

## Sosei Heptares Acquires Idorsia's Pharmaceuticals Business in Japan and APAC (ex-China), Accelerating its Transformation into a Fully Integrated Biopharmaceutical Company

- *Transaction adds complementary late-stage clinical development capability with profitable and fast-growing commercial operations in Japan*
- *Lean, go-to-market commercial model, well positioned to scale rapidly to generate significant value from Japan and APAC (ex-China) geographic expansion*
- *Includes Japan and APAC (ex-China) rights<sup>1</sup> to two life-changing medicines with significant growth potential:*
  - *PIVLAZ<sup>®</sup> (clazosentan; commercially available in Japan for cerebral vasospasm; NHI sales of ~JPY7.5 billion in FY22A launch year, with ~76% year-on-year growth expected for FY23E), and*
  - *Daridorexant (Japan filing expected 2H 2023 for insomnia, marketed in US/Europe as QUVIVIQ<sup>®</sup>)*
  - *Plus, exclusive options and selected rights to up to seven other products from Idorsia's global clinical development pipeline*
- *Brings highly experienced team, with proven clinical development and commercial launch track record, led by Dr. Satoshi Tanaka*
- *Purchase price of approximately JPY65 billion<sup>2</sup> is fully funded by existing cash and a new long-term, low-rate corporate loan*
- *Transaction will be cash flow positive in the first full calendar year – Sosei Heptares will have approximately JPY42 billion in cash post completion of the transaction*
- *The Company will host an investor and press conference (live and virtually) to discuss the Transaction at 5pm JST (9am BST) on Thursday, 20 July 2023 (details below)*

Tokyo, Japan and Cambridge, UK, 20 July 2023 – Sosei Group Corporation (“the Company”; TSE: 4565) announces that it has resolved, at a meeting of the Board of Directors held on 20 July 2023, to acquire from Idorsia Ltd and Idorsia Pharmaceutical Ltd (together “Idorsia”) all shares of Idorsia Pharmaceuticals Japan Ltd (“IPJ”) and Idorsia Pharmaceuticals Korea Co., Ltd (“IPK”) (the “Transaction”).

The strategic Transaction also includes the Japan and APAC (ex-China)<sup>1</sup> territory rights to an exciting pipeline of medicines from Idorsia's portfolio, with lead product PIVLAZ<sup>®</sup> (clazosentan) already commercially available and with fast-growing sales in Japan following a successful launch

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in April 2022. Sosei Heptares will fully finance the Transaction, which is valued at approximately JPY65 billion<sup>2</sup>, through a combination of JPY25 billion of existing cash from its balance sheet and a new JPY40 billion long-term (7-year), low-rate unsecured corporate loan through Mizuho Bank.

The Company will host an investor and press conference in Tokyo (live and virtually) to discuss the Transaction at 5pm JST (9am BST) on Thursday, 20 July 2023. The meeting is open to all existing and potential investors, sell-/buy-side analysts, and journalists and will consist of a presentation followed by a Q&A session. Please click [here](#) to pre-register, which will provide a link to access the meeting.

**Chris Cargill, President & CEO of Sosei Heptares, commented:** “Since the acquisition of the Heptares Therapeutics GPCR drug discovery platform in 2015, we have patiently and diligently searched for the right opportunity to accelerate our mission to deliver life-changing new medicines to patients in Japan and globally. This fully funded transaction is truly transformational and achieves one of our key strategic objectives, establishing the Company as a fully integrated Japan-focused biopharmaceutical business, with growing commercial sales and an expected new product launch next year. The addition of a highly experienced clinical development and entrepreneurial commercial team in Japan led by Dr. Satoshi Tanaka, one of the country’s most successful drug developers in recent times, fast-tracks our vision to become one of Japan’s global biopharmaceutical champions.

“The Japan pharmaceutical market, given its size, large ageing population and attractive high quality clinical development and regulatory environment is the key next step for Sosei Heptares’ growth ambitions. We see fantastic potential to build a significant position in this market as an agile and lean participant, and at the same time now have the full platform capabilities to be a development and commercialization partner of choice in the territory. The businesses we are acquiring are highly complementary to our existing UK and Japan operations and provide exciting opportunities and optionality to develop and commercialize our own portfolio, as well as partnered and future in-licensed products in Japan. We are confident that this transaction, which will be cash-flow positive in year one<sup>3</sup>, will allow us to deliver significant value and benefits to all our key stakeholders.”

