PRESS RELEASE

Sosei Heptares notes Enerzair® approval in Japan – the world's first approval of this novel LABA/LAMA/ICS combination for treating bronchial asthma

- *Announcement by Novartis Pharma K. K. highlights key milestone for once-daily Enerzair® (IND/GLY/MF) complete with new sensor-enabled Breezhaler® device*
- *Sosei Heptares to receive a milestone payment from Novartis*
- *IND/GLY/MF recently recommended for approval in the European Union and is under regulatory review in other countries*

Tokyo, Japan and London, UK, 29 June 2020 – Sosei Group Corporation ("the Company"; TSE: 4565) notes that Novartis Pharma K.K., the Japan business of strategic alliance partner Novartis, announced today the world's first manufacturing and marketing approval for its Enerzair® Inhalation Capsules (medium-dose and high-dose) in Japan as a treatment of bronchial asthma (in cases requiring combination use of inhaled corticosteroid, inhaled long-acting β2-adrenergic agonist and inhaled long-acting anticholinergic agent). The achievement of this milestone will result in a payment to Sosei Heptares from Novartis under the terms of the 2005 Development and Licensing agreement.

Enerzair®, which contains the long-acting beta$_2$-agonist (LABA) indacaterol acetate, the long-acting muscarinic antagonist (LAMA) glycopyrronium bromide and the inhaled corticosteroid (ICS) mometasone furoate (IND/GLY/MF), is a LABA/LAMA/ICS combination and delivers its bronchodilating and anti-inflammatory action through treatment once per day with the Breezhaler® inhaler. The two medium-dose and high-dose specifications each contain 150 µg of indacaterol acetate and 50 µg of glycopyrronium bromide, with 80 µg and 160 µg respectively of mometasone furoate.

For the first time in Japan, a new digital device combining a sensor with the Breezhaler® inhaler is being made available. The sensor connects with a smartphone to record daily treatment doses and provide medication reminders. It also enables communication between patients and their physicians, contributing to the long-term management of insufficiently controlled asthma.

The full announcement in Japanese from Novartis Pharma K.K. is available at https://www.novartis.co.jp/news.

High-dose IND/GLY/MF received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) in April 2020. Additional regulatory reviews are currently underway in multiple countries, including Switzerland and Canada.

Shinichi Tamura, President and CEO of Sosei Heptares, commented: "I would like to congratulate Novartis for achieving this important milestone with Enerzair®. The addition of this new product and the new digital device combining a sensor with the Breezhaler® inhaler provides a new option for the treatment and long-term management of under-controlled asthma. We look forward to the final decision by the European Commission in the near future 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, including approximately 8 million people in Japan, and can cause a significant personal, health and financial burden when not adequately controlled[1,2,3]. 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[4,5]. Patients with uncontrolled asthma may downplay or underestimate the severity of their disease and are at a higher risk of exacerbation, hospitalization or death[6,7,8]. Barriers, such as treatment mismatch, safety issues with an oral corticosteroid and ineligibility for biologics, have created an unmet medical need in asthma[9,10].

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 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.

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.