



## **MedDay Pharmaceuticals Announces Full Patient Enrollment for MD1003 Phase III Clinical Trial (SPI2) in Progressive Multiple Sclerosis**

- Top-line results of the SPI2 trial expected by Q1 2020
- NDA (USA) and MAA (Europe) filings expected by H2 2020

**Paris, France, November 9, 2018** – MedDay Pharmaceuticals, an international pioneering biopharmaceutical company focusing on the development of products for the treatment of central nervous system disorders, today announced full enrollment of SPI2, a phase III clinical trial designed to confirm the potential of its investigational drug MD1003 in progressive MS as shown in MS-SPI phase III trial. MedDay is pursuing the clinical development of MD1003 with the objective of filing a New Drug Application (NDA) in the USA and a Marketing Authorization Application (MAA) in Europe in H2 2020.

**Enrollment complete in SPI2 phase III study investigating MD1003 in Progressive MS -** MedDay has finalized full patient enrollment of its second phase III clinical trial (SPI2) which is aimed at confirming and reinforcing the positive results of the first phase III trial (MS-SPI) that demonstrated the potential of its investigational drug MD1003 to reverse disease progression in progressive MS<sup>1,2</sup>.

SPI2, a randomized double blind, placebo-controlled trial, is similar in design to the previous phase III study (MS-SPI) using the same endpoint measuring reversal of disease progression, with a larger patient population (n=642) and an extended treatment duration of 15 months minimum. Secondary endpoints include time to EDSS progression, clinical global impression of improvement (CGI and SGI) and mean change in TW25. Exploratory endpoints include brain MRI measures among others. Baseline demographic data recently presented at theECTRIMS October 2018 Congress confirmed that the study enrolled a population of non-relapsing but progressing patients. In the SPI2 trial, 90 clinical sites are active globally (48 sites in the USA and Canada, 39 in Europe and 3 in Australia). Top-line data of SPI2 study are expected by Q1 2020, with NDA and MAA filing in H2 2020.

**Regulatory strategy focused on gaining marketing approval for investigational drug MD1003 in major markets** - MedDay interacts continuously with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) on the development of its investigational drug MD1003 in progressive MS. The company held an in-person EOP2 meeting with FDA in July 2018.

**Christian Chavy, Chief Executive Officer of MedDay, commented:** *“The mechanism of action of our investigational product MD1003 has significant potential in the treatment of Progressive Multiple Sclerosis. MedDay is fully committed to advance its clinical program as initially planned with a view of offering a new therapeutic alternative to patients.”*

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### **About MD1003**

The lead product of MedDay, MD1003 is a patented formulation of high dose Pharmaceutical grade Biotin (hdPB) which is under development in progressive multiple sclerosis (MS) and other demyelinating diseases. MS-SPI, a positive phase III study, with MD1003 in patients with progressive multiple sclerosis, met its primary endpoint<sup>1,2</sup>. MD1003 has a mode of action which potentially acts on two targets related to progressive MS: (1) it activates the Krebs cycle, the main route for energy production that protects against axonal degeneration and (2) it activates acetyl-CoA carboxylases (ACC1 and ACC2), the rate-limiting enzymes in the synthesis of fatty acids required for myelin repair. MD1003 is an investigational product and has not been approved as safe and effective by the FDA or EMA.

### **About MedDay**

Founded in 2011, MedDay is an international pioneering biopharmaceutical company targeting brain metabolism to treat nervous system disorders. The lead product, MD1003, is a patented formulation of high dose pharmaceutical grade biotin (hdPB) developed and under study in progressive multiple sclerosis and other demyelinating diseases. MedDay explores brain metabolic pathways through its metabolomics research platform, SPECMET, which supports the discovery of additional pipeline assets. SPECMET screens cerebrospinal fluid (CSF) of patients suffering from different central nervous system (CNS) disorders in order to identify the disrupted metabolic pathways. Compounds that are known to affect these metabolic pathways are then identified and further developed to address the identified disorder. SPECMET was developed in collaboration with the Commissariat à l'Energie Atomique (CEA) and in March 2017, MedDay acquired the health division of Profilomic SA, an innovative company formed out of the CEA in 2010, which significantly strengthened MedDay's research capabilities as the company aims to expand its pipeline. MedDay is supported by leading 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](http://www.medday-pharma.com)

More details on the SPI2 trial are available at:

<https://clinicaltrials.gov/ct2/show/NCT02936037?term=spi2&rank=1>

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<sup>1</sup> Tourbah A, Lebrun-Frenay C, Edan G et al. MD1003 (high-dose biotin) for the treatment of progressive multiple sclerosis: A randomised, double-blind, placebo-controlled study. *Mult Scler* 2016; 22 (13): 1719–1731.

<sup>2</sup> The primary endpoint of MS-SPI study was the proportion of patients with disability reversal at month 9, confirmed at month 12, defined as an EDSS decrease of  $\geq 1$  point ( $\geq 0.5$  for EDSS 6–7) or a  $\geq 20\%$  decrease in timed 25-foot walk time compared with the best baseline among screening or randomization visits, and 154 patients were randomized. A total of 12.6% of MD1003-treated patients achieved the primary endpoint versus none of the placebo-treated patients ( $p = 0.005$ ). MD1003 treatment also reduced EDSS progression and improved clinical impression of change compared with placebo. Efficacy was maintained over follow-up, and the safety profile of MD1003 was similar to that of placebo.