MedDay Reports Top-Line Data from Phase III Trial "SPI2" for Treatment of Progressive Forms of Multiple Sclerosis

Paris, France, March 10, 2020 – MedDay Pharmaceuticals announced today that the second pivotal Phase III trial (SPI2) of its investigational product MD1003 has not met its primary and secondary endpoints. There were no treatment emergent safety signals. SPI2 was designed to confirm the results of the first positive Phase III study, MS-SPI, in progressive multiple sclerosis (MS). Detailed results of the SPI2 trial will be presented to the medical community at the upcoming American Academy of Neurology (AAN) 2020 Annual Meeting on April 29th in Toronto, Canada.

"We are clearly disappointed that SPI2 did not meet its primary and secondary endpoints. Going forward, we will continue to evaluate the trial data and confer with regulators," commented Catherine Moukheibir, Chief Executive Officer of MedDay Pharmaceuticals. "We would like to thank our collaborators including the participating clinicians, medical staff and, most importantly, the patients for all of their efforts and participation in the trial. All were invaluable partners throughout the process of completing the SPI2 trial."

"We will review the findings in detail to understand these outcomes to help inform future clinical research in progressive MS and other neurological diseases," commented Frédéric Sedel, MD, PhD, Chief Scientific Officer and co-Founder of MedDay Pharmaceuticals. "I remain confident of the importance of the neurometabolic approach to neurodegenerative diseases with high unmet medical need."

The randomized, double-blind, and placebo controlled SPI2 trial evaluated safety and efficacy of three daily doses of 100mg of MD1003 versus placebo in 642 patients with progressive MS without recent relapses, also called not-active progressive MS. The primary endpoint for the study was reversal of functional disability as measured by the proportion of patients with an improvement in either the Expanded Disability Status Scale (EDSS) or in the time needed to walk 25 feet (TW25) over a 12-month time frame and confirmed at 15 months. Secondary endpoints included the relative reduction in the risk of disability progression; global impression of response to treatment evaluated independently by both the patient and the evaluating physician; and mean change in TW25. Additional exploratory endpoints incorporated in this trial included brain MRI measures, quality of life measures and measurements of ambulation using a Fitbit® device. For more information on the trial design, please visit: https://clinicaltrials.gov

About MedDay

MedDay was founded on the premise that neurodegenerative disorders can be treated by targeting key neurometabolic pathways. For more information, please visit: www.medday-pharma.com

About MD1003

MD1003 is an investigational neurometabolic modulator[1-5] designed to target both neurodegenerative and demyelination processes through its non-immunological mechanism. As

a coenzyme involved in cellular metabolism, MD1003, a high-dose Pharmaceutical-grade Biotin, has the potential to (i) enhance Krebs cycle activation to support increased energy demands of demyelinated axons and (ii) promote ensheathment through enhanced oligodendrocytes energetics. Preclinical studies support MD1003's potential to counteract axonal energy deficiency and enhance oligodendrocytes ensheathment[6-8].

Disclaimer

High-dose Pharmaceutical-grade Biotin (hdPB), MD1003, is an investigational product that has not been approved by regulatory authorities in any country at this stage (including the USA and Europe).
The information presented here is not intended as guidance to healthcare professionals.
MD1003® and hdPB® are registered trademarks of MedDay Pharmaceuticals.

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