PRESS RELEASE

Sosei Heptares notes that Enerzair® Breezhaler® (QVM149) has been recommended for approval in the European Union for treating uncontrolled asthma

- *Positive opinion received from European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP)*
- *Enerzair® Breezhaler® (QVM149) is a once-daily, potential first-in-class inhaled LABA/LAMA/ICS combination for asthma patients in the EU*

Tokyo, Japan and London, UK, 1 May 2020 – Sosei Group Corporation ("the Company"; TSE: 4565) notes that its strategic alliance partner Novartis (SWX: NOVN) announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended the approval in the European Union of Enerzair® Breezhaler® (QVM149; indacaterol acetate, glycopyrronium bromide and mometasone furoate [IND/GLY/MF]) as a maintenance treatment of uncontrolled asthma in adult patients. Uncontrolled patients are those whose asthma is 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.

The European Commission (EC) reviews the CHMP recommendation and usually delivers its final decision in approximately two months. If the EC follows this recommendation and approves Enerzair® Breezhaler®, it will become the first LABA/long-acting muscarinic antagonist (LAMA)/ICS fixed-dose combination for uncontrolled asthma patients. Additional regulatory filings for QVM149 are currently underway in multiple countries, including Switzerland, Japan and Canada.

The full announcement from Novartis, including data from the clinical trial programs supporting the CHMP recommendation, is available at www.novartis.com.

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 Enerzair® Breezhaler® (QVM149). Under the agreement, Sosei Heptares is entitled to certain development and sales-based milestones, and royalties on net sales upon successful commercialisation of Enerzair® Breezhaler®.

While the CHMP positive opinion does not trigger a milestone payment, Sosei Heptares will be eligible to receive a $5m milestone on final approval by the EC and thereafter a low-single digit royalty on net sales. The event reported therefore has no immediate impact on the consolidated financial results for the accounting period ending December 2020.

Shinichi Tamura, President and CEO of Sosei Heptares, commented: "The recommendation for the approval of Enerzair® Breezhaler® is a great step towards it becoming available to the many uncontrolled asthma patients in the European Union. The extensive clinical trial program conducted by Novartis demonstrated robust efficacy and safety data with once-daily IND/GLY/MF showing significant improvements in lung function over a standard-of-care therapy If approved, this novel product would become the first LABA/LAMA/ICS combination therapy for uncontrolled asthma administered using a single inhaler with additional features in-built to support treatment adherence. We look forward to the final decision by the EC in the next two months and further updates in relation to filings 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[1,2]. 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 uncontrolled[3,4]. Patients with uncontrolled asthma may downplay or underestimate the severity of their disease and are at a higher risk of exacerbation, hospitalization or death[5,6,7]. Barriers, such as treatment mismatch, safety issues with an oral corticosteroid and ineligibility for biologics, have created an unmet medical need in asthma[8,9].

References

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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 Allergan, AstraZeneca, Daiichi-Sankyo, Genentech (Roche), Novartis, Pfizer and Takeda; and with innovative biotechnology companies, including Kymab, MorphoSys and PeptiDream. Sosei Heptares is headquartered in Tokyo, Japan with R&D facilities in Cambridge, UK.

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.