MedDay Reports Last Patient Study Visit in Second Phase 3 Clinical Trial with MD1003®*, an Important Milestone Towards Completion of the SPI2 Study in Progressive Multiple Sclerosis

SPI2 Study Evaluating High Dose Pharmaceutical Grade Biotin is on Track to Report Top-Line Results in Q1 2020

Paris, France, December 12, 2019 – MedDay Pharmaceuticals, a pioneering biotechnology company focusing on the development of solutions for the treatment of neurodegenerative disorders, announced today that the last patient study visit in the double-blinded part of its SPI2 clinical study has occurred according to schedule. SPI2, the second pivotal Phase 3 clinical trial was designed to confirm the therapeutic potential of MD1003 as was demonstrated in a first pivotal Phase 3 trial, MS-SPI, in both primary and secondary progressive multiple sclerosis (MS). The company also confirmed that it anticipates reporting top-line results of SPI2 by the end of Q1 2020.

"At MedDay, we are committed to providing compelling scientific and clinical evidence for the therapeutic value of our patented formulation of high dose Pharmaceutical grade Biotin (hdPB®) in progressive MS. We believe that with the conclusion of a positive outcome of the SPI2 trial, MedDay will have a robust package for regulatory submission of MD1003 in the US and Europe" commented Catherine Moukheibir, Chief Executive Officer of MedDay Pharmaceuticals. "In the months ahead, we will continue to interact with the respective regulatory authorities to actively prepare these submissions. We also would like to take the opportunity and thank the entire staff at all 90 clinical centers involved for their hard and diligent work and commitment to patients participating in our trial."

The randomized, double-blind, and placebo controlled SPI2 trial evaluated three daily doses of 100mg of MD1003 versus placebo in 642 patients with progressive MS. The primary endpoint for the study was reversal of disease progression 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. This endpoint has been developed for the MD1003 clinical program to substantiate reversal of disease progression and is considered an ambitious goal in progressive MS, a pathology during which patients slowly and progressively worsen. Secondary endpoints include the time to confirmed EDSS progression, global impression of improvement evaluated independently by both the patient and the evaluating physician, and mean change in TW25. Additional exploratory endpoints incorporated in this trial include 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

At the time of submission, MedDay will be able to present a comprehensive data package based on a complete manufacturing, pre-clinical and clinical set of studies to demonstrate the potential of MD1003. The first trial, MS-SPI, conducted in France in 154 patients met its primary endpoint and demonstrated MD1003's potential to reverse disease progression in progressive MS over 12 months. The second SPI2 trial expands on MS-SPI by evaluating MD1003 in a substantially larger patient population (n=642) at 90 clinical trial centers in the USA, Canada, Europe and

Australia. The SPI2 trial includes an extended treatment duration of a minimum of 15 months with maximum duration of the double-blinded period per patient of 27 months.

About MD1003®

The lead product of MedDay, MD1003 is a patented formulation of high dose Pharmaceutical grade Biotin (hdPB®) which is in development for primary and secondary progressive multiple sclerosis (MS) and other conditions. MS-SPI, a Phase 3 study, with MD1003 in patients with progressive MS, met its primary endpoint. MD1003's unique non-immunologic mode of action is directed at two targets related to progressive MS: (1) activation of the Krebs cycle, the main route for energy production that protects against axonal degeneration and (2) potential activation of acetyl CoA carboxylases (ACC1 and ACC2), the rate-limiting enzymes in the synthesis of fatty acids required for myelin repair. SPI2 represents the second, pivotal, confirmatory Phase 3 trial.

About MedDay

Founded in 2011, MedDay is a pioneering biotechnology company addressing neurodegenerative disorders in areas of potential high unmet medical needs. The lead product is MD1003, in development for progressive multiple sclerosis and other conditions. At MedDay, we are driven by patients' needs, placing people living with neurodegenerative conditions and their families at the heart of everything we do.

MedDay explores brain metabolic pathways through its innovative and proprietary research platform, SPECMET, to support the discovery of additional assets. SPECMET enables examination of metabolomic and lipidomic signatures of the cerebrospinal fluid (CSF) of patients suffering from central nervous system (CNS) disorders to identify disrupted metabolic pathways. Compounds that are known to affect these metabolic pathways are then identified and further developed to address the identified disorder.

MedDay is supported by leading European investors including Sofinnova Partners, InnoBio, Andera Partners and Bpifrance Large Venture. MedDay is headquartered in Paris, France with an affiliate based in Boston, USA.

For more information, please visit: www.medday-pharma.com

*MD1003® is an investigational product and has not been approved as safe and effective by the FDA or EMA.
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