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ASIA EDITION

Sosei Heptares initiates new clinical development programme

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First subject dosed in Phase I study of HTL0030310, a selective SSTR5 (somatostatin 5) receptor agonist in development to treat endocrine disorders



Sosei Group Corporation, has announced that the first healthy subject has been dosed with a novel small molecule HTL0030310 in a Phase I clinical study, marking the start of a new in-house clinical program targeting endocrine disorders, including Cushing's disease.

HTL0030310 is a potent and selective agonist of the SSTR5 (somatostatin 5) receptor and the sixth molecule designed by the Company using its GPCR Structure-Based Drug Design (SBDD) platform to enter clinical development.

HTL0030310 has been designed to modulate the excess release of hormones from adenomas (benign tumors) of the pituitary gland. Highly elevated plasma levels of pituitary hormones result in a number of serious endocrine disorders, including Cushing's Disease. Cushing's disease is characterized by excessive cortisol release, crucial in regulating metabolism, maintaining cardiovascular function and helping the body respond to stress.

A key design feature of HTL0030310 is its significant selectivity for SSTR5 over SSTR2. This selectivity is expected to improve the balance of efficacy vs. dose-limiting side effects and therefore, presents an opportunity to develop a best-in-class medicine for patients with Cushing's disease, in particular.

The clinical trial with HTL0030310 is a double-blind, randomised, placebo-controlled first-in-human study in which single ascending subcutaneous doses of HTL0030310 will be administered to healthy male and female adult subjects. The study is being conducted in the UK and will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of HTL0030310 in up to 64 subjects.

Preliminary results are expected in the second half of 2019 and will provide a first insight into the effects of HTL0030310 on the control of glucose and other endocrine hormones and the potential to target Cushing's disease and other endocrine disorders.

These candidates present new prospects for our emerging proprietary pipeline, as well as unique opportunities for partnering, and provide a solid foundation to execute our strategy," said, Dr. Malcolm Weir, Executive VP and Chief R&D Officer.