PRESS RELEASE

Sosei Heptares notes Enerzair® Breezhaler® approval in the European Union as a treatment for uncontrolled asthma

- *European Commission approves once-daily Enerzair® Breezhaler® (QVM149; IND/GLY/MF) in the EU, the first-in-class LABA/LAMA/ICS fixed-dose combination for patients whose asthma is uncontrolled with LABA/ICS*[1]
- *Optional digital companion with sensor and app that provide inhalation confirmation, medication reminders and access to objective data to better support therapeutic decisions also covered by EC approval*
- *Sosei Heptares to receive a milestone payment of US$5 million from Novartis and is eligible for royalties on future sales*
- *Enerzair® Breezhaler® is approved in Japan and is under regulatory review in multiple countries*

Tokyo, Japan and London, UK, 7 July 2020 – Sosei Group Corporation ("the Company"; TSE: 4565) notes that strategic alliance partner Novartis announced today that the European Commission (EC) has approved Enerzair® Breezhaler® (QVM149; indacaterol acetate, glycopyrronium bromide and mometasone furoate [IND/GLY/MF]) as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta$_2$-agonist (LABA) and a high-dose of an inhaled corticosteroid (ICS) who experienced one or more asthma exacerbations in the previous year.

Once-daily Enerzair® Breezhaler® is the first LABA/long-acting muscarinic antagonist (LAMA)/ICS fixed-dose combination available in the European Union (EU) for these patients. The approval also includes an optional digital companion with sensor and app that provides inhalation confirmation, medication reminders and access to objective data to better support therapeutic decisions.

EC approval is based on robust efficacy and safety data from over 3,000 asthma patients in Novartis' Phase III IRIDIUM study, in which once-daily Enerzair® Breezhaler® was superior to once-daily Atectura® Breezhaler® (IND/MF) in improving the lung function of patients whose asthma is uncontrolled with LABA/ICS standard-of-care treatment[2].

The EC decision is applicable to all 27 European Union member states as well as the UK, Iceland, Norway and Liechtenstein.

Once-daily Enerzair® Breezhaler® has been approved in Japan and Canada, and additional regulatory reviews are currently underway in multiple countries, including Switzerland.

The achievement of this milestone results in a payment to Sosei Heptares of US$5 million from Novartis under the terms of its 2005 Development and Licensing agreement. Sosei Heptares is

eligible to receive royalties from future sales of Enerzair® Breezhaler® in the EU and other markets in which it is approved.

The full announcement from Novartis, which includes further product and clinical information, is available at www.novartis.com.

Shinichi Tamura, President and CEO of Sosei Heptares, commented: "I would like to congratulate Novartis for achieving this important milestone with Enerzair® Breezhaler®. The addition of this new product and the novel digital companion provides a new option for many patients whose asthma remains uncontrolled despite existing therapies. We look forward to further updates in relation to filings and launches of this innovative new product in other countries over the coming year."

About Uncontrolled Asthma

Asthma affects an estimated 358 million people worldwide and can cause a significant personal, health and financial burden when not adequately controlled[3,4]. Despite current therapy, over 40% of patients with asthma at Global Initiative for Asthma (GINA) Step 3, and over 45% at GINA Steps 4 and 5 remain inadequately controlled[5,6]. Patients with uncontrolled asthma may downplay or underestimate the severity of their disease and are at a higher risk of exacerbation, hospitalization or death[7-9]. Barriers, such as less than optimal adherence, incorrect inhaler technique, treatment mismatch, safety issues with oral corticosteroids and ineligibility for biologics, have created an unmet medical need in asthma[10-13].

*About Enerzair® Breezhaler® (IND/GLY/MF) in the EU

The EC approved high-dose Enerzair® Breezhaler® (IND/GLY/MF) 150/50/160 µg once-daily as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a LABA and a high-dose of an ICS who experienced one or more asthma exacerbations in the previous year[1]. This formulation combines the bronchodilation of indacaterol acetate (a LABA) and glycopyrronium bromide (a LAMA) with mometasone furoate (ICS) in a precise once-daily formulation, delivered via the dose-confirming Breezhaler® device. Glycopyrronium bromide certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei Heptares and Vectura. Mometasone furoate is exclusively licensed to Novartis from a subsidiary of Merck & Co., Inc, Kenilworth, NJ, USA, for use in IND/GLY/MF (worldwide excluding the US).

Novartis developed the optional digital companion in collaboration with Propeller Health, which includes the Propeller Health app and sensor custom-built for the Breezhaler® device. The sensor is a CE marked Medical Device, designed and licensed to Novartis for use with the Breezhaler® inhaler worldwide. The sensor includes a microchip, a microphone, Bluetooth capabilities, an antenna and a battery. The sensor does not alter the drug delivery characteristics of the Breezhaler® inhaler itself but produces a recording of each administered dose. Based on the patient's recorded medication usage, personalized content is presented within the app to help the patient better self-manage their asthma.

References

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Enerzair®, Atectura® and Breezhaler® are registered trademarks of Novartis AG.

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About Sosei Heptares

We are an international biopharmaceutical group focused on the discovery and early development of new medicines originating from our proprietary GPCR-targeted StaR® technology and structure-based drug design platform capabilities. We are advancing a broad and deep pipeline of novel medicines across multiple therapeutic areas, including CNS, immuno-oncology, gastroenterology, inflammation and other rare/specialty indications.

We have established partnerships with some of the world's leading pharmaceutical companies, including AbbVie, AstraZeneca, Genentech (Roche), Novartis, Pfizer and Takeda, and additionally with multiple emerging biotechnology companies. Sosei Heptares is headquartered in Tokyo, Japan with R&D facilities in Cambridge, UK.

"Sosei Heptares" is the corporate brand and trademark of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565). Sosei, Heptares, the logo and StaR® are trademarks of Sosei Group companies.

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Forward-looking statements

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