

Sosei Heptares and Cancer Research UK Announce the Dosing of the First Patient in a Phase I/IIa Trial with Cancer Immunotherapy Drug HTL0039732

- *HTL0039732 is a novel EP4 antagonist designed by Sosei Heptares with potential to treat a wide range of cancers in combination with other immunotherapies*

Tokyo, Japan, London and Cambridge, UK, 10 August 2023 – Sosei Group Corporation (“the Company”; TSE: 4565), the world-leader in GPCR-focused structure-based drug design (SBDD) and development, and Cancer Research UK, the world’s largest independent funder of cancer research, today announce that the first patient has been dosed in a Phase I/IIa clinical trial evaluating Sosei Heptares’ orally available small molecule cancer immunotherapy drug HTL0039732 for advanced solid tumors.

HTL0039732 works by blocking signalling through a specific type of prostaglandin receptor, the prostaglandin E2 (PGE2)-type prostanoid receptor 4 (EP4). In cancer, PGE2 acts in the tumor microenvironment to trigger cancer cells to evade the immune system. Targeting EP4 to block the effects of PGE2 increases the ability of the immune system to detect and control cancer cells and makes HTL0039732 a potential candidate to treat patients with cancers that generally do not respond well to current immunotherapies, such as microsatellite stable* colorectal, gastroesophageal, head and neck, and castrate-resistant prostate cancer. Positive results from the trial will bring effective treatment closer to these underserved patient populations.

Cancer Research UK’s Centre for Drug Development (CDD) is sponsoring, designing and conducting the Phase I/IIa trial with three main objectives: to define the toxicity, tolerability and pharmacokinetics of HTL0039732, to identify the recommended dose for Phase II studies, and to assess its antitumor activity as a monotherapy and in combination with the PD-L1 inhibitor atezolizumab. Phase IIa of the trial will expand the optimal combination dose in up to four cohorts in specified cancer indications. Sosei Heptares holds a license to the results generated under the trial to continue the clinical development and commercialization of HTL0039732.

Chief Investigator Dr. Bristi Basu, University of Cambridge, and Co-Chief Investigator Dr. Debashis Sarker, King’s College London, are leading the trial. Patient recruitment has been initiated in the UK at Cambridge University Hospitals and Guy’s and St Thomas’ NHS Foundation Trusts, with additional sites across the Experimental Cancer Medicine Centre (ECMC) network to open soon.

Please refer [here](#) for more details on this trial.

Matt Barnes, President of Heptares Therapeutics and Head of UK R&D, said: “We are very pleased to be collaborating with Cancer Research UK to advance HTL0039732 into clinical development.

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This novel oral small molecule drug candidate was rationally designed using our SBDD platform and has the potential to become a best-in-class approach to enhance the efficacy of immunotherapies used to treat many cancer patients.”

Dr. Bristi Basu, University of Cambridge, said: “We are excited to be opening a new UK clinical trial using HTL0039732 to target a protein called EP4, a member of the prostaglandin receptor family that has been implicated in creating the immunosuppressive environment which promotes tumor growth in multiple cancer types. By studying HTL0039732 alone and in combination with immunotherapy, we aim to understand more about how to optimize modulation of the immune system to fight cancers. We hope that this EP4-targeting approach will deliver a promising route to improving treatment options for patients with a broad range of cancers.”

Dr. Nigel Blackburn, Director of Cancer Research UK’s CDD, said: “We are delighted to have reached this next significant milestone in our partnership with Sosei Heptares. The fact that immunotherapy works for some patients but not others means we desperately need more trials like this to open up potentially life-saving treatment options to more people.”

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted HTL0039732 an Innovation Passport, the first step in its Innovative and Licensing Access Pathway (ILAP), which aims to improve patient access to new medicines by reducing the time to market. The MHRA grants Innovation Passports to medicines that treat life-threatening or seriously debilitating conditions, and where there is a significant patient or public health need.

-ENDS-

Notes to editors

*Approximately 80–85% of colorectal cancer patients are classified as ‘microsatellite stable’ (MSS), which means they have low instability in short, repeated sequences of DNA in their tumours, known as microsatellites. MSS tumours often exist in an environment that suppresses the immune system and do not respond well to immunotherapies.

About the agreement between Cancer Research UK and Sosei Heptares

Cancer Research UK and Sosei Heptares signed a Clinical Trial and Licence Agreement in July 2022 to allow Cancer Research UK’s Centre for Drug Development (CDD) to sponsor, design and execute a first-in-human Phase I/IIa clinical trial of HTL0039732. Sosei Heptares was responsible for enabling activities and other pre-clinical studies before the trial began and holds a license to the results generated to continue the clinical development and commercialization of the drug. The CDD was responsible for obtaining the Clinical Trial Authorisation.

About Cancer Research UK’s Centre for Drug Development

Cancer Research UK has an impressive record of developing novel treatments for cancer. The Cancer Research UK Centre for Drug Development has been pioneering the development of new cancer treatments for 25 years, taking over 140 potential new anti-cancer agents into clinical trials

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in patients. It currently has a portfolio of 21 new anti-cancer agents in preclinical development, Phase I or early Phase IIa clinical trials. Six of these new agents have made it to market including temozolomide for brain cancer, abiraterone for prostate cancer and rucaparib for ovarian cancer. Two other drugs are in late development Phase III trials. www.cruk.org.uk/cdd

About Cancer Research UK

- Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research.
- Cancer Research UK's pioneering work into the prevention, diagnosis and treatment of cancer has helped save millions of lives.
- Cancer Research UK receives no funding from the UK government for its life-saving research. Every step it makes towards beating cancer relies on vital donations from the public.
- Cancer Research UK has been at the heart of the progress that has already seen survival in the UK double in the last 40 years.
- Today, 2 in 4 people survive their cancer for at least 10 years. Cancer Research UK's ambition is to accelerate progress so that by 2034, 3 in 4 people will survive their cancer for at least 10 years.
- Cancer Research UK supports research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses.
- Together with its partners and supporters, Cancer Research UK's vision is to bring forward the day when all cancers are cured.

For further information about Cancer Research UK's work or to find out how to support the charity, please call 0300 123 1022 or visit www.cancerresearchuk.org. Follow us on Twitter and Facebook.

About Sosei Heptares

Sosei Heptares is a fully integrated biopharmaceutical company focused on bringing life-changing medicines based on world-class science to patients globally. Our vision is to become one of Japan's global biopharmaceutical champions.

Our global business combines our world-leading GPCR-targeted StaR® technology, structure-based drug design and early development capabilities in the UK with a highly experienced clinical development capability and a commercial operation in Japan.

We are leveraging these capabilities to generate and advance a broad and deep pipeline of novel medicines across multiple therapeutic areas, including neurology, immunology, gastroenterology and inflammatory diseases. We intend to develop these opportunities for patients in Japan and globally both internally and through our partnerships with global biopharmaceutical companies and emerging technology companies.

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Sosei Heptares operates from key locations in Tokyo and Osaka (Japan), London and Cambridge (UK) and Seoul (South Korea).

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