PRESS RELEASE

Sosei Group Announces Marketing Approval for PIVLAZ™ (clazosentan sodium) 150 mg in South Korea

- *PIVLAZ™, a new drug for prevention of Cerebral Vasospasm in patients with Aneurysmal Subarachnoid Hemorrhage (aSAH), approved in South Korea*
- *PIVLAZ will become commercially available in South Korea in early 2025*

Tokyo, Japan, Seoul, South Korea, and Cambridge, UK, 7 December 2023 – Sosei Group Corporation ("Sosei Heptares" or "the Company"; TSE: 4565) today announces that PIVLAZ™ (clazosentan sodium) 150 mg has received marketing approval from the Ministry of Food and Drug Safety (MFDS) in South Korea for the prevention of cerebral vasospasm, vasospasm-related cerebral infarction, and cerebral ischemic symptoms after aneurysmal subarachnoid hemorrhage (aSAH) securing.

The MFDS approval is based on scientific and clinical data from an extensive Japanese Phase 3 program submitted by Idorsia Pharmaceuticals Korea ("IPK"), a Sosei Group company. The trials, which involved patients who had undergone clipping surgery or coiling treatment for aSAH, showed that PIVLAZ™ significantly reduced the incidence of cerebral vasospasm-related complications and all-cause mortality within six weeks of aneurysmal subarachnoid hemorrhage. The trials also confirmed the safety profile of PIVLAZ™.

In South Korea, the Marketing Authorization of PIVLAZ™ is held by IPK, and will become commercially available to patients in early 2025.

PIVLAZ™ received marketing approval in Japan in January 2022 and was launched in April 2022 by Idorsia Pharmaceuticals Japan ("IPJ"), also a Sosei Group company. PIVLAZ™ has been used in approximately 8,900 patients in Japan as of November 2023.

Aneurysmal subarachnoid hemorrhage is a condition involving sudden life-threatening bleeding occurring in the subarachnoid space. It is caused by the rupture of an aneurysm – a weak, bulging spot on the wall of a cerebral artery. Emergency procedure (endovascular coiling or microsurgical clipping) is required to stop the hemorrhage. The bleeding and the release of endothelin, a potent vasoconstrictor produced by the neighboring vascular endothelium, can lead to cerebral vasospasm (constriction of arteries in the brain), usually occurring between four and 14 days after aneurysm securing. This diminishes blood flow to the brain, and about one third of patients consequently experience worsening of their neurological condition. Cerebral vasospasm is one of the leading secondary causes of disability and death in patients with aSAH.

Professor Park Ik-seong, Chairman of the Korean Society of Cerebrovascular Surgeons (Professor of neurosurgery at Bucheon St. Mary's Hospital), said: "Cerebral vasospasm after subarachnoid hemorrhage is a serious symptom that can lead to death. However, the lack of effective medication has made it difficult to treat. Now that PIVLAZ™, a drug that can prevent symptoms before they occur, has been approved in South Korea, I hope that it will become available and widely accessible as soon as possible for the sake of patients."

Satoshi Tanaka, Dr Med Sci., Executive Officer and Executive Vice President of Sosei Heptares, Chairman of Idorsia Pharmaceuticals Korea, added: "This approval for PIVLAZ™ in a second major market in the APAC region is a significant achievement and brings this groundbreaking and potential life-changing therapeutic advance one step closer to patients in South Korea. Cerebral vasospasm is one of the leading secondary causes of disability and death in patients with subarachnoid hemorrhage. With an occurrence of 9.0 per 100,000 person-years, aSAH is more frequent in South Korea compared to global occurrence rate of 7.9. Therefore, PIVLAZ could be a meaningful treatment option for the patients. Our commercialization plans are well advanced, having benefited hugely from a successful launch in Japan, and we are confident we will be able to make PIVLAZ™ available to physicians and patients in South Korea in early 2025."

Sosei Heptares gained Japan and Asia-Pacific (ex-China) rights to PIVLAZ™, a potent, selective endothelin receptor antagonist, from Idorsia Pharmaceuticals Ltd in July 2023 in the context of its acquisition of IPJ and IPK.

PIVLAZ™ is a trademark of Sosei Group.

-ENDS-

Notes to Editors

About the Japanese Phase 3 program

The Phase 3 program consisted of two double-blind, randomized, placebo-controlled studies assessing the efficacy and safety of clazosentan in reducing vasospasm and vasospasm-related morbidity and all-cause mortality events in adult Japanese patients post-aSAH. Patients were randomized 1:1 to receive continuous infusion of either 10 mg/hr of clazosentan or placebo for up to a cumulative maximum of 15 days following the onset of aSAH. The two studies followed the same study design, with one enrolling 221 patients whose aneurysm was secured by surgical clipping and the other enrolling 221 patients whose aneurysm was secured by endovascular coiling.

Both studies showed that clazosentan reduced the occurrence of cerebral vasospasm-related morbidity and all-cause mortality within 6 weeks post-aSAH with statistical significance ($p<0.01$ for both studies). The composite endpoint was defined by at least one of the following: All death / New cerebral infarction due to cerebral vasospasm / Delayed ischemic neurologic deficit due to cerebral vasospasm adjudicated blindly by an independent committee. The effect of clazosentan on all-cause morbidity and mortality was also significant ($p<0.05$) in a pre-planned analysis of the pooled studies whereas a numerical trend was observed in each study on this endpoint.

In these Phase 3 studies in Japanese patients post-aSAH, there were no unexpected safety findings. Treatment-emergent adverse events occurring in >5% of the clazosentan group (with a difference

of >2% compared to placebo) were vomiting and signs of hemodilution or fluid retention (i.e., hyponatremia, hypoalbuminemia, anemia, pleural effusion, brain and pulmonary edema).

Key Literature

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About Idorsia Pharmaceuticals Korea Co., Ltd

Idorsia Pharmaceuticals Korea (“IPK”) was established, under the leadership of Dr. Satoshi Tanaka, in 2022 to conduct clinical development and prepare the commercialization of innovative and promising compounds for patients in South Korea. IPK is a wholly owned subsidiary of Sosei Group Corporation.

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 https://soseiheptares.com/
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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.