



Nova Mentis Granted Health Canada Section 56 Exemption to Begin Psilocybin Clinical Trial

Vancouver, British Columbia – February 14, 2023 – 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 it has received an exemption under Section 56 of the Controlled Drugs and Substances Act allowing the Company to proceed with the first-ever Phase IIA clinical trial assessing repetitive, oral microdose psilocybin therapy for fragile X syndrome (FXS), the leading genetic cause of autism spectrum disorder (ASD).

A Section 56 exemption enables an approved medical professional to prescribe select controlled substances without legal consequence, in order to better treat people with otherwise treatment-resistant conditions.

“Securing this latest regulatory approval from the Canadian government is a critical step in NOVA’s research and drug development program and allows us to begin our groundbreaking clinical trial. We are eager to begin recruiting participants as we seek to better understand the therapeutic potential of psilocybin in the treatment of fragile X syndrome,” stated William Rascan, NOVA’s President & CEO.

[KGK Science](#) and NOVA have partnered to conduct a pioneering first clinical trial to investigate the effects of microdose psilocybin on the cognitive and behavioural symptoms associated with FXS. 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.

“KGK Science is thrilled to have received all of the regulatory approvals required to conduct this cutting-edge clinical trial. We believe that this study will be an impactful assessment of the potential of psilocybin in a disorder that truly affects the lives of many families and that has not yet been studied,” commented Najla Guthrie, CEO of Wellbeing and KGK. “We look forward to working with Nova Mentis and contributing to the science.”

The trial will be led by KGK Science and recruiting efforts are expected to begin in late Q1 2023. The clinical trial received a [No Objection Letter from Health Canada](#) in December of 2022 and is one of the first approved studies that will permit participants to take home the drug for dosing every other day.

Nova Mentis has completed production of pharmaceutical grade cGMP synthetic psilocybin 1.5 mg microdose capsules that will be used to advance the necessary research and development steps needed for successful drug regulatory approval and future commercialization.



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 FXS.

NOVA's goal is to diagnose and treat debilitating chronic conditions that have unmet medical needs, such as ASD and FXS.

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

About KGK Science

A subsidiary of Wellbeing Digital Sciences, KGK Science is a leading North American contract research organization based in London, Ontario that primarily provides high-quality clinical research trials with a focus on nutraceutical and emerging health care products. Founded in 1997, the business has successfully helped hundreds of companies with custom designed clinical trials and claim substantiation strategies to move products into global markets. KGK's other existing service lines include expert regulatory support and compliance solutions, participant recruitment, research support services and consulting services. Furthermore, the company has produced over 150 publications, executed over 400 clinical trials across more than 40 indications, amassed 25,000 participants in its database, and collected 10 million data points. For additional information, please visit www.kgkscience.com.

On Behalf of the Board

Will Rascan, President & CEO
Nova Mentis Life Science Corp.

Phone: 778-819-0244
Toll Free: 1-833-542-5323

Twitter: @novamentislsc
Instagram: @novamentislsc
Facebook: @novamentislsc

Neither the Canadian Securities Exchange nor its Market Regulator (as that term is defined in the policies of the Canadian Securities Exchange) accepts responsibility for the adequacy or accuracy of this release.



This news release contains statements that constitute “forward-looking statements.” Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause Nova Mentis Life Science’s actual results, performance or achievements, or developments in the industry to differ materially from the anticipated results, performance or achievements expressed or implied by such forward-looking statements. Forward looking statements are statements that are not historical facts and are generally, but not always, identified by the words “expects,” “plans,” “anticipates,” “believes,” “intends,” “estimates,” “projects,” “potential” and similar expressions, or that events or conditions “will,” “would,” “may,” “could” or “should” occur.