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PRESS RELEASE

## Sosei Heptares Initiates Phase 1 Trial with Novel Small-Molecule CGRP Antagonist under Collaboration with Biohaven

- *First clinical trial with lead candidate HTL0022562 (BHV3100) to be conducted by Sosei Heptares*
- *Candidate discovered by Sosei Heptares and developed successfully through preclinical development demonstrating promising and differentiated properties to target CGRP-mediated disorders*
- *Tenth GPCR-targeted drug candidate overall generated from Sosei Heptares' structure-based drug design (SBDD) platform to enter clinical development*

Tokyo, Japan and Cambridge, UK, 23 June 2021 – Sosei Group Corporation (“the Company”; TSE: 4565) today announces that the first healthy subject has been dosed with HTL0022562 in a Phase 1 clinical study. HTL0022562 (also known as BHV3100) is a novel, small molecule CGRP\* receptor antagonist discovered by Sosei Heptares and the lead compound in a portfolio of CGRP antagonists licensed to Biohaven Pharmaceutical Holding Company Ltd. (“Biohaven”, NYSE: BHVN) in December 2020 for development as new therapies for CGRP-mediated disorders.

The trial is a Phase 1, randomized, double-blind, placebo-controlled, first-in-human study to evaluate the safety, tolerability, and pharmacokinetics of a single ascending dose and multiple ascending doses of subcutaneous HTL0022562 in healthy adult subjects. The trial aims to enroll 88 subjects at a single center in the UK and is expected to complete in 2022.

Sosei Heptares has advanced HTL0022562 successfully through a preclinical development program demonstrating its promising and differentiated properties for further investigation in human trials.

Under the global collaboration and license agreement with Biohaven, Sosei Heptares will conduct the Phase 1 clinical trial itself, receiving a milestone payment for its initiation, and is also eligible for development costs for conducting the trial. Biohaven will lead all future studies and development activities and Sosei Heptares will be eligible for further milestone payments and royalties.

Although the event reported today has no significant impact on the consolidated financial results for the accounting period ending 31 December 2021, the Company considers that an important developmental milestone has been achieved with HTL0022562 becoming the tenth drug candidate overall generated from Sosei Heptares' SBDD platform to enter clinical development, and therefore makes this announcement.

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**Tim Tasker, Executive Vice President and Chief Medical Officer of Sosei Heptares, said:** “We are pleased to initiate this new clinical trial with HTL0022562 following the successful discovery and preclinical development work conducted by Sosei Heptares. We are also delighted at the speed of progress and the positive collaborative approach that has developed between our team and our partners at Biohaven and the confidence they have shown in our early clinical development capabilities. Together, we are committed to developing this novel differentiated agent to treat CGRP-mediated diseases with unmet need.”

*\*Abbreviations used: CGRP - calcitonin gene-related peptide*

**-ENDS-**

### **About the Agreement with Biohaven**

Sosei Heptares and Biohaven entered a global collaboration and license agreement in December 2020 under which Biohaven received exclusive global rights to develop, manufacture and commercialize a portfolio of novel, small-molecule CGRP receptor antagonists discovered by Sosei Heptares for the treatment of CGRP-mediated disorders. Sosei Heptares received an upfront payment of US\$10 million on signing in cash and Biohaven common shares and is eligible to receive additional research funding, up to US\$370 million in development, regulatory and commercialization milestone payments, plus tiered royalties on net sales of products resulting from the collaboration.

### **About CGRP**

CGRP is an important neuropeptide believed to be involved in multiple neuro-inflammatory and neuro-immune diseases. CGRP receptor antagonism interrupts pathologic signals in CGRP-mediated diseases, such as migraine. Following the success of this approach in migraine, Biohaven is exploring the potential of this approach in other neuro-inflammatory and neuro-immune diseases, including COVID-19.

### **About Sosei Heptares**

We are an international biopharmaceutical group focused on the discovery and early 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 neurology, immunology, gastroenterology and inflammatory diseases.

We have established partnerships with some of the world’s leading pharmaceutical companies, including AbbVie, AstraZeneca, Biohaven, Genentech (Roche), GSK, Novartis, Pfizer and Takeda and additionally with multiple emerging technology companies. Sosei Heptares is headquartered in Tokyo, Japan with corporate and R&D facilities in Cambridge, UK.

“Sosei Heptares” is the corporate brand and trademark of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565). Sosei, Heptares, the logo and StaR® are trademarks of Sosei Group companies.

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For more information, please visit <https://www.loseiheptares.com/>  
LinkedIn: [@loseiheptaresco](#) | Twitter: [@loseiheptaresco](#) | YouTube: [@loseiheptaresco](#)

### About Biohaven

Biohaven (NYSE: BHVN) is a commercial-stage biopharmaceutical company with a portfolio of innovative, best-in-class therapies to improve the lives of patients with debilitating neurological and neuropsychiatric diseases, including rare disorders. Biohaven's neuroinnovation portfolio includes FDA-approved NURTEC™ ODT (rimegepant) for the acute treatment of migraine and a broad pipeline of late-stage product candidates across three distinct mechanistic platforms: CGRP receptor antagonism for the acute and preventive treatment of migraine; glutamate modulation for obsessive-compulsive disorder, Alzheimer's disease, and spinocerebellar ataxia; and myeloperoxidase (MPO) inhibition for multiple system atrophy and amyotrophic lateral sclerosis. More information about Biohaven is available at [www.biohavenpharma.com](http://www.biohavenpharma.com)

NURTEC is a trademark of Biohaven Pharmaceutical Ireland DAC.

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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.