

Nova Mentis Receives Health Canada Approval for First-of-its-Kind Psilocybin Clinical Trial

The human study will evaluate the Company's proprietary psilocybin drug (NM-1001) in the treatment of Fragile X Syndrome

Vancouver, British Columbia – December 22, 2022 – 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 proud to announce that the company has received a No Objection Letter from Health Canada, allowing NOVA to proceed with the first-ever Phase II A clinical trial assessing repetitive, oral microdose psilocybin therapy for fragile X syndrome (FXS), the leading genetic cause of autism spectrum disorder (ASD).

"We are thrilled to receive Health Canada approval for our pioneering psilocybin study. NOVA is the first company in the world to conduct a human trial testing the efficacy of psilocybin on adults diagnosed with fragile X," stated William Rascan, President and CEO of NOVA. "We are eager to gather the necessary clinical data to develop a groundbreaking new therapy to help improve the behavioural and cognitive symptoms associated with autism."

The results of the 10-person, open-label study will be used to support NOVA's drug development program under FDA Orphan Drug designation, which was received in late 2021. The trial will be led by KGK Science, NOVA's clinical research organization (CRO) partner, and recruiting efforts are expected to begin 1st quarter 2023.

In <u>September</u>, NOVA completed production of pharmaceutical grade, cGMP synthetic psilocybin 1.5 mg microdose capsules that will be used in the study as the Company advances the necessary research and development steps required for successful drug regulatory approval and future commercialization.

NOVA's <u>preclinical</u> research results, which were recently published in an international science <u>journal</u>, showed that a low microdose formulation of the Company's psilocybin drug significantly modulated behavioural and cognitive defects in a genetic model of FXS.

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. Nova is the first biotech company to achieve orphan drug designation in both the United States and European Union for the use of psilocybin in the treatment of Fragile X Syndrome (FXS).



Our goal is to diagnose and treat debilitating chronic conditions that have unmet medical needs, such as autism spectrum disorder (ASD) and FXS.

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

On Behalf of the Board

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