

Nova Mentis Launches Autism Microbiome Study in the United States

VANCOUVER, BC, March 3, 2021 /CNW/ - **Nova Mentis Life Science Corp.** (CSE: NOVA) (FSE: HN3Q) (OTCQB: NMLSF) ("**NOVA**" or the "**Company**"), a leader in the development of psilocybin and other entheogens, is pleased to announce the launch of its US-based Observational Study NM-101: "*Microbiotic Diversity in Autism Spectrum Disorder (ASD): Improving Diagnostics by Differentiating Subtypes.*"

"NOVA's mission is to discover more precise ways to diagnose and treat autism spectrum disorder (ASD), an unmet medical need," stated Julia V. Perederiy, PhD, NOVA's Lead Scientist and Principal Investigator on the study.

"This clinical investigation is an important first step in accurately defining subsets or cohorts of ASD patients that can best respond to specific psilocybin and entheogen therapy. Microbiome science and investigation continues to gain deeper insights into gut biology and its influence over brain activity and behaviour," she continued.

This study will assess the gut microbiome across various subtypes of ASD (including fragile X syndrome) via genetic analysis of fecal samples, comparing bacterial profiles with those from age-matched neurotypical controls. This research is significant because shifts in gut bacteria contribute to the pathophysiology of GI disorders¹, which are four times more common among children with ASD² and are associated with worsening of behavioural symptoms, including anxiety, hypersensitivity and rigid-compulsive behaviours³.

NOVA's observational clinical study aims to recruit at least 300 participants across the U.S.: 200+ with moderate/severe ASD and 100+ neurotypical controls. The large-scale design of this study, as well as inclusion of multidimensional datasets and proprietary machine learning systems, aims to resolve inconsistencies in prior clinical studies regarding the role of gut microbiota in ASD, particularly with regard to diagnostics and treatment - currently an unmet medical need.

"A study of this size will allow us to use machine learning to segment the patient population into groups based on microbiome characteristics, genomics and performance on behavioural tests," said Kyle H. Ambert, PhD, of NOVA's Scientific Advisory Board. "Our findings here will help improve ASD diagnostic methods, allowing us to quantify disease severity using something besides behavioural methods alone."

Study data will allow NOVA to develop an ASD Diagnostic Index and assist the company in the design and implementation of a planned Phase I Clinical Trial for NOVA's lead psychedelic compound (PILZ 1013). Moreover, this study will be used in preliminary conversations with the