Sosei’s Strategic Minority Investment Company, MiNA Therapeutics, Presents Initial Results at ASCO from First-in-Human MTL-CEBPA Study in Advanced Liver Cancer Patients

- Well tolerated in patients with healthy and impaired liver function
- Blood samples demonstrate proof of RNA-activating mechanism
- Evidence of target engagement

Tokyo, Japan and London, UK, 5 June 2018 – Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) announces that MiNA Therapeutics ("MiNA"), a UK company in which Sosei has a strategic minority holding, today announced preliminary results from its ongoing Phase I study of small activating RNA (saRNA) candidate MTL-CEBPA in advanced liver cancer. Below is an excerpt of today’s press release from MiNA. For full details, please see the media section of MiNA’s website here (English only).

In the study, MTL-CEBPA was found to mediate RNA-activating activity in white blood cells. The data are being presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in a poster titled "Preliminary results of a first-in-human, first-in-class phase I study of MTL-CEBPA, a small activating RNA (saRNA) targeting the transcription factor C/EBP-a in patients with advanced liver cancer" in the Developmental Therapeutics – Clinical Pharmacology and Experimental Therapeutics poster discussion session being held on Monday 4 June 2018 from 3:00pm to 4:15pm CDT.

MTL-CEBPA was evaluated in the dose escalation part of a Phase I clinical trial in patients with advanced liver cancer. As of the data cut-off date of 31 March 2018, 23 patients had been treated once weekly at six dose levels (ranging from 28 mg/m² to 160 mg/m²) and five patients had been treated twice weekly at 70 mg/m².

MTL-CEBPA was well tolerated in patients at all doses and no Maximum Tolerated Dose has yet been identified. The large majority of adverse events (AEs) reported by investigators were mild to moderate in severity. Twelve (43%) patients experienced AEs no higher than Grade 2. AEs of Grade 3 or higher included hyperbilirubinaemia (11%), elevated gamma glutamyl transferase (GGT) (11%), hypophosphatemia (11%), anaemia (7%) and hypertension (7%). Only three (11%) patients discontinued treatment with MTL-CEBPA due to possible drug-related toxicities including acute coronary syndrome, hyperbilirubinaemia, and elevated GGT.

Pharmacokinetic data from this study showed that Cmax (peak plasma concentration of drug) and AUC (area under the curve) were dose proportional with no evidence of drug accumulation.

CEBPA gene expression was analysed in white blood cells of ten patients across multiple dose levels and timepoints. The level of CEBPA gene expression was significantly higher on treatment than at baseline, supporting target engagement of MTL-CEBPA. Consistent with
up-regulation of CEBPA, which has a role in myeloid differentiation, significant and repeated increases in neutrophils were observed after dosing MTL-CEBPA.

Enrollment in the dose escalation part of the Phase I clinical trial has been completed. Enrollment is starting for the dose expansion part of the Phase I clinical trial in multiple sites in the United Kingdom and Asia. For more information, please contact MiNA at outreach@minatx.com.

MiNA Therapeutics is an associate company of Sosei. In May 2017, Sosei acquired a 25.6% equity share and an exclusive option to potentially acquire MiNA Therapeutics.

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About MTL-CEBPA
MTL-CEBPA consists of a double stranded RNA formulated into a SMARTICLES® liposomal nanoparticle and is designed to activate the CEBPA gene. By restoring CEBPA expression to normal levels, MTL-CEBPA has been demonstrated to attenuate or reverse liver disease in a range of pre-clinical studies including models of liver cancer, liver cirrhosis, non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). MTL-CEBPA is currently under evaluation in OUTREACH, a first-in-human Phase I clinical study in patients with severe liver cancer. The multi-centre Phase I study is assessing the safety and tolerability of MTL-CEBPA in patients with advanced liver cancer who are ineligible or resistant to standard therapies. To learn more about the OUTREACH clinical study, please visit our listing at clinicaltrials.gov.

About MiNA Therapeutics
Harnessing an innate mechanism of gene activation, MiNA Therapeutics' platform enables the development of new medicines that restore normal function to patients’ cells. We are applying our technology and clinical know-how to transform the therapy landscape of severe liver and other diseases. www.minatx.com

About Sosei
Sosei is an international biopharmaceutical company focused on the design and development of new medicines originating from its proprietary GPCR-targeted StaR® technology and structure-based drug design platform capabilities. The Company is advancing a broad and deep pipeline of partnered and wholly owned product candidates in multiple therapeutic areas, including CNS, cancer, metabolic diseases and other rare/specialty indications. The Company’s leading clinical programs include a proprietary Phase 2 candidate for dementia with Lewy bodies (DLB) in Japan, together with partnered candidates aimed at the symptomatic treatment of Alzheimer's disease (with Allergan) and immuno-oncology approaches to treat cancer (with AstraZeneca). Sosei’s additional partners and collaborators include Novartis, Pfizer, Daiichi-Sankyo, PeptiDream, Kymab and MorphoSys. The Company is headquartered in Japan with R&D facilities in the UK.
Sosei is listed on the Mothers Index of the Tokyo Stock Exchange (ticker: 4565). For more information, please visit http://www.sosei.com/en/.

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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’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.