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PRESS RELEASE

## **Sosei Heptares notes that a valid Marketing Authorization Application for QVM149, a potential new inhaled combination therapy for asthma, has been filed with the European Medicines Agency**

- *Sosei Heptares to receive US\$2.5 million milestone payment*
- *MAA filing ahead of expectations*

**Tokyo, Japan and London, UK, 24 May 2019** – Sosei Group Corporation (“the Company”; TSE: 4565) announces it has been notified today by its strategic alliance partner Novartis (SWX: NOVN) that it has submitted a valid Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for QVM149, a potential new inhaled combination therapy for asthma. The MAA filing, which was previously planned for Q4 2019, has triggered a US\$2.5 million payment to Sosei Heptares from Novartis.

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.

QVM149 is currently being investigated in Phase III/IIIb studies (IRIDIUM<sup>1</sup> and ARGON<sup>2</sup>), which are expected to complete in Q3 2019.

**Shinichi Tamura, Chairman, President and CEO of Sosei Heptares, said:** “The acceptance of the MAA submission for QVM149 is an important milestone in the development of this novel, once daily, inhaled combination therapy for asthma patients. More than one-third of asthma patients have uncontrolled disease despite the availability of multiple therapies. With the filing of the MAA for approval in Europe, we are greatly looking forward to see QVM149 become available to patients and improve the lives of those with uncontrolled asthma.”

*\* Breezhaler® is a registered trademark of Novartis AG.*

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<sup>1</sup> Phase III CQVM149B2302 study (ClinicalTrials.gov Identifier: NCT02571777)

<sup>2</sup> Phase III CQVM149B2306 study (ClinicalTrials.gov Identifier: NCT03158311)

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### About QVM149 (IND/GLY/MF)

Indacaterol acetate, glycopyrronium bromide and mometasone furoate (IND/GLY/MF) is currently in 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 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.

“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/>

LinkedIn: [@soseiheptaresco](#) | Twitter: [@soseiheptaresco](#) | YouTube: [@soseiheptaresco](#)

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 **PRESS RELEASE****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.