PRESS RELEASE

Sosei Heptares notes the announcement of positive results from Phase III IRIDIUM study of inhaled combination QVM149 in patients with uncontrolled asthma

- *Primary endpoint was met, with once-daily QVM149 demonstrating statistically significant improvement in lung function versus QMF149*[1,2]
- *Further data findings from other QVM149 clinical studies presented by Novartis at European Respiratory Society (ERS) International Congress 2019*

Tokyo, Japan and London, UK, 1 October 2019 – Sosei Group Corporation ("the Company"; TSE: 4565) notes that Novartis has announced positive results from its Phase III IRIDIUM trial.

The results showed that the investigational, once-daily, inhaled combination QVM149 (indacaterol acetate, glycopyrronium bromide* and mometasone furoate or IND/GLY/MF) achieved a superior improvement in lung function than QMF149 (indacaterol acetate and mometasone furoate or IND/MF) in asthma patients who were uncontrolled on treatment with a long-acting beta agonist/inhaled corticosteroid (LABA /ICS)[1].

In meeting the primary endpoint, QVM149 was shown to be superior to QMF149 in improving trough forced expiratory volume in one second (FEV_1) after 26 weeks. QVM149 was generally well tolerated, and safety was comparable across treatment arms[1].

The key secondary endpoint was improvement in Asthma Control Questionnaire (ACQ-7) score for QVM149 versus QMF149. Tested treatments delivered clinically meaningful improvements in this measure of symptoms from baseline at Week 26, but the key secondary endpoint was not met[1]. Among other secondary endpoints, IRIDIUM explored reduction of asthma exacerbation rates, where a substantial reduction was observed in moderate-to-severe and severe asthma exacerbation rates with QVM149 compared with an established LABA/ICS standard of care (twice-daily salmeterol/fluticasone 50/500 µg)[1].

Detailed results from the IRIDIUM trial will be presented at upcoming medical congresses.

As previously announced, the regulatory submission for QVM149 was accepted for review by the European Medicines Agency in May 2019. QVM149 is also being investigated in the Phase IIIb ARGON study[3], which compares it with a combination of salmeterol/fluticasone and tiotropium. Results from the completed ARGON study will be announced after the data are analyzed.

*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 QVM149. Under the agreement, Sosei Heptares is entitled to certain development and sales-based milestones, and

royalties on net sales upon successful commercialisation of QVM149. The event reported today, however, does not generate a milestone payment and therefore has no immediate impact on the consolidated financial results for the accounting period ending December 2019.

Shinichi Tamura, Chairman, President and CEO of Sosei Heptares, said: "We are pleased to see that QVM149, a novel combination therapy, continues to generate positive clinical data that support its potential to become new treatment option for patients with uncontrolled asthma. We look forward to additional results from this study and others, such as the ARGON study, which we hope will further demonstrate the clinical benefits of QVM149 for these patients."

Further clinical data from the broader development program of Novartis with QVM149 are being presented at the European Respiratory Society (ERS) International Congress 2019 (28 September – 2 October, Madrid, Spain). The abstracts and posters are available to view on the ERS International Congress 2019 website.

About the IRIDIUM Clinical Trial[2]

IRIDIUM is a Phase III, multicenter, randomized, double-blind, parallel-group study, designed to compare the efficacy and safety of QVM149 (IND/GLY/MF) with QMF149 (IND/MF) in patients with asthma. The purpose of the trial was to evaluate the efficacy and safety of two different doses of IND/GLY/MF (150/50/80 µg and 150/50/160 µg) versus two respective IND/MF doses (150/160 µg and 150/320 µg) in uncontrolled patients with asthma, as determined by pulmonary function testing and effects on asthma control.

All patients were required to be symptomatic at screening despite being on treatment with medium or high stable doses of LABA/ICS. Approximately 3,092 male and female adult patients with asthma were randomized 1:1:1:1:1 (approximately 618 patients in each of the treatment groups)[1] to receive either:

- IND/GLY/MF 150/50/80 µg (once daily)
- IND/GLY/MF 150/50/160 µg (once daily)
- IND/MF 150/160 µg (once daily)
- IND/MF 150/320 µg (once daily)
- Salmeterol xinafoate/fluticasone propionate (SFC) 50/500 µg (twice daily, via Accuhaler®)

The primary objective of this study was to demonstrate superiority of either IND/GLY/MF 150/50/80 µg versus IND/MF 150/160 µg or IND/GLY/MF 150/50/160 µg versus IND/MF 150/320 µg, all delivered once daily, in improving trough FEV_1 (volume of air that can be forced out in the first second of expiration approximately 24 hours post administration of study drug) after 26 weeks of treatment in patients with asthma.

The key secondary objective was to demonstrate the superiority of either IND/GLY/MF 150/50/80 µg versus IND/MF 150/160 µg or IND/GLY/MF 150/50/160 µg versus IND/MF 150/320 µg, in improvement of ACQ-7 after 26 weeks of treatment in patients with asthma.

Other secondary endpoints also included reduction of exacerbation rate, comparing IND/GLY/MF 150/50/80 µg to IND/MF 150/160 µg and IND/GLY/MF 150/50/160 µg to IND/MF 150/320 µg. Exacerbation rate was also measured for both doses of IND/GLY/MF compared to SFC (50/500 µg).

Full information on all of the endpoints measured in the study can be accessed at ClinicalTrials.gov (Identifier: NCT02571777).

About Uncontrolled Asthma

Patients with asthma who have poor symptom control or frequent exacerbations despite current therapy may be considered uncontrolled. International guidelines such as ERS/ATS criteria developed by The European Respiratory Society/American Thoracic Society Task Force and Global Initiative for Asthma (GINA) provide exact definitions depending on the frequency of symptoms, reliever use, activity limitation and exacerbations[4,5].

Despite current therapy, over 40% of patients with asthma at GINA Step 3, and over 45% at GINA Steps 4 and 5 remain uncontrolled[4,6]. Uncontrolled asthma patients may downplay or underestimate the severity of their disease, and are at a higher risk of exacerbation, hospitalization or death[7,8,9]. Unresolved barriers such as treatment mismatch, safety issues with oral corticosteroid, and ineligibility for biologics have created an unmet medical need in asthma[10,11].

References

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PRESS RELEASE

About Sosei Heptares

We are an international biopharmaceutical group focused on the design and 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. Our leading clinical programs include partnered candidates aimed at the symptomatic treatment of Alzheimer's disease (with Allergan) and next-generation immuno-oncology approaches to treat cancer (with AstraZeneca). Our additional partners and collaborators include Takeda, Genentech, Novartis, Pfizer, Daiichi-Sankyo, PeptiDream, Kymab, MorphoSys. Sosei Heptares is headquartered in Tokyo, Japan with R&D facilities in Cambridge, UK.

"Sosei Heptares" is the corporate brand of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565).

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