

## Sosei Heptares' Oral, Selective M4 Receptor Agonist Advancing into Phase 2 Clinical Development under Multi-Program Collaboration with Neurocrine Biosciences

- *Neurocrine to conduct placebo-controlled Phase 2 study to investigate NBI-1117568 (formerly HTL-0016878) as a potential new treatment for schizophrenia*
- *Clinical development milestone triggers payment of US\$30 million to Sosei Heptares from Neurocrine*
- *NBI-1117568 is the most advanced candidate under the multi-program muscarinic receptor agonist collaboration between Sosei Heptares and Neurocrine*

Tokyo, Japan and Cambridge, UK, 5 August 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, has been notified by its partner Neurocrine Biosciences Inc. (“Neurocrine”; Nasdaq: NBIX) that the U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) Application for a Phase 2 clinical trial of NBI-1117568 for the treatment of schizophrenia has been accepted by the FDA and that the study may proceed. The achievement of this important clinical development milestone triggers a \$30 million payment to Sosei Heptares from Neurocrine.

NBI-1117568 is an oral, selective muscarinic M4 receptor agonist in development for the treatment of schizophrenia and other neuropsychiatric disorders. As a selective M4 orthosteric agonist, NBI-1117568 offers the potential to deliver therapeutic effects without the need of combination therapy to minimize side effects, as required with non-selective muscarinic agonists, whilst also avoiding the requirement for cooperativity with acetylcholine (ACh) when compared to positive allosteric modulators. Clinical studies completed to date have shown NBI-1117568 to be generally well tolerated.

NBI-1117568 is the most advanced candidate from a broad portfolio of novel clinical and preclinical subtype-selective muscarinic M4, M1 and dual M1/M4 receptor agonists discovered by Sosei Heptares and in development under the 2021 collaboration with Neurocrine for the treatment of major neurological disorders. Upon successful completion of pre-clinical studies, Neurocrine anticipates initiating Phase 1 studies for a dual M1/M4 and selective M1 agonist. Advancing additional compounds into clinical studies would trigger further milestone payments from Neurocrine to Sosei Heptares.

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**Chris Cargill, President and CEO of Sosei Heptares, commented:** “We are delighted with the progress of NBI-1117568 and of our collaboration with Neurocrine across our portfolio of novel selective M4 and M1 agonists. Muscarinic receptors are important drug targets in psychosis and cognitive disorders and through the application of our StaR® technology platform and expertise in GPCR-focused structure-based drug design, we have discovered agonists selective to M4 and M1. These novel drug candidates have been designed to deliver improved therapeutic effects while avoiding the unwanted activation of M2 and M3 and its associated side effects. Our selective muscarinic agonist approach is supported by significant scientific and clinical evidence reinforcing its potential to address major unmet needs in neurological and psychiatric diseases and we are excited to be advancing developments in this area with Neurocrine.”

**Eiry Roberts, Chief Medical Officer of Neurocrine, commented:** “We are excited to advance the lead asset in our strategic collaboration, NBI-1117568, into a Phase 2 study for the treatment of schizophrenia this year and look forward to our continued partnership with the Sosei Heptares team.”

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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 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 Biosciences 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.

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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 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.

"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.

For more information, please visit <https://soseiheptares.com/>

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### 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](http://neurocrine.com), and follow the company on LinkedIn, Twitter, and Facebook. (\*in collaboration with AbbVie).

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**Sosei Group Corporation 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.

**Neurocrine Biosciences Forward-Looking Statements**

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements related to the benefits to be derived from NBI-1117568 development and commercialization. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: our future financial and operating performance; risks or uncertainties related to the development of NBI-1117568; risks that the FDA or other regulatory authorities may make adverse decisions regarding NBI-1117568; risks that NBI-1117568 clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that NBI-1117568 is safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for NBI-1117568; risks that NBI-1117568 may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; and other risks described in our periodic reports filed with the SEC, including without limitation our quarterly report on Form 10-Q for the quarter ended March 31, 2022. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.