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## Sosei Heptares starts new clinical development program

First subject dosed in Phase I study of HTL0030310, a selective SSTR5 (somatostatin 5) receptor agonist in development to treat endocrine disorders

**Tokyo, Japan and London, UK, 20 February 2019** – Sosei Group Corporation (“the Company”; TSE: 4565), announces that the first healthy subject has been dosed with a novel small molecule HTL0030310 in a Phase I clinical study, marking the start of a new in-house clinical program targeting endocrine disorders, including Cushing’s disease.

HTL0030310 is a potent and selective agonist of the SSTR5 (somatostatin 5) receptor and the sixth molecule designed by the Company using its GPCR Structure-Based Drug Design (SBDD) platform to enter clinical development.

HTL0030310 has been designed to modulate the excess release of hormones from adenomas (benign tumors) of the pituitary gland. Highly elevated plasma levels of pituitary hormones result in a number of serious endocrine disorders, including Cushing’s Disease. Cushing’s disease is characterized by excessive cortisol release, crucial in regulating metabolism, maintaining cardiovascular function and helping the body respond to stress.

A key design feature of HTL0030310 is its significant selectivity for SSTR5 over SSTR2. This selectivity is expected to improve the balance of efficacy vs. dose-limiting side effects and therefore, presents an opportunity to develop a best-in-class medicine for patients with Cushing’s disease, in particular.

The clinical trial with HTL0030310 is a double-blind, randomised, placebo-controlled first-in-human study in which single ascending subcutaneous doses of HTL0030310 will be administered to healthy male and female adult subjects. The study is being conducted in the UK and will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of HTL0030310 in up to 64 subjects. Preliminary results are expected in the second half of 2019 and will provide a first insight into the effects of HTL0030310 on the control of glucose and other endocrine hormones and the potential to target Cushing’s disease and other endocrine disorders.

**Dr. Malcolm Weir, Executive VP and Chief R&D Officer, said:** “HTL0030310 is a novel and highly selective molecule, and is the sixth candidate originating from our SBDD platform to advance into human trials. We are not only pleased to begin this new study but also delighted with the productivity of our unique platform to generate attractive candidates targeting GPCRs involved in multiple diseases. These candidates present new prospects for our emerging proprietary pipeline, as well as unique opportunities for partnering, and provide a solid foundation to execute our strategy.”

### About Cushing's disease

Cushing's disease is a debilitating endocrine disorder caused by the overproduction of the hormone cortisol and is often triggered by a pituitary adenoma (benign tumour) secreting excess

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adrenocorticotrophic hormone (ACTH). Cortisol has a crucial role regulating metabolism, maintaining cardiovascular function and helping the body respond to stress. Symptoms may include weight gain, central obesity, a round, red full face, severe fatigue and weakness, striae (purple stretch marks), high blood pressure, depression and anxiety. Cushing's disease affects 10-15 individuals per million people every year, most commonly adults between 20 to 50 years and women more often than men. The first line and most common treatment approach for Cushing's disease is surgical removal of the pituitary tumor followed by radiotherapy and drug therapy designed to reduce cortisol production.

Ref: [American Association of Neurological Surgeons \(AANS\)](#)

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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<sup>®</sup> 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 <https://www.soseiheptares.com/>

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### Enquiries:

#### Sosei Heptares

Investor Relations and Corporate Communications

Shinichiro Nishishita, Yu Okada

+81 (0)3 5210 3399

[IR@SoseiHeptares.com](mailto:IR@SoseiHeptares.com)

#### Citigate Dewe Rogerson (for international media)

Mark Swallow, David Dible

+44 (0)20 7638 9571

[SoseiHeptares@citigatedewerogerson.com](mailto:SoseiHeptares@citigatedewerogerson.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.