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**Syndesi Therapeutics announces positive results from two additional Phase I studies of its novel SV2A modulator SDI-118, providing strong support for the initiation of further clinical trials in cognitive impairment**

Belgium – 27th January 2021 – Syndesi Therapeutics SA, a clinical stage biotechnology company developing novel modulators of the synaptic vesicle protein SV2A for the treatment of cognitive impairment, announces results from two Phase I studies of its lead compound SDI-118, supporting further development of this promising molecule.

Results from a multiple ascending dose study demonstrated SDI-118 was safe and well tolerated over 14 days dosing in both young and elderly male and female participants. The highest dose tested is calculated to result in greater than 95% SV2A occupancy. Furthermore, the compound showed a very favourable pharmacokinetic profile and is suitable for once-daily dosing.

The second Phase I study investigated the effects of single doses of SDI-118 on electroencephalogram (EEG) recordings of brain activity in healthy young volunteers. The compound produced a unique profile of changes in quantitative EEG relative frequency power, consistent with the novel mechanism of action. These functional data complement the PET target engagement data generated in the first-in-human clinical study previously conducted. SDI-118 was also shown to be safe and well tolerated in this study.

The company is now preparing two further clinical studies of SDI-118 in two groups of subjects. One study will recruit participants in remission from major depressive disorder reporting cognitive impairment. The second study will recruit elderly subjects with evidence of cognitive decline. Both studies will employ fMRI imaging in addition to cognitive testing to explore the effect of SDI-118 on the cognitive deficits seen in these populations. These studies are planned to commence during H1 2021.

Commenting on the Phase I results and further clinical development plan for SDI-118, Jonathan Savidge CEO of Syndesi said *“These clinical study results are very promising and provide an excellent basis for the further development of SDI-118. We look forward to commencing the two proof-of-principle clinical studies in different populations of subjects reporting a cognitive deficit with the aim to explore the therapeutic potential of SDI-118 as broadly as possible.”*

### **About Syndesi Therapeutics**

Syndesi Therapeutics is a clinical stage biotechnology company pioneering the development of novel therapeutics that modulate synaptic function to relieve the symptoms of cognitive impairment. Synaptic dysfunction, with the consequent disruption of connectivity between brain regions, underlies cognitive impairment seen in multiple CNS disorders, including Alzheimer’s Disease and schizophrenia. There is a major unmet need for new therapies that can improve cognitive function across these various CNS disorders. Unlike other therapeutic approaches, our unique molecules act pre-synaptically to enhance synaptic efficiency by positively modulating the function of synaptic vesicle protein 2A (SV2A) which plays a central role in regulating synaptic transmission. The lead molecule, SDI-118, has successfully completed three Phase I studies including PET target engagement and biomarker measures.

The company is financed by a syndicate of international and Belgian investors: Novo Holdings, Fountain Healthcare, Johnson & Johnson Innovation – JJDC, Inc., SRIW (Société Régionale d’Investissement de Wallonie), V-Bio Ventures and Vives Fund, along with UCB Ventures. The Phase I program has been supported in part by funding from the Walloon Region.