

Sosei Heptares notes new positive Phase II data for QVM149, a potential novel inhaled combination for treating asthma, were presented at ATS 2019

- *QVM149 demonstrates significant improvements over current standard-of-care inhaled treatment for asthma*
- *Improvements in lung function versus placebo also established irrespective of administration time*

Tokyo, Japan and London, UK, 22 May 2019 – Sosei Group Corporation (“the Company”; TSE: 4565) notes that its partner Novartis presented key Phase II data for QVM149, a potential new inhaled combination therapy for asthma, at the 2019 annual international congress of the American Thoracic Society (ATS) in Dallas, USA (17–22 May 2019).

QVM149 is an investigational, once-daily, fixed dose combination asthma treatment containing indacaterol acetate, glycopyrronium bromide and mometasone furoate (IND/GLY/MF), delivered with the dose-confirming Breezhaler® inhalation device. Glycopyrronium bromide and certain intellectual property relating to its use and formulation were exclusively licensed to Novartis in April 2005 by Sosei Heptares and Vectura Group PLC (LSE: VEC). Novartis is responsible for the development and commercialization of QVM149, which is currently being investigated in a Phase III clinical program expected to complete in Q3 2019.

In two Phase II clinical studies¹, QVM149 was shown to be superior to the comparators, salmeterol/fluticasone propionate (the standard-of-care treatment) and placebo, separately by demonstrating improvement in lung function in patients with asthma. In one study, QVM149 also demonstrated improvements versus placebo irrespective of administration time of morning or evening. The safety data from both studies also suggest that QVM149 has a favorable safety and tolerability profile.

“These data continue to support QVM149’s therapeutic benefits in patients with asthma,” said **Shinichi Tamura, Chairman, President and CEO of Sosei Heptares**. “We look forward to results from the Phase III clinical program and further progress in the development of this novel inhaled combination therapy.”

The abstracts presented by Novartis at ATS 2019 are available at the links below – the presented posters and a summary of key findings have also been added to the [Science Center](#) section of our website.

¹ Phase II CQVM149B2208 study (ClinicalTrials.gov Identifier: NCT03063086)
Phase II CQVM149B2209 study (ClinicalTrials.gov Identifier: NCT03108027)

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PRESS RELEASE

[Abstract A1277/P665](#): Watz, H. *et al.* The Combination of Indacaterol / Glycopyrronium / Mometasone Furoate is Superior to High-Dose Salmeterol/Fluticasone Propionate in Improving Lung Function in Patients with Asthma

[Abstract A7081/503](#): Beier, J. *et al.* The Efficacy of the Combination Indacaterol / Glycopyrronium / Mometasone Furoate is Independent of Time of Dosing in Patients with Asthma

* *Breezhaler*[®] is a registered trademark of Novartis AG.

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About QVM149 (IND/GLY/MF)

Indacaterol acetate, glycopyrronium bromide and mometasone furoate (IND/GLY/MF) is currently in Phase III clinical development. This formulation combines comprehensive bronchodilation of indacaterol acetate (a LABA [long-acting beta agonist]) and glycopyrronium bromide (a LAMA [long-acting muscarinic receptor antagonists]) with mometasone furoate (high- or medium-dose ICS [inhaled corticosteroid]) in a precise once-daily formulation, delivered with the dose-confirming Breezhaler[®] inhalation device.

About the referenced Phase II clinical studies with QVM149

CQVM149B2208 study (ClinicalTrials.gov Identifier: NCT03063086) was a Phase II, randomized, double-blind, double-dummy, active-controlled, 3-period complete cross-over study to assess the bronchodilator effect and safety of two doses of QVM149 compared to a fixed dose combination of salmeterol/fluticasone in patients with asthma.

CQVM149B2209 study (ClinicalTrials.gov Identifier: NCT03108027) was a Phase II, randomized, double-blind, repeat dose cross-over study to assess the bronchodilator effects of once daily QVM149 following morning or evening dosing for 14 Days compared to placebo in patients with asthma.

About Sosei Heptares

We are an international biopharmaceutical group focused on the design and development of new medicines originating from its proprietary GPCR-targeted StaR[®] technology and structure-based drug design platform capabilities. The Company is advancing a broad and deep pipeline of partnered and wholly owned product candidates in multiple therapeutic areas, including CNS, immuno-oncology, gastroenterology, inflammation and other rare/specialty indications. Its leading clinical programs include partnered candidates aimed at the symptomatic treatment of Alzheimer's disease (with Allergan) and next generation immuno-oncology approaches to treat cancer (with AstraZeneca). Our additional partners and collaborators include Novartis, Pfizer, Daiichi-Sankyo, PeptiDream, Kymab and MorphoSys. The Company is headquartered in Tokyo, Japan and houses its main R&D facility in Cambridge, UK.

 **PRESS RELEASE**

“Sosei Heptares” is the corporate brand of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565).

For more information, please visit <https://www.soseiheptares.com/>
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Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development and commercialization of products. Various risks may cause Sosei Group Corporation’s actual results to differ materially from those expressed or implied by the forward-looking statements, including: adverse results in clinical development programs; 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 commercialize 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 commercialization 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.