

# PRESS RELEASE

# Sosei Heptares to receive US\$2.5 million milestone payment from Formosa Pharmaceuticals

- Payment follows IND approval from US FDA for first-in-human clinical trial of APP13007 for post-operative inflammation of the eye
- Sosei Heptares remains eligible to receive undisclosed milestone payments based on the progression of Activus' pipeline at Formosa

Tokyo, Japan and London, UK, 18 July 2019 – Sosei Group Corporation ("the Company"; TSE: 4565) announces that Formosa Pharmaceuticals, Inc. ("Formosa") has received approval from the US Food and Drug Administration ("FDA") of its Investigational New Drug ("IND") application for APP13007 to commence a first-in-human ("FIH") clinical trial in the United States. APP13007 is a nanoparticle formulation of the corticosteroid clobetasol in development for the treatment of post-operative inflammation of the eye. The milestone has triggered a US\$2.5 million payment to Sosei Heptares from Formosa.

APP13007 was originally designed and developed at Activus Pharma Inc. ("Activus"), formerly a wholly owned subsidiary of the Company. Activus was divested in August 2017 to Formosa, a wholly owned subsidiary of Formosa Laboratories, Inc., a leading manufacturer of Active Pharmaceutical Ingredients ("APIs") listed on the Taiwan Stock Exchange. The divestment was part of Sosei Heptares' redirected growth strategy towards the design and development of new medicines originating from its proprietary GPCR-targeted StaR® technology and structure-based drug design platform capabilities.

By this transfer of all voting stocks, Sosei Heptares received US\$3.5 million plus JPY 5 million in upfront cash on signing the agreement and is entitled to receive undisclosed milestone payments based on progression of Activus' pipeline as well as royalties from the commercialization of certain products should they reach the market.

Activus was originally developing APP13007 by applying its patented proprietary APNT (Activus Pure Nanoparticle Technology) to the corticosteroid clobetasol propionate to create a novel nanoparticle formulation for treating post-operative inflammation of eye. Since the divestment, Formosa has progressed the development of APP13007 and is now planning FIH trials in the United States.

Shinichi Tamura, Chairman, President and CEO of Sosei Heptares, said: "We are pleased to see the encouraging progress that Formosa is making with the development of APP13007 as evidenced by the IND approval to begin FIH clinical trials. Formosa is well positioned to advance new drug candidates using the APNT platform to generate new products for patients and value for stakeholders. We continue to wish the team at Formosa all the best in its future business endeavors."



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## **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 Genentech, Novartis, Pfizer, Daiichi-Sankyo, PeptiDream, Kymab and 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 <a href="https://www.soseiheptares.com/">https://www.soseiheptares.com/</a> LinkedIn: @soseiheptaresco | Twitter: @soseiheptaresco | YouTube: @soseiheptaresco

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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.