

# Sosei Heptares' Partner Neurocrine Biosciences Confirms its Plans to Evaluate Two New Muscarinic Agonist Candidates in Phase 1 Clinical Studies

- Both NBI-1117569 (an M4-preferring agonist) and NBI-1117567 (an M1preferring agonist) are investigational, oral, muscarinic agonists discovered by Sosei Heptares that may have the potential to treat neurological and neuropsychiatric conditions
- Neurocrine Biosciences confirmed a Phase 1 clinical study of NBI-1117569 has started and a Phase 1 study of NBI-1117567 will be initiated in 2024

Tokyo, Japan and Cambridge, UK, 6 December 2023 – Sosei Group Corporation ("the Company"; TSE: 4565), notes its partner Neurocrine Biosciences Inc. ("Neurocrine"; Nasdaq: NBIX), a leading neuroscience-focused biopharmaceutical company, has confirmed its plans to evaluate two new muscarinic agonist candidates in Phase 1 first-in-human clinical studies. The studies are designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of NBI-1117569 and NBI-1117567 in healthy adult participants. NBI-1117569, a muscarinic M4-preferring agonist, and NBI-1117567, a muscarinic M1-preferring agonist are both investigational, oral compounds, which may have the potential to treat neurological and neuropsychiatric conditions and were developed utilizing Sosei Heptares' structure-based drug design platform. Neurocrine confirmed a Phase 1 clinical study of NBI-1117569 has started and a Phase 1 study of NBI-1117567 will be initiated in 2024.

Matt Barnes, President of Heptares Therapeutics and Head of UK R&D, said: "We are delighted that Neurocrine is progressing these unique M4-preferring and M1-preferring agonists into clinical development to target important unmet medical needs in neurological and neuropsychiatric disorders. NBI-1117569 and NBI-1117567 are the third and fourth candidates to advance into clinical trials from the portfolio of selective muscarinic receptor agonists discovered and licensed by Sosei Heptares to Neurocrine in 2021. Neurocrine has the largest portfolio of muscarinic compounds in clinical development, and we look forward to future progress under this highly productive partnership, including the Phase 2 clinical data on NBI-1117568, a muscarinic M4 selective agonist, expected in the second half of 2024."

The clinical development milestones achieved with both compounds as announced do not trigger a milestone payment from Neurocrine to Sosei Heptares under the terms of the 2021 agreement between the companies. Milestone payments, under the agreement, are payable upon the achievement of multiple, defined development events for each program. Sosei Heptares will announce the receipt of any milestone payments in accordance with TSE reporting requirements.



#### 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 BioSciences 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 leading 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 underaddressed 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 a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core 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, and follow the company on LinkedIn, X, and Facebook.

\*\*in collaboration with AbbVie\*

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#### About Sosei Heptares

Sosei Heptares is a fully integrated biopharmaceutical company focused on bringing life-changing medicines based on world-class science to patients globally. Our vision is to become one of Japan's global biopharmaceutical champions.

Our global business combines our world-leading GPCR-targeted StaR® technology, structure-based drug design and early development capabilities in the UK with a highly experienced clinical development capability and a commercial operation in Japan.

We are leveraging these capabilities to generate and advance a broad and deep pipeline of novel medicines across multiple therapeutic areas, including neurology, immunology, gastroenterology and inflammatory diseases. We intend to develop these opportunities for patients in Japan and globally both internally and through our partnerships with global biopharmaceutical companies and emerging technology companies.

Sosei Heptares operates from key locations in Tokyo and Osaka (Japan), London and Cambridge (UK), Basel (Switzerland) and Seoul (South Korea).

"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 <a href="https://soseiheptares.com/">https://soseiheptares.com/</a>

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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, Inc. Forward-Looking Statement**

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 potential benefits of NBI-1117570. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks that clinical development activities may not be initiated or completed on time or at all, or may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; our future financial and operating performance; risks associated with our dependence on third parties for development, manufacturing, and commercialization activities for our products and product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our product candidates; risks that the potential benefits of the agreements with our collaboration partners may never be realized; risks that our products, and/or our product candidates 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 associated with U.S. federal or state legislative or regulatory and/or policy efforts which may result in, among other things, an adverse impact on our revenues or potential revenue; risks associated with potential generic entrants for our products; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in th