Nova Mentis Files Fragile X Orphan Drug Designation with European Medicines Agency

VANCOUVER, BC, Aug. 12, 2021 /CNW/ - **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 filed for orphan drug designation with the European Medicines Agency (EMA) for its propriety psilocybin drug to help treat patients with fragile X syndrome (FXS), the leading genetic cause of symptoms related to autism spectrum disorder (ASD).

"NOVA is continuing to advance our research and drug development program to explore the clinical potential of psilocybin for chronic neuroinflammatory conditions with unmet medical needs," says Will Rascan, NOVA's CEO & President. "Orphan drug designation would give our Company a wide range of incentives that include assistance with trial protocols, reduced regulatory fees and 10 years of market exclusivity after drug approval."

NOVA's R&D plan towards successful regulatory approval and commercial launch of psilocybin in ASD and FXS follows standard procedures in drug development, used by established pharmaceutical companies. Our proprietary manufacturing process will deliver >98% cGMP psilocybin – repetitively and consistently. The Company is setting up a data bank of biologic markers associated with ASD and FXS, which will supplement behavioural results, improve identification of specific disease subsets, and aid development of patient-specific treatments. In the immediate future, NOVA plans to submit regulatory documents to the FDA and EMA that support psilocybin's potential therapeutic efficacy. These will include statistical analyses of baseline observational data and biomarkers of disease outcomes, including the neurotransmitter serotonin and other physiologically active biomarkers involved in the development of ASD and FXS. Finally, NOVA will conduct clinical trials to evaluate how ASD and FXS patients may benefit from psilocybin therapy. These trials will be designed according to ethical principles and rooted in insights gained from our non-interventional studies and novel biomarker panels.

"NOVA's lead drug candidate psilocybin (NM1010), in a preclinical model of FXS, has revealed positive improvement in cognition without apparent psychedelic side effects," stated Dr. Marvin S. Hausman MD, Chairman of NOVA's Scientific Advisory Board. "I am also excited to report that psilocybin-treated animals showed changes in inflammatory biomarkers that are potentially involved in the ASD disease process."

FXS is a genetic neurological disorder in which the reduction/absence of the FMR1 protein (FMRP) leads to dysfunction in neural signaling and behavioral abnormalities. The total number of patients in the European Union (EU) was estimated to be ~88,000 for an overall prevalence of 2 in 10,000, which is below the ceiling for orphan designation of 5 in 10,000.

There are currently no approved prevention or treatment methods, though psychiatric approaches to autism spectrum disorder have been used in FXS with some success. Currently available therapies for FXS – including pharmaceutical and behavioural interventions – fail to address the emotional aspects of the disorder, offering a patchwork of solutions that have limited efficacy and high toxicity.

Psilocybin is proposed as a novel, first-in-class treatment for FXS. Beyond the promising cognitive benefits, psilocybin also has peripheral effects, including the capacity for curbing inflammation and modulating microbiota. Given the high prevalence of GI disorders in FXS, psilocybin and other tryptamine derivatives may offer additional benefit in the gut. Psilocybin is expected to modulate molecular and behavioural underpinnings of FXS, including improvements in brain plasticity and reduction in anxiety and behavioural rigidity - a significant step above currently available methodologies.

The 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. The prevalence of the condition in the EU must not be more than 5 in 10,000 and the medicine must fulfil certain criteria.

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).

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

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.

SOURCE Nova Mentis Life Science Corp.

View original content to download multimedia:
http://www.newswire.ca/en/releases/archive/August2021/12/c8296.html

%SEDAR: 00023830E

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

CO: Nova Mentis Life Science Corp.

CNW 08:00e 12-AUG-21