

## Sosei Heptares' Partner Neurocrine Biosciences Initiates Phase 2 Clinical Study Evaluating NBI-1117568 in Adults with Schizophrenia

- *NBI-1117568 is an Investigational, First-in-Class, Muscarinic M4 Selective Agonist*

Tokyo, Japan and Cambridge, UK, 28 October 2022 – Sosei Group Corporation (“the Company”; TSE: 4565), the world leader in G protein-coupled receptor (GPCR) focused structure-based drug design (SBDD) and development, notes its partner Neurocrine Biosciences Inc. (“Neurocrine”) announced the first patient has been randomized for its Phase 2 placebo-controlled, inpatient clinical study evaluating the efficacy, safety, tolerability, and pharmacokinetics of investigational compound NBI-1117568 in adults with schizophrenia. NBI-1117568 is an investigational, muscarinic M4 selective acetylcholine receptor agonist believed to be a key regulator of neurotransmitters impacted by schizophrenia.

“Initiation of this Phase 2 study for NBI-1117568 brings forward a first-in-class, orally active, highly selective investigational M4 agonist as a potential treatment for schizophrenia, a serious and complex psychiatric syndrome impacting 0.5-1.0% of the U.S. population and approximately 20 million people worldwide,” said **Eiry W. Roberts, M.D., Chief Medical Officer of Neurocrine Biosciences**. “The differentiated profile of NBI-1117568 in terms of its selectivity as an M4 agonist may provide an opportunity for efficacy in treating the symptoms of psychosis with a potentially different side effect profile.”

The NBI-1117568 Phase 2 multi-arm, multi-stage study will enroll approximately 200 adults and is being conducted at 15 centers throughout the United States. The placebo-controlled study will evaluate multiple active dose levels of NBI-1117568. The primary outcome measure will be the change in total Positive and Negative Syndrome Scale (PANSS) score from baseline to Week 6. For more information about this study (NBI-1117568-SCZ2028), visit [ClinicalTrials.gov](https://clinicaltrials.gov).

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### About Muscarinic Receptors

Muscarinic receptors are G protein-coupled receptors (GPCRs) found in multiple tissues including the brain, cardiovascular system, and gastrointestinal tract. Selective activation of M4 and M1 receptors in the brain is a clinically validated approach to treating cognitive and neuropsychological symptoms of neurological diseases, including Schizophrenia, dementia associated with Alzheimer’s disease, Parkinson’s disease, and others.

Until now, attempts to develop medicines that selectively target M4 and M1 receptors have been unsuccessful because of side effects caused by the activation of M2 and M3 receptors. Highly

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selective M4 or M1 agonists that do not activate M2 or M3 therefore are highly sought after and expected to have the potential to address major unmet medical needs with blockbuster potential.

#### **About the Agreement with Neurocrine Biosciences**

Sosei Heptares and Neurocrine entered a collaboration and licensing agreement in November 2021 to develop novel muscarinic receptor agonists for the treatment of schizophrenia, dementia and other neuropsychiatric disorders.

Under the terms of the agreement, Neurocrine gains development and commercialization rights to a broad portfolio of novel clinical and preclinical subtype-selective muscarinic M4, M1 and dual M1/M4 receptor agonists discovered by Sosei Heptares. Neurocrine is responsible for development costs associated with the programs globally, except for M1 agonists being developed in Japan. Sosei Heptares retains rights to develop M1 agonists in Japan for any indication, with Neurocrine receiving co-development and profit share options.

Sosei Heptares is eligible to receive R&D funding plus development, regulatory and commercial milestones of up to US\$2.6 billion, with further product royalties, provided the criteria under the agreement are satisfied.

#### **About Neurocrine Biosciences**

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine, and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis\* and uterine fibroids\*, as well as over a dozen mid- to late-stage clinical programs in multiple therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit [neurocrine.com](https://www.neurocrine.com), and follow the company on [LinkedIn](#), [Twitter](#), and [Facebook](#). (\*in collaboration with AbbVie).

#### **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 and multiple emerging technology companies, including AbbVie, AstraZeneca, Genentech (Roche), GSK, Kallyope, Neurocrine Biosciences, Novartis, Pfizer, Takeda and Verily. Sosei Heptares is headquartered in Tokyo, Japan with corporate and R&D facilities in Cambridge, UK.

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**Enquiries:****Sosei Heptares – Media and Investor Relations**

Hironoshin Nomura, Chief Financial Officer

Shinichiro Nishishita, VP Investor Relations, Head of Regulatory Disclosures

Candelle Chong, SVP Investor Relations and Corporate Strategy

*Japan:* +81 (0)3 5210 3399 | *United Kingdom:* +44 (0)1223 949390 | [IR@SoseiHeptares.com](mailto:IR@SoseiHeptares.com)

**MEDISTRAVA Consulting (for International Media)**

Mark Swallow, Frazer Hall, Eleanor Perkin

+44 (0)203 928 6900 | [SoseiHeptares@medistrava.com](mailto:SoseiHeptares@medistrava.com)

**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.