



## Update on Ultibro<sup>®</sup> Breezhaler<sup>®</sup> and Seebri<sup>®</sup> Breezhaler<sup>®</sup> for COPD

**Tokyo, Japan – 29 January 2014:** Sosei Group Corporation (“Sosei”; TSE Mothers Index: 4565) confirms that an update on Ultibro<sup>®</sup> Breezhaler<sup>®</sup> (“Ultibro”) and Seebri<sup>®</sup> Breezhaler<sup>®</sup> (“Seebri”) has been provided as part of the Novartis AG FY2013 financial results announcement.

Key points from the announcement are as follow:

- Following approvals in Europe and Japan, Ultibro has been approved by Health Canada as a long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
- A Phase III clinical trial program has been initiated to evaluate once-daily NVA237 (development code for Seebri) in patients with uncontrolled asthma. Seebri has already been approved as a maintenance bronchodilator treatment for COPD in Europe, Japan, Canada and Australia.
- US filing for both Seebri and Ultibro is expected in Q4 2014.

-Ends-

### Enquiries:

Sosei Group Corporation  
Tokyo Office  
Milica STOJKOVIC,  
Investor Relations  
+81-(0)3-5210-3399  
mstojkovic@sosei.com

London Office  
Kathryn LYDON, PA to CEO & Corporate  
Communication  
+44-(0)20-7691-0983  
klydon@sosei.com

### About Seebri

Once-daily Seebri<sup>®</sup> Breezhaler<sup>®</sup> (EU)/ Seebri<sup>®</sup> 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 was first approved in the EU and Japan in September 2012 as a maintenance bronchodilator treatment for COPD; it has been approved in over 50 countries including Canada and Australia and launched in Germany, the UK, Japan and other major markets.

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

### **About Ultibro**

Once-daily Ultibro<sup>®</sup> Breezhaler<sup>®</sup> (EU)/ Ultibro<sup>®</sup> Inhalation Capsules (Japan) is an inhaled, once-daily, fixed-dose combination of the LAMA, glycopyrronium bromide and the LABA, indacaterol maleate and was developed by Novartis under the name QVA149. Dual bronchodilation with Ultibro is expected to set a new standard of care in COPD by combining the proven efficacy benefits and safety profiles of two established Novartis COPD treatments, the LABA, Onbrez<sup>®</sup> Breezhaler<sup>®</sup> (EU) /Onbrez<sup>®</sup> Inhalation Capsules 150 mcg (Japan) (indacaterol), and the LAMA, Seebri<sup>®</sup> Breezhaler<sup>®</sup> (glycopyrronium bromide).

Ultibro has been approved in Europe, Japan and Canada, and is launched in Germany, Netherlands, Denmark, Ireland and Japan.

Ultibro<sup>®</sup>, Seebri<sup>®</sup>, Onbrez<sup>®</sup> and Breezhaler<sup>®</sup> are registered trademarks of Novartis AG.

### **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<sup>1</sup>. It affects an estimated 210 million people worldwide<sup>2</sup> and is projected to be the third leading cause of death by 2020<sup>1</sup>. 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<sup>3</sup> and reductions in workforce participation<sup>3,4</sup>.

### **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](http://www.sosei.com).

### **References:**

1. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2013. <http://www.goldcopd.org/guidelinesglobal-strategy-for-diagnosis-management.html>. [Accessed 18 September 2013].
2. 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/](http://www.who.int/gard/publications/GARD_Manual/en/). [Accessed 18 September 2013].
3. 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.
4. 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 doi: 10.2147/COPD.S29280. [Accessed 18 September 2013].

### **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.*