U.S. FDA Approves Nova Mentis Orphan Drug Application

Psilocybin Fragile X Syndrome Treatment

Vancouver, British Columbia – November 2, 2021 – Nova Mentis Life Science Corp. (CSE: NOVA) (FSE: HN3Q) (OTCQB: NMLSF) ("NOVA" or the "Company"), a biotechnology company and global leader in first-in-class psilocybin-based therapeutics and complementary diagnostics for neuroinflammatory disorders, is pleased to announce that the U.S. FDA has approved the Company's proprietary psilocybin drug Orphan Drug Application to treat patients with fragile X syndrome (FXS), the most common inherited cause of autism spectrum disorder (ASD).

"NOVA has established a unique position in the field of psychedelic therapy by having its FXS program achieve orphan drug status in both the United States and European Union," says Will Rascan, NOVA's CEO & President. "I am pleased to announce that we are the first biotech company to have psilocybin registered for treatment of FXS in the drug regulatory logs of both the FDA and EMA."

Medicines that have been granted an orphan designation from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) receive benefits, including but not limited to:

- Seven-Ten years of market exclusivity: FDA and EMA cannot approve the same drug for the same indication.
- 25% federal tax credit for expenses incurred in conducting clinical research within the United States.
- Waiver of Prescription Drug User Fee Act (PDUFA) fees: a value of approximately $2.9 million.
- Ability to qualify to compete for research grants from the Office of Orphan Products Development (OOPD) to support clinical studies.
- Eligibility to receive regulatory assistance and guidance from the FDA in the design of an overall drug development plan.

"The attainment of Orphan Drug status in both the U.S. and Europe is a significant milestone towards launch of psilocybin FXS phase 2 clinical studies," stated Dr. Marvin S. Hausman MD, Chairman of NOVA's Scientific Advisory Board. "The U.S. FDA has issued guidance concerning the usage of observational clinical study Real-World Evidence (RWE) to support the potential benefits of a medical product (1). NOVA intends to immediately launch an IRB approved ASD observational study to provide baseline clinical biomarker RWE data in support of its psilocybin IND to treat FXS."

(1) https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

About Nova Mentis Life Science Corp.

Nova Mentis Life Science Corp. is a Canadian-based biotechnology company and global leader in developing diagnostics and psilocybin-based therapeutics for neuroinflammatory disorders. The goal is to diagnose and treat debilitating chronic conditions that have unmet medical needs, such as autism spectrum disorder (ASD) and Fragile X Syndrome (FXS).

For further information on the Company, please visit https://www.novamentis.ca or email info@novamentis.ca.

On Behalf of the Board

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