PRESS RELEASE

Sosei Heptares notes presentation of post hoc analysis showing high-dose Enerzair® Breezhaler® reduces asthma exacerbations versus medium-dose, complementing key pivotal IRIDIUM study findings

- *Analysis presented at the European Respiratory Society (ERS) Virtual International Congress 2020*

Tokyo, Japan and London, UK, 7 September 2020 – Sosei Group Corporation ("the Company"; TSE: 4565) notes that its strategic alliance partner Novartis announced today that high-dose, once-daily Enerzair® Breezhaler® (indacaterol acetate, glycopyrronium bromide and mometasone furoate [IND/GLY/MF]) significantly reduces both moderate-to-severe and severe asthma exacerbation rates in patients whose asthma is uncontrolled on medium- or high-dose LABA/ICS*, when compared with a once-daily medium-dose of the same treatment.

The post hoc analysis – presented at the European Respiratory Society (ERS) Virtual International Congress 2020 – showed high-dose Enerzair® Breezhaler® (150/50/160 µg) significantly reduced the annualized rate of moderate-to-severe asthma exacerbations by 21% (p=0.026) and severe exacerbations by 31% (p=0.003) in asthma patients not adequately controlled on current inhaled therapies, compared with medium-dose (150/50/80 µg) over 52 weeks[1].

High-dose Enerzair® Breezhaler® also reduced the annualized rate of all exacerbations (mild, moderate and severe) by 14% (p=0.132) compared with medium-dose, but this finding was not statistically significant. Both doses tested presented with a favorable safety and tolerability profile.

The post hoc analysis complements findings from Novartis' pivotal Phase III IRIDIUM study, recently published in *The Lancet Respiratory Medicine*[2]. The data also showed the safety profile for high-dose Enerzair® Breezhaler® was in line with previous studies in the Phase III/IIIb PLATINUM clinical development program.

Enerzair® Breezhaler®, which includes an optional digital companion (sensor and app) is the first LABA/LAMA/ICS fixed-dose combination approved for patients whose asthma is uncontrolled with a LABA/ICS[3]. The product is approved in the European Union, Japan and Canada. Further regulatory reviews are currently underway in other countries.

The full announcement from Novartis 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 commercialization of Enerzair® Breezhaler®.

Shinichi Tamura, President and CEO of Sosei Heptares, commented: "A significant proportion of asthma patients do not achieve optimal symptom control on existing therapies. These latest findings from a post-hoc analysis of the IRIDIUM study not only support the use of high-dose Enerzair® Breezhaler® to significantly improve lung function and reduce exacerbations relative to standard of care LABA/ICS, but also its potential as a step-up treatment option in patients with uncontrolled asthma."

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

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[4,5]. 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[6,7]. Patients with uncontrolled asthma may downplay or underestimate the severity of their disease and are at a higher risk of exacerbation, hospitalization or death[8-10]. 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[11-14].

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.

For more information, please visit https://www.soseiheptares.com/
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