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Syndesi Therapeutics announces commencement of dosing in clinical trial of SDI-118 in elderly subjects with cognitive impairment

Belgium –21 October 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 that dosing has commenced in the first clinical trial in the next phase of development of its lead compound, SDI-118.

The double-blind, placebo-controlled, parallel group study will evaluate the safety, tolerability, and pharmacodynamics of SDI-118 in elderly male and female participants with cognitive decline. Eligibility for enrollment in the study includes self-reported and companion-confirmed decline in memory, as well as a below average performance on a delayed word recall test as an objective measurement of cognitive deficit. The study includes fMRI imaging, both at rest and during cognitive tasks, as a biomarker of drug effect, as well as a battery of cognitive tests conducted at baseline and following approximately two weeks dosing with SDI-118 or placebo. The design of the study was the subject of a presentation at the recent European College of Neuropsychopharmacology (ECNP) annual conference ⁽¹⁾, held 2-5 October 2021

Subjects are currently being enrolled at St Pancras Clinical Research in London, with additional sites in Germany to be initiated shortly.

Commenting on the initiation of the study, Jonathan Savidge CEO of Syndesi said *“We are very excited to get this proof of principle study with SDI-118 underway to explore the potential of this novel synaptic mechanism to mitigate cognitive impairment due to underlying synaptic loss.”*

Torsten Madsen, Syndesi’s CMO added *“We are incorporating fMRI both before and after treatment in all subjects to translate preclinical results and build on findings from*

fMRI measures in a prior clinical study. Together with the battery of cognitive tests, this will provide a wealth of information on this novel synaptic mechanism to optimize the late stage development program”

(1) See:

<https://www.ecnp.eu/Congress2021/ECNPcongress/programme/Programme#!abstractdetails/0000469100>

About Syndesi Therapeutics SA

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 Partners, 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 enabling the current trials was supported in part by funding from the Walloon Region.