**Shinichi Tamura, Chairman of Sosei Heptares, said:** “Today is an historic day for the Company and marks a step change in delivering on our ambitious growth strategy. The addition of a first-rate, scalable development and commercial capability in Japan provides us with greater control of our own destiny and enhances our ability to generate value for our shareholders. I would like to congratulate Chris and his team for successfully concluding this transaction. I would also like to welcome Dr. Satoshi Tanaka and the other members of the IPJ and IPK teams to Sosei Heptares. I am confident that, by combining their expertise with our world-leading GPCR-targeted discovery capabilities based in the UK, we can create a new leader in the Japanese biopharma industry with the ability to bring transformative medicines to patients both in Japan and globally.”

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**Dr. Satoshi Tanaka, President of IPJ, added:** “My team and I are thrilled by the opportunity to join Sosei Heptares and build a competitive and lean pharma business in Japan and across other Asia-Pacific markets. With PIVLAZ® already launched and Japan sales growing fast and daridorexant nearing J-NDA filing later this year, we have a strong foundation from which to grow, enhanced by access to an extensive and sustainable pipeline of novel candidates generated by Sosei Heptares’ world-leading GPCR-targeted drug design platform and capabilities. Our team in Japan has a strong track record for delivering products to market, and with our shared strategic vision and integrated capabilities we have an exciting future ahead of us.”

### Reasons for the Transaction

In 2022, the new leadership team at Sosei Heptares began executing an evolved corporate strategy designed to leverage its proprietary platform, pipeline and capabilities and build a balanced and integrated business with a commercial capability in Japan/APAC and partnering opportunities globally. A key element of this strategy is focused on building an agile, scalable and effective clinical development and commercialization business capability that would enable the Company to deliver life-changing medicines to patients in Japan and capitalize on the significant underserved opportunities that it sees within this large attractive market.

The acquisition of IPJ and IPK addresses this objective and is the conclusion of a rigorous global search by the Sosei Heptares team. The cash-flow positive Transaction, which is fully funded by existing cash and a new long-term, low-rate corporate loan, provides Sosei Heptares with multiple strategic benefits by:

- Accelerating the Company’s mission by adding experienced clinical development capability and profitable commercial operations in Japan, with a lean model for sales and marketing, and the ability to scale and create further value.
- Securing and expanding the Company’s future pipeline with two major products PIVLAZ® and daridorexant; exclusive opt-ins for cenerimod and lucerastat; and selected rights to up to five additional clinical-stage programs from Idorsia’s global pipeline.
- Bringing a highly skilled team with a proven track record of excellence and delivery, led by Dr. Satoshi Tanaka, who has directed several J-NDA (Japan) and MFDS (South Korea) approvals and successful commercial launches over the past two decades.
- Leveraging Japan’s quality clinical environment to target underserved, specialty disease areas; and providing the platform to expand across broader APAC regions and extend product launches.

The Transaction also brings together complementary capabilities to develop and commercialize novel medicines across Japan and APAC (ex-China) from three sources of innovation: (i) Sosei Heptares’ wholly owned discovery and early development pipeline, (ii) selected clinical candidates

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from Idorsia's pipeline, and (iii) in-licensing of Japan/APAC (ex-China) rights to clinical product candidates from third parties.

In addition, the Company will continue to seek partners for novel candidates or programs discovered by Sosei Heptares for development and commercialization outside of Japan/APAC territories where significant unmet needs exist as well as the requirements for substantial expertise and resources.

### **Building a Japan biopharmaceutical business**

In executing this Transaction, Sosei Heptares immediately adds a profitable, fast-growing commercial operation, well positioned to progress the development and commercialization of potentially life-changing medicines, licensed as part of the Transaction, to patients in Japan. Furthermore, there is opportunity to scale rapidly by exploiting products from Sosei Heptares' internal pipeline, from its partnered pipeline and, as a regional partner of choice, from further in-licensing Japan and APAC (ex-China) rights for other attractive product opportunities.

The Japanese pharma market is the second-largest developed single market in the world (ex-China) valued at USD85 billion<sup>3</sup> in 2021 and, with a large, ageing population, is expected to continue to grow rapidly over the coming years as patients demand the latest and most effective treatments.

The Company aims to capture value from this major opportunity by leveraging Japan's quality clinical environment to target underserved, specialty disease areas and by adopting a lean, agile and efficient operating model built around its core development and commercial expertise.

