Sosei Heptares Doses First Subject in Phase I Trial with HTL0048149, a First-in-Class GPR52 Agonist for Schizophrenia

- **HTL’149 has been designed as a once-daily oral treatment to address positive and negative symptoms and cognitive impairment in schizophrenia patients without the adverse effects typically associated with existing antipsychotic drugs**

**Tokyo, Japan and Cambridge, UK, 3 July 2023** – Sosei Group Corporation (“the Company”; TSE: 4565), the world leader in G protein-coupled receptor (GPCR) focused structure-based drug design (SBDD) and development, announces it has dosed the first subject in a Phase I trial evaluating HTL0048149 (HTL’149), a first-in-class GPR52 agonist, which represents a novel mechanism of action for the treatment of schizophrenia and related neurological diseases.

HTL’149 was developed, leveraging insights generated from Sosei Heptares’ StaR® technology and SBDD platform, as a once-daily, orally available small molecule drug with an antipsychotic and pro-cognitive profile and to avoid the adverse effects typically associated with existing antipsychotic drugs. HTL’149 achieves this profile through selectively targeting the orphan GPR52 receptor in the brain to address positive symptoms (e.g. psychosis, delusions, hallucinations), negative symptoms (e.g. social withdrawal) and cognitive impairment (e.g. attention, working memory and executive function) associated with schizophrenia.

Through this novel mechanism of action, HTL’149 aims to address the significant proportion of schizophrenia patients who do not respond to or suffer side effects leading to compliance issues from using existing antipsychotics. Furthermore, current antipsychotic drugs do not effectively treat the negative or cognitive symptoms of disease.

The Phase I trial is a two-part, randomized, double-blind, placebo-controlled, single- and multiple-ascending dose study to assess the safety, pharmacokinetics, and pharmacodynamics of oral HTL’149 in healthy volunteers aged 18-55 years. The trial will be conducted in the UK and is expected to read-out initial data in 12-18 months.

**Matt Barnes, President of Heptares Therapeutics and Head of UK R&D, said**: “The progression of this wholly owned, first-in-class asset into clinical trials is a very important milestone for Sosei Heptares. It is the culmination of a rigorous internal program that began with the selection of GPR52 as the right target to address the significant unmet needs of schizophrenia patients and the subsequent design of a novel and potentially first-in-class agonist molecule with the right therapeutic profile. Progression of HTL’149 from discovery into clinical trials is a great example of the power of our StaR/SBDD platform to generate high-quality candidates utilizing the combined expertise of our platform, discovery and translational medicine teams.”
About Sosei Heptares

Sosei Heptares’ mission is to make life-changing medicines using world-leading science and our vision is to become one of Japan’s global biopharmaceutical champions.

We are a science and technology-led company focused on the discovery and early development of new medicines originating from our proprietary GPCR-targeted StaR® technology and structure-based drug design platform. 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 biopharmaceutical companies and multiple emerging technology companies, including AbbVie, AstraZeneca, Genentech (Roche), GSK, Kallyope, Lilly, Neurocrine Biosciences, Novartis, Pfizer, Sanofi, Takeda and Verily.

Sosei Heptares is headquartered in Tokyo, Japan with corporate and R&D facilities in Cambridge, UK.

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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.