PRESS RELEASE

# Sosei Heptares notes Phase IIIb ARGON study with Enerzair® Breezhaler® (QVM149) meets primary endpoint in patients with uncontrolled asthma

- *Once-daily Enerzair® Breezhaler® (QVM149; IND/GLY/MF) met primary endpoint, demonstrating non-inferiority to a free combination of twice-daily Sal/Flu plus once-daily Tio in improving quality of life in people with uncontrolled asthma*[1]
- *IND/GLY/MF recently received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) and is currently under regulatory review in multiple countries*
- *If approved, once-daily IND/GLY/MF will be the first LABA/LAMA/ICS fixed-dose combination for patients whose asthma is uncontrolled with LABA/ICS treatment and could provide an effective and convenient alternative to the current standard-of-care regimen*

**Tokyo, Japan and London, UK, 5 June 2020** – Sosei Group Corporation ("the Company"; TSE: 4565) notes that its strategic alliance partner Novartis (SWX: NOVN) has announced that full results from the Phase IIIb ARGON study were published online in *Respiratory Medicine*[1].

The Phase IIIb open label ARGON study showed that once-daily treatment with single inhaler, high- and medium-dose Enerzair® Breezhaler® (QVM149; indacaterol acetate, glycopyrronium bromide and mometasone furoate [IND/GLY/MF]) demonstrated non-inferiority to a free combination of twice-daily, high-dose salmeterol xinafoate/fluticasone propionate (Sal/Flu) plus once-daily tiotropium (Tio), delivered in two different devices, in improving quality of life in people with uncontrolled asthma[1]. Among secondary analyses, improvements in lung function, asthma control, health status, and reductions in moderate exacerbations were observed with high-dose once-daily IND/GLY/MF compared to high-dose Sal/Flu plus Tio[1].

The ARGON study assessed IND/GLY/MF, a once-daily, fixed-dose combination of a long-acting beta-2 agonist (LABA), a long-acting muscarinic antagonist (LAMA) and an inhaled corticosteroid (ICS) in high- (150/50/160 µg) and medium- (150/50/80 µg) doses, delivered via the dose-confirming Breezhaler®, compared with a free combination of twice-daily high-dose Sal/Flu (50/500µg) plus once-daily Tio (5µg) in patients with asthma not adequately controlled on current inhaled therapies, over 24 weeks of active treatment[1].

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 Japan.

The full announcement from Novartis on the results of the ARGON Phase IIIb study is available at www.novartis.com.

The event reported today does not generate a milestone payment and 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 results from the ARGON Phase IIIb study add to the extensive clinical data that Novartis has generated with once-daily IND/GLY/MF. These data show the potential of this novel combination product as an effective and convenient therapy in patients with uncontrolled asthma. We look forward to the final decision by the EC and other Health Authorities on the potential first approvals of once-daily IND/GLY/MF in the weeks ahead."

## 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 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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PRESS RELEASE

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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.

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