In time, the Company expects to capitalize on development and commercial opportunities across the broader APAC (ex-China) region and from new product opportunities.

### **Adding a highly experienced and successful team in Japan**

The IPJ and IPK team joining Sosei Heptares brings significant experience in drug development and commercialization with a strong footprint in Japan that extends into the APAC (ex-China) region. The team of 135 people (130 in Japan, five in South Korea) includes experts in clinical development and product commercialization, including regulatory and medical affairs, pricing and market access and sales and marketing. This team is led by Dr. Satoshi Tanaka, who joins Sosei Group as Representative Director and President of the Japanese and South Korean legal entities, and as a newly appointed Executive Officer of the Company.

Dr. Tanaka is one of the most successful drug developers in Japan in recent years, having led development and commercialization activities in the region for Actelion (2001-2018) and Idorsia (2018-present). Idorsia began operations after demerging from Actelion following Actelion's USD30 billion acquisition by Johnson & Johnson in 2017.

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Dr. Tanaka has launched several products onto the Japanese market, including Tracleer® (bosentan), the world's first oral medication for pulmonary arterial hypertension (PAH) (2005) and several label extensions in other indications over subsequent years; Opsumit® (macitentan), also for the treatment for PAH (2015); and PIVLAZ® (clazosentan), for the treatment of cerebral vasospasm, a type of stroke (2022).

Importantly, the IPJ team adds significant complementary expertise to Sosei Heptares' world-leading discovery and early clinical development team in Cambridge, UK, and its existing development team in Japan. The enlarged Japan team also provides a platform to expand commercial operations beyond Japan to other APAC markets and extend the regional product range over time.

### **Adding de-risked, late-stage product opportunities in Japan**

Under the terms of the Transaction, Sosei Heptares gains select rights for Japan and APAC (ex-China)<sup>1</sup> from Idorsia to two GPCR-targeted products: PIVLAZ® and daridorexant, plus exclusive opt-ins for the Phase 3 cenerimod and lucerastat programs; and selected rights to up to five additional clinical-stage programs from Idorsia's development portfolio.

PIVLAZ® (clazosentan) 150mg, was launched in April 2022 in Japan. PIVLAZ® is a potent, selective endothelin A (ETA) receptor antagonist indicated for the prevention of cerebral vasospasm, vasospasm-related cerebral infarction, and cerebral ischemic symptoms after aneurysmal subarachnoid hemorrhage (aSAH). PIVLAZ® is a fast-growing product that has already been used to treat approximately 6,500 patients. Since its launch in Japan, PIVLAZ® generated NHI sales of approximately JPY7.5 billion for full year 2022 and is forecast to generate over JPY13 billion in full year 2023.

In October 2022, daridorexant, a dual orexin receptor antagonist (DORA), achieved positive Phase 3 top-line results in Japanese patients with insomnia. This successful trial paves the way for a potential regulatory submission in Japan in 2H 2023. Daridorexant is approved for treating insomnia in the US and Europe where it will continue to be marketed under the brand name QUVIVIQ® by Idorsia. If approved in Japan, daridorexant will be marketed under an existing co-promotion agreement with Mochida.

### **Near-term objectives and milestones**

#### *Japan/APAC*

- Integrate IPJ and IPK teams rapidly into Sosei Heptares to ensure smooth transition and continued operational efficiency with respect to ongoing development and commercial activities.
- Inclusion of PIVLAZ® in the Japanese treatment guidelines for cerebral vasospasm was confirmed in Q3 2023.

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- Continue preparations for a regulatory decision for PIVLAZ® in South Korea during 2H 2023 and subsequent commercialization, with launch expected in 2H 2024, if approved.
- Focus on completing Japan NDA filing for daridorexant for treating insomnia in 2H 2023. Decision expected in 2H 2024. Continue plans for commercialization based on an expected 2025 launch, if approved.
- Commence Phase 3 trial of daridorexant in South Korea in 2H 2023 to complete registrational requirements and enable launch in the next 2-3 years.
- Decisions to exercise opt-in rights for Phase 3 and other programs from Idorsia's pipeline
- Continue to seek further in-licensing opportunities for new Japan and APAC (ex-China) business.

### *Rest of World*

- Progress internal pipeline programs into and through early clinical development, including: HTL0048149 (a novel GPR52 agonist for Schizophrenia) currently in a Phase 1 trial; HTL0039732 (a novel EP4 antagonist for immune-oncology) expected to begin Phase 1 trials in 2H 2023; further preclinical candidates progressing towards clinical development (e.g. EP4 agonist in Inflammatory Bowel Disease, M1 agonist in neurological disorders).
- Clinical data expected from programs under development by global partners.
- Look to sign additional collaborations (ex-Japan/APAC) with global partners around internal pipeline assets and GPCR-targeted discovery capabilities.

### **Future outlook**

By transforming Sosei Heptares into a fully integrated biopharmaceutical business through this transaction, the Company gains greater ability to maximize the value from its extensive discovery pipeline alongside revenue streams from partnered programs and marketed products, thereby providing a higher degree of control over its own destiny and potential value catalysts.

Following this transaction, Sosei Heptares has the breadth and depth of scale to accelerate its growth plans delivering important medicines to patients across key markets starting with Japan. The newly enlarged group now employs over 370 people across all locations.

Sosei Heptares has an ambitious strategy to profitably grow the business in Japan and beyond into APAC (ex-China) regions, with opportunities to build from its existing solid base through geographic and further portfolio expansion.

Today's transaction is a key step in the successful execution of the Company's evolved strategy, which was set out in 2022, and will further enhance the ability of Sosei Heptares to generate value for all key stakeholders as a fully integrated biopharmaceutical company delivering life-changing medicines to patients.

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### Financial impact

Post-closing, financial results of the acquired entities will be reflected in the Group's consolidated financial results. The Transaction is expected to be cash flow positive in the first full calendar year.

Following the completion of the Transaction, the Company will have approximately JPY42 billion cash on balance sheet.

Centerview Partners UK LLP acted as exclusive financial adviser and Orrick, Herrington & Sutcliffe LLP acted as legal advisor to Sosei Group Corporation in connection with the Transaction.

<sup>1</sup> APAC (ex-China) territory rights includes Japan, South Korea, Australia, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam

<sup>2</sup> Assumes currency exchange rate between CHF1 = JPY162 as at 19 July 2023

<sup>3</sup> Source: IQVIA Institute: The Global Use of Medicines 2022, Outlook to 2026

*Tracleer® and Opsumit® are registered trademarks of Actelion Pharmaceuticals Ltd. QUVIVIQ® is a registered trademark of Idorsia.*

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### About Idorsia

Idorsia Ltd is reaching out for more – We have more ideas, we see more opportunities and we want to help more patients. In order to achieve this, we will develop Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech-hub – Idorsia is specialized in the discovery, development and commercialization of small molecules to transform the horizon of therapeutic options. Idorsia has a 20-year heritage of drug discovery, a broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, and commercial operations in Europe, Japan, and the US – the ideal constellation for bringing innovative medicines to patients.

Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 1,300 highly qualified specialists dedicated to realizing our ambitious targets. [www.idorsia.com](http://www.idorsia.com)

### 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.

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Sosei Heptares has a leading development capability and a profitable and growing commercial operation in Japan, which it intends to expand into additional selected markets in the Asia-Pacific region.

Sosei Heptares is advancing a broad and deep pipeline of novel medicines created using its world-leading GPCR-targeted StaR<sup>®</sup> technology and structure-based drug design platform across multiple therapeutic areas, including neurology, immunology, gastroenterology, and inflammatory diseases.

In addition, we have leveraged our unique discovery and development capabilities to establish multiple value-generating partnerships with world-leading biopharmaceutical companies, including AbbVie, Genentech (Roche), GSK, Lilly, Neurocrine Biosciences, Novartis, Pfizer, Sanofi and Takeda.

Sosei Heptares is headquartered in Tokyo, Japan with corporate and R&D facilities in London and 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<sup>®</sup> are trademarks of Sosei Group companies.*

For more information, please visit <https://soseiheptares.com/>  
LinkedIn: [@soseiheptaresco](#) | Twitter: [@soseiheptaresco](#) | YouTube: [@soseiheptaresco](#)

### Enquiries

#### Sosei Heptares – Media and Investor Relations

Hironoshin Nomura, Chief Financial Officer

Shinichiro Nishishita, VP Investor Relations, Head of Regulatory Disclosures

Maya Bennison, Communications Manager

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

#### MEDiSTRAVA Consulting (for International Media)

Mark Swallow, Frazer Hall

+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.