonary disease and cancer. *Curr Opin Pulm Med* 2012;18:97-103.

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.