Sosei Heptares to receive US$15 million milestone payment from AstraZeneca with first partnered program moving towards Phase 2

Milestone achieved with next generation immuno-oncology candidate AZD4635, a novel adenosine 2A receptor antagonist

Tokyo, Japan and London, UK, 7 January 2019 – Sosei Group Corporation (“the Company”; TSE: 4565), announces it has been notified today by its strategic alliance partner AstraZeneca (LSE: AZN) that it has reached a clinical development milestone with its partnered next generation immuno-oncology candidate AZD4635, triggering a US$15 million payment from AstraZeneca.

AZD4635 is a potent and selective, orally available, small molecule adenosine 2A receptor antagonist discovered by the Company and exclusively licensed to AstraZeneca globally in 2015. The candidate has been advancing through a Phase 1 clinical program as a single agent and in combination with AstraZeneca’s anti-PD-L1 antibody durvalumab (IMFINZI®) in patients with solid tumours.

The clinical study to date has established the maximum-tolerated dose of AZD4635 as a single agent and in combination with durvalumab. The study has progressed successfully to the point where the therapeutic potential of AZD4635 is being explored in multiple solid tumours. As a result, AstraZeneca is moving the trial towards Phase 2, thereby triggering the milestone payment to Sosei Heptares. Headline data from the Phase 1 study is planned to be presented at a scientific congress in 2019.

“At AstraZeneca, we are exploring next generation immuno-oncology approaches by seeking to develop novel combinations that overcome key immunosuppressive mechanisms, and thereby expand the potential for anti-tumour activity of immune checkpoint inhibition. It is increasingly recognised that the adenosine pathway is critical in tumour immunosuppression and AZD4635 complements our portfolio in this area,” said Susan Galbraith, Senior Vice President and Head of Oncology, Innovative Medicines and Early Development (IMED) Biotech Unit at AstraZeneca.

Dr. Malcolm Weir, Executive VP and Chief R&D Officer, said: “Adenosine production in the tumour microenvironment is becoming well-recognised as a key survival mechanism employed by tumour cells to evade immune detection and destruction. Our A2A antagonist AZD4635, which aims to block this mechanism and make tumour cells vulnerable again to the immune system, has made very encouraging and rapid progress in partnership with AstraZeneca, a world leader in immuno-oncology. We believe this is a very exciting candidate and look forward to results from these initial clinical studies in due course.”

The Company expects to receive the $15 million payment by the end of the first quarter ended 31 March 2019.
PRESS RELEASE

About adenosine-mediated immune evasion and A2A receptor antagonists

Tumour cells have evolved mechanisms to evade the immune system, including through the production of a natural anti-inflammatory molecule called adenosine. By stimulating A2A receptors, adenosine prevents T-cells within the immune system from being activated and reduces their ability to destroy cancer cells. Blocking A2A receptors can therefore promote the anti-cancer response of T-cells within the tumour microenvironment.

In preclinical studies, AZD4635 has been shown to be effective in reversing adenosine-mediated T-cell suppression and enhancing anti-tumour immunity. Blockade of A2A signalling with AZD4635 was found to reduce tumour growth when used alone and in combination with anti-PD-L1 checkpoint inhibitors (presented at the 2017 American Association of Cancer Research Annual Meeting).

About the clinical studies with AZD4635

AZD4635 is in a Phase 1 open-label, multicenter study as a single agent and in combination with a PD-L1 antibody, durvalumab in patients with solid malignancies. ClinicalTrials.gov Identifier: NCT02740985

AZD4635 is also in a Phase 1/2a open-label, multicenter, study in combination with oleclumab (formerly MEDI9447), an anti-CD73 antibody developed by MedImmune, in patients with previously treated advanced EGFR-driven non-small cell lung cancer (NSCLC). ClinicalTrials.gov Identifier: NCT03381274

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About Sosei Heptares

We are an international biopharmaceutical group focused on the design and development of new medicines originating from its proprietary GPCR-targeted StaR® technology and structure-based drug design platform capabilities. The Company is advancing a broad and deep pipeline of partnered and wholly owned product candidates in multiple therapeutic areas, including CNS, immuno-oncology, gastroenterology, inflammation and other rare/specialty indications. Its 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 Novartis, Pfizer, Daiichi-Sankyo, PeptiDream, Kymab and MorphoSys. The Company is headquartered in Tokyo, Japan with R&D facilities in Cambridge, UK and Zurich, Switzerland.

“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 www.soseiheptares.com.
PRESS RELEASE

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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.