Nova Mentis Launches Autism Clinical Study

VANCOUVER, BC, May 6, 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 that its North American autism clinical study has been listed on ClinicalTrials.gov (NCT04869930), a database of privately and publicly funded clinical studies conducted around the world.

The US-based Observational Study, NM101: *Establishing a Diagnostic and Therapeutic Index in Autism Spectrum Disorder (ASD) and Fragile X Syndrome (FXS)* is a large-scale effort to examine the dynamic roles of microbiota, serotonin signaling and the immune system in gut and brain development of ASD and FXS, particularly as these forces work together to manifest classic behavioral symptoms. AI-driven computational analysis of collected datasets will be used to establish a "Diagnostic and Therapeutic Index (ASD-DTI)" – an objective set of tools that can help differentiate subtypes of ASD and develop more accurate methods of diagnosis and response to drug treatment.

"We are developing this set of multidimensional biomarkers to help differentiate subsets of symptomatic, as well as pre-symptomatic, ASD and FXS patients – an approach that currently does not exist in clinical practice," stated Julia V. Perederiy, PhD, NOVA's Lead Scientist and Principal Investigator on the study. "Furthermore, we will use the index to subsegment participants in upcoming Phase 1 and Phase 2 clinical trials of NOVA's proprietary psilocybin formulation – an essential step for study design and development of hard endpoints to corroborate clinical results."

NOVA aims to recruit at least 300 participants across the U.S and Canada: 200+ with diagnosed ASD or FXS and 100+ neurotypical controls, including pre-symptomatic/undiagnosed children under age 5. Participants will be asked to provide samples of cheek cells, urine, finger/toe-prick blood and feces, which will be used to quantify serotonin levels and related cell signaling pathways, as well as evaluate commensal bacterial species and their function in the gut. Samples will be compared with those from age-matched neurotypical controls.

The study has been approved by an Institutional Review Board (IRB) in the United States, with planned expansion of the approval into Canada in the near future. IRBs are ethics committees designed to help regulatory agencies ensure that companies employ rigorous protocol standards and adhere to strict regulations surrounding the ethical treatment of human subjects. The study's data collection and storage protocols are also compliant under the Health Insurance Portability and Accountability Act (HIPAA), which sets the standard for protection of sensitive patient data.

ClinicalTrials.gov is a web-based resource that provides patients, their family members, health care professionals, researchers and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The web site is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH).

NOVA's ClinicalTrials.gov Identifier is: NCT04869930:
https://clinicaltrials.gov/ct2/show/NCT04869930

For more information about the study, please email clinicaltrials@novamentis.ca or call 1-888-505-NOVA.

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

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