

# Sosei Heptares Operational Highlights and Consolidated Results for the First Half of FY2019

Strong momentum continues across all areas of the business

**Tokyo, Japan and London, UK, 13 August 2019** – Sosei Group Corporation ("the Company"; TSE: 4565) provides an update on operational activities and reports its consolidated results for the first half of FY2019. The full report can be accessed by <u>clicking here</u>.

### **Operational Highlights**

- Excellent progress with partnered programs AstraZeneca (AZD4635), Pfizer (two candidate nominations), Novartis (QVM149), all triggering progress-related milestones to Sosei Heptares
- Positive clinical data readouts of partnered programs Preclinical and Phase 1a data for AZD4635 presented at AACR 2019 by AstraZeneca, Phase 2 data for QVM149 presented by Novartis at ATS 2019
- **Progress with in-house (pre-partnered) pipeline** SSTR5 candidate successfully dosed in subject, new clinical programs initiated and other programs advancing
- Creation of two spin-out companies Spin out of discovered assets (orexin agonists) into Orexia Ltd and Inexia Ltd with funding of up to €40 million from Medicxi
- Launch of marketed products ORAVI® Mucoadhesive Tablets 50mg for Oropharyngeal Candidiasis in Japan, Ultibro®Breezhaler® and Seebri®Breezhaler® for COPD in China

#### Post H1 Events

- Two new multi-target collaborations initiated with major global partners Genentech and Takeda together bringing more than \$50m in upfront and near-term milestone payments, with potential for significant future payments plus royalties
- Milestone payment received from Formosa Pharmaceuticals on advancement of APP13007
  a divested candidate for post-operative inflammation of the eye
- Update on global R&D collaboration with Allergan work continues to advance programs through development, and multiple compounds with the potential to be new candidates have been generated. Clinical development of HTL0018318 in Alzheimer's disease remains voluntarily suspended while investigative work is continuing.
- Update on Phase 2 trial of HTL0018318 in DLB patients in Japan decision made to withdraw study in order to minimize CRO expenditure while clinical trial activities are suspended. The Company remains committed to the DLB program in Japan and plans to file a new clinical trial application with the Japanese PMDA in the future.



## Financial Highlights for the Six-month Period ending 30 June 2019

- Revenue totalled JPY 5,056 million (US\$45.9 million) (an increase of JPY 3,253 million (US\$29.5 million) vs. the prior corresponding period), and related primarily to strong growth in milestones, plus royalty payments received.
- Total cash operating expenses¹ were down to JPY 3,101 million (US\$28.2 million) (an improvement of JPY 1,911 million (US\$17.2 million) vs. the prior corresponding period), primarily due to a decrease in R&D costs.
- Cash profit<sup>2</sup> totalled JPY 1,578 million (US\$14.3 million) vs. a cash loss of JPY 3,096 million (US\$28.1 million) in the prior corresponding period, as a result of strong revenue growth and tight cost management
- Net profit totalled JPY 395 million (US\$3.6 million) vs. a net loss of JPY 3,327 million (US\$30.2 million) in the prior corresponding period, on the back of strong business plan execution
- The Company remains well capitalized, with Cash at Hand of JPY 16,915 million (US\$157.0 million) as at 30 June 2019

Shinichi Tamura, Chairman, President and CEO of Sosei Heptares, added: "We have made excellent progress in strengthening our business during the first half of 2019 and are well-positioned to capitalize on a number of strategic opportunities. Our highly productive GPCR-focused drug discovery platform has generated multiple new exciting candidates, and we have actively increased partnered and co-development activities, whilst simultaneously investing to advance our pipeline of emerging in-house candidates to be partnered in the future. The recent collaborations with Genentech and Takeda further exemplify our core strategy in action and reinforce our leadership position in the generation of best- and first-in-class candidates targeting this important class of drug targets."

Abbreviations used: COPD – chronic obstructive pulmonary disease; DLB – dementia with Lewy bodies; GPCR – G protein-coupled receptors

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#### **About Sosei Heptares**

We are an international biopharmaceutical group focused on the design and development of new medicines originating from its 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 CNS, immuno-oncology, gastroenterology, inflammation and other rare/specialty indications. Our leading clinical programs include partnered candidates aimed at the symptomatic treatment of Alzheimer's disease (with Allergan) and next-generation immuno-oncology approaches to treat cancer (with AstraZeneca). Our additional partners and collaborators include Takeda, Genentech, Novartis, Pfizer, Daiichi-Sankyo,

<sup>&</sup>lt;sup>1</sup> Non-GAAP

<sup>&</sup>lt;sup>2</sup> Non-GAAP



PeptiDream, Kymab and MorphoSys. Sosei Heptares is headquartered in Tokyo, Japan with R&D facilities in Cambridge, UK.

"Sosei Heptares" is the corporate brand of Sosei Group Corporation, which is listed on the Tokyo Stock Exchange (ticker: 4565).

For more information, please visit <a href="https://www.soseiheptares.com/">https://www.soseiheptares.com/</a> LinkedIn: <a href="mailto:@soseiheptaresco">@soseiheptaresco</a> | Twitter: <a href="ma

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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.