

Sosei Heptares Notes its Partner Tempero Bio has Received FDA Clearance to Advance Clinical Development of TMP-301 for Treatment of Alcohol and Substance Use Disorders

- *TMP-301 (formerly HTL0014242) is a potent, selective, and orally available mGluR5 negative allosteric modulator (NAM) candidate discovered by Sosei Heptares and out-licensed to Tempero Bio*
- *Phase 1 study in healthy volunteers expected to begin in Q1 2023 with support from a US\$5.3M grant from the US National Institute on Drug Abuse (NIDA)*
- *Tempero Bio was created by Aditum Bio in collaboration with Sosei Heptares in 2020 to advance the clinical development of mGluR5 NAM candidates to develop therapies targeting substance use disorders and anxiety*
- *Sosei Heptares holds a strategic equity stake in Tempero Bio and retains an economic interest in TMP-301 and other compounds in the mGluR5 NAM program out-licensed to Tempero Bio*

Tokyo, Japan and Cambridge, UK, 5 January 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, notes its partner Tempero Bio has announced FDA clearance of its Investigational New Drug (IND) application for TMP-301 (formerly HTL0014242) for the treatment of alcohol and substance use disorders. Tempero Bio is planning to initiate a Phase 1 study with TMP-301 in healthy volunteers in Q1 2023 with support from a recently awarded USD\$5.3M grant from the US National Institute on Drug Abuse (NIDA). The full announcement from Tempero Bio is [here](#).

Matt Barnes, Head of UK R&D, Sosei Heptares, commented: “We would like to congratulate the team at Tempero Bio on reaching this important milestone. We look forward to further clinical development progress from Tempero Bio with TMP-301 and its mGluR5 NAM pipeline as it seeks to develop effective treatments for patients with serious substance and alcohol use disorders.”

Tempero Bio was created in 2020 by the venture firm Aditum Bio (established by industry veterans Joe Jimenez and Mark Fishman) in collaboration with Sosei Heptares to advance the clinical development of a portfolio of potent, orally available metabotropic glutamate receptor 5 (mGluR5) negative allosteric modulator (NAM) modulators, including TMP-301, discovered by Sosei Heptares to develop therapies targeting substance use disorders and anxiety.

PRESS RELEASE

Under the terms of the agreement, Tempero Bio acquired exclusive global rights to Sosei Heptares' portfolio of mGluR5 NAM candidates. In return, Sosei Heptares received a strategic equity stake in Tempero Bio and is eligible to receive future success-based development and commercial milestone payments plus tiered royalties from any future product sales.

The regulatory milestone achieved as noted in this announcement does not trigger a payment from Tempero Bio to Sosei Heptares.

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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, Lilly, 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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Forward-looking statements



PRESS RELEASE

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.