Nova Mentis Earns Psilocybin Orphan Drug Designation in Europe for Fragile X Syndrome

Vancouver, British Columbia – October 26, 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 it has received orphan drug designation from the European Medicines Agency (EMA) for its propriety psilocybin drug for the treatment of fragile X syndrome (FXS), the leading genetic cause of symptoms related to autism spectrum disorder (ASD).

"Orphan Drug designation of our proprietary psilocybin formulation in Europe is a significant milestone on the pathway to drug approval," says Will Rascan, NOVA's CEO & President. "This achievement has the potential to rapidly advance our company's clinical program in Europe with the goal of approval of psilocybin in the treatment of FXS, a major unmet medical need. Nova intends to move expeditiously to begin a phase 2 study with psilocybin in FXS." Medicines that have been granted an orphan designation receive the following benefits:

- Ten years of market exclusivity: once approved, NOVA's proprietary formulation is protected from competition with similar medicines in similar indications.
- Reduced fees for protocol assistance and other regulatory activities.
- Access to grants from the European Commission and other sources.
- Scientific advice and administrative and procedural assistance.
- Access to a centralized marketing authorization with a single application.

There are currently no approved prevention or treatment methods for FXS. Current therapies, including pharmaceutical and behavioural interventions, offer a patchwork of solutions that have limited efficacy and high toxicity. Psilocybin has the capacity to influence cognition and behaviour as well as modulate the immune system and neural signaling pathways. Likewise, psilocybin is non-toxic and is not expected to have adverse side effects in humans.

"Our proprietary psilocybin drug is being proposed as a novel, first-in-class treatment for fragile X," stated Dr. Marvin S. Hausman MD, Chairman of NOVA's Scientific Advisory Board. We have achieved several drug development breakthroughs this year, including a significant therapeutic effect in validated preclinical models of ASD and FXS, identification of an effective dose and no observed psilocybin toxicity. We look forward to working closely with EMA to advance our efforts to receive European regulatory marketing approval for our leading psilocybin drug candidate."

EMA is a decentralised agency of the EU responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. Orphan designation is a status assigned to a medicine intended for use against a rare condition.

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

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

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