PRESS RELEASE

# Sosei Heptares notes publication of Phase III IRIDIUM data in *The Lancet Respiratory Medicine* showing benefit of Enerzair® Breezhaler® (QVM149) in uncontrolled asthma

- *Enerzair® Breezhaler® (QVM149) is a first-in-class inhaled LABA/LAMA/ICS* combination for asthma patients approved in the European Union and under regulatory review in multiple other countries*

**Tokyo, Japan and London, UK, 10 July 2020** – Sosei Group Corporation ("the Company"; TSE: 4565) notes that its strategic alliance partner Novartis announced today that full results from its Phase III IRIDIUM study were published in the prestigious peer-reviewed journal *The Lancet Respiratory Medicine*. Novartis announced topline results in October, 2019.

The IRIDIUM trial met its primary endpoint with once-daily treatment with high- and medium-dose Enerzair® Breezhaler® (QVM149; indacaterol acetate, glycopyrronium bromide and mometasone furoate [IND/GLY/MF]) demonstrating statistically significant improvements in lung function compared with once-daily QMF149 (IND/MF) in patients whose asthma is uncontrolled with LABA/ICS treatment[1].

The key secondary endpoint was improvement in Asthma Control Questionnaire (ACQ-7) score for IND/GLY/MF versus IND/MF. Although both treatments delivered clinically meaningful improvements in this measure, the key secondary endpoint was not met[1]. In secondary analyses, improvements in lung function and clinically meaningful reductions in moderate-to-severe and severe asthma exacerbation rates were observed with high-dose IND/GLY/MF compared to high-dose salmeterol xinafoate/fluticasone propionate (Sal/Flu)[1].

The overall incidence of adverse events (AE) and serious adverse events (SAE) for IND/GLY/MF and IND/MF in the IRIDIUM study were generally low and comparable among treatment groups. Asthma exacerbation was the most reported AE and SAE[1].

Enerzair® Breezhaler® is approved in the EU, Japan and Canada. Further regulatory reviews are currently underway in other countries.

IND/GLY/MF will be administered via the dose-confirming Breezhaler® device, which enables once-daily inhalation using a single inhaler. IND/GLY/MF is the first asthma treatment in the EU that can be prescribed together with a digital companion; the Propeller Health app and a sensor custom-built for the Breezhaler® device. The digital companion will provide patients with inhalation confirmation, medication reminders and access to objective data that can be shared with their physician in order to help them make better therapeutic decisions.

The full announcement from Novartis, including data from the clinical trial programs supporting the EC approval, 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. Novartis is responsible for the development and commercialization of Enerzair® Breezhaler® (QVM149). Under the agreement, Sosei Heptares is entitled to certain development milestones, and royalties on net sales upon successful commercialisation of Enerzair® Breezhaler®.

**Shinichi Tamura, President and CEO of Sosei Heptares, commented:** "The IRIDIUM data are compelling and show a clear benefit of once-daily IND/GLY/MF in treating patients whose asthma is uncontrolled despite receiving current standard of care. These data suggest that this LABA/LAMA/ICS combination could make a positive difference to the lives of the significant proportion of asthma patients who continue to experience debilitating symptoms."

**Abbreviations used: LABA – long acting beta$_2$-agonist (e.g. IND and Sal); LAMA – long-acting muscarinic antagonist (e.g. GLY); ICS - inhaled corticosteroid (e.g. MF and Flu)*

## 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[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 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[9-12].

## References


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Enerzair® 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 neurology, immunology, gastroenterology and inflammatory diseases.

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 technology 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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