

Sosei Provides Update on HTL0018318

Tokyo, Japan and London, UK, 18 September 2018 – Sosei Group Corporation (“Sosei” or the “Company”; TSE Mothers Index: 4565), the world leader in GPCR medicine design and development, announces that the Company and Allergan, its license partner for HTL0018318, have decided to voluntarily suspend clinical development activities with HTL0018318 pending the investigation of an unexpected toxicology finding in an animal study involving non-human primates. This voluntary suspension is not based on any human findings.

Sosei’s programs with other partners as well as its in-house pipeline are not impacted by the finding announced today.

HTL0018318 is a selective small molecule muscarinic M1 receptor agonist under clinical investigation as a potential new symptomatic treatment for cognitive impairment in patients with Alzheimer’s disease (AD) and other dementias, including dementia with Lewy bodies, (DLB). The compound is in Phase 1 clinical development in the US (sponsored by Allergan), and a Phase 2 clinical study in Japan in patients with DLB. A further Phase 1b study in AD patients has completed its clinical phase in Europe and the data is being analysed (sponsored by Sosei’s subsidiary Heptares Therapeutics).

To date, HTL0018318 has been investigated in approximately 310 human subjects in the US and Europe, including healthy volunteers and patients with mild/moderate AD. Data available from the human studies have found it to be well tolerated and with no serious adverse effects at the tested doses for up to 28 days.

Patient safety is of the utmost importance to Sosei and Allergan. The decision by Sosei and Allergan to voluntarily suspend clinical development activities with HTL0018318 was taken as a precaution based on emerging results from a single animal toxicology study in non-human primates. This animal toxicology study was investigating different dosing levels of HTL0018318 over a nine-month period. The toxicological finding (neoplastic, rare tumor) was observed at doses and durations exceeding those used clinically in humans to date. No serious safety findings were observed in any species in any other animal toxicology studies with HTL0018318 extending as long as six months. Scientists from both Sosei and Allergan will be investigating these findings which are currently of unknown cause.

Sosei and Allergan have reported the safety finding of the study to the US Food & Drug Administration (FDA) and the Japan Pharmaceutical & Medical Devices Agency (PMDA). Other regulatory authorities in countries where studies that have been completed were also informed. The Company is undertaking a thorough investigation to identify the significance and cause of the safety finding and determine the next steps. Data from previous preclinical and clinical studies will be reviewed as part of the investigation.



Dr Tim Tasker, Chief Medical Officer of Sosei, said: “We were very surprised to see these results given the safety profile HTL0018318 has exhibited across all previous animal and clinical studies. We have taken these steps in the best interests of patient safety which is our number one priority. We are committed to working with clinical investigators, R&D teams and regulatory authorities to understand better the reason for the findings from this animal toxicology study and so enable the human clinical development program with HTL0018318 to continue as soon as possible. We remain confident that this compound has the potential to deliver important benefits to patients with AD and DLB.”

This toxicology finding, and subsequent investigations, will delay the start of planned Phase 2 studies in AD and DLB patients by at least six months. Because of this delay, there will be a revenue impact next year as the Company no longer expects to receive a major milestone payment from Allergan in 2019 relating to progress of the partnered muscarinic M1 agonist program for AD. The costs associated with investigating this safety finding are covered under the terms of our 2016 global R&D and commercialization agreement with Allergan. Regarding the 9-month period to 31 December 2018, we expect R&D expenses will decline because of reduced external spending. The voluntary suspension of clinical development activities with HTL0018318 does not automatically trigger impairment of assets or goodwill. We will fully assess the financial impact of the voluntary suspension and make adjustments to the carrying value of relevant assets, if any, in our results for the quarter ended 30 September 2018 which will be reported on 8 November 2018. We will also provide an update on the outlook for the accounting period ended December 2018 at that time.

The Company will host a video webcast today at 4:30 p.m. JST. To view, please access the following web address <http://www.c-hotline.net>. A replay of the video webcast will be available from 6:30 p.m. on the Investor Relations section of the Sosei website at www.sosei.com/en/ir.

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About the Sosei and Allergan Partnership

Sosei and Allergan entered a global R&D and commercialization partnership in April 2016 under which Allergan licensed exclusive global rights to a broad portfolio of novel subtype-selective muscarinic receptor agonists (M1, M4 and dual M1/M4 agonists) in development for the treatment of major neurological disorders, including Alzheimer’s disease (AD). The companies are investigating selective M1 agonists in clinical studies as a potential treatment for symptomatic cognitive deficits in AD patients; a clinical programme to assess the potential of a selective M4 agonist (HTL0016878) to treat certain neurobehavioral symptoms of AD is underway; and dual M1/M4 agonists with potential to treat both cognitive and neurobehavioral symptoms are being developed through preclinical studies. Sosei also intends to investigate the selective M1 agonist HTL0018318 in patients with Dementia with Lewy Bodies (DLB) in clinical trials in Japan.

About Muscarinic Receptors



Muscarinic receptors are G protein-coupled receptors (GPCRs) found in multiple tissues. Until now, attempts to develop medicines that target M1 and M4 receptors have been unsuccessful because of side effects caused by the activation of M2 and M3 receptors. Selective M1 or M4 agonists that do not activate M2 or M3 therefore are highly sought after and expected to address major unmet medical needs with blockbuster potential.

About Cognitive Impairment in Alzheimer's Disease and other CNS Diseases¹

There is significant unmet medical need and heavy economic burden across multiple diseases characterized by cognitive impairment and dementia. In Alzheimer's disease (AD), currently available drugs provide limited and transient effects on cognition. Healthcare costs associated with AD and dementia (estimated at over \$640 billion for North America, Western Europe and Asia-Pacific) including nursing home care, continue to grow dramatically and new therapies with better and more durable efficacy are urgently needed. It is estimated that over 45 million people worldwide have dementia (4.8 million in North America, 7.5 million in Western Europe, 3.6 million in Asia-Pacific) and this is expected to increase to over 130 million in 2050. Alzheimer's disease is the most common cause of dementia and may contribute to 60–70% of cases.

Enquiries:

Sosei Group

+81 (0) 3 5210 3399

Investor Relations and Corporate Communications

Shinichiro Nishishita, Yu Okada

IR@sosei.com

Citigate Dewe Rogerson (for international media)

+44 (0) 20 7638 9571

Mark Swallow, David Dible

sosei@citigatedewerogerson.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.

¹ Sources: World Health Organization, Alzheimer's Disease International, National Institute of Mental Health, Lewy Body Dementia Association



Sosei is listed on the Mothers Index of the Tokyo Stock Exchange (ticker: 4565). For more information, please visit <http://www.sosei.com/en/>.