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Syndesi Therapeutics announces successful completion of first-in-human Phase I study of novel SV2A modulator, SDI-118, in development for the treatment of cognitive impairment.

Belgium – 5 November 2019 – Syndesi Therapeutics SA, a biotechnology company developing novel modulators of the synaptic vesicle protein SV2A for the treatment of cognitive impairment, today announced that the first-in-human Phase I study of its lead molecule, SDI-118, has been successfully completed.

The first-in-human Phase I study was a randomized, placebo controlled, single ascending dose study in healthy male subjects designed to investigate the safety, tolerability and pharmacokinetics of oral doses of SDI-118. The study also included PET imaging in a group of subjects to directly measure SV2A target engagement by SDI-118 in the brain.

SDI-118 was safe and well tolerated at all doses administered, with no serious adverse events. All adverse events considered to be related to SDI-118 administration were reported as mild. SDI-118 also showed favorable pharmacokinetic properties suitable for once daily dosing. Data from PET imaging following administration of a range of SDI-118 doses demonstrated a clear relationship between central SV2A occupancy and plasma exposure. Importantly, these results also demonstrated that the plasma exposures reached in the study, shown to be safe and well tolerated, provided essentially complete brain SV2A occupancy.

Commenting on the results, Jonathan Savidge CEO of Syndesi, said *“We are very pleased with the excellent data generated in this first-in-human study. Single doses of the compound that result in high SV2A occupancy were shown to be safe and well tolerated. The results of the study provide an excellent basis for further clinical development, with the PET data informing the choice of doses in future studies. We will be initiating a further Phase I trial investigating multiple doses of SDI-118, including in elderly subjects.”*

About Syndesi Therapeutics

Syndesi Therapeutics was established to develop a series of novel, pro-cognitive small molecule SV2A modulators licensed from UCB. In February 2018 the company



announced €17M in Series A funding from a syndicate of Belgium and international investors. In March 2019, Syndesi announced the award of up to €3.2 M in non-dilutive funding from the Walloon Region to support the development of the lead molecule SDI-118 through Phase I clinical development. Syndesi is investigating the potential of these novel SV2A modulators to improve cognition in diseases such as Alzheimer's Disease and other dementias, as well other conditions such as major depression and cognitive impairment associated with schizophrenia. For more information please visit www.syndesitherapeutics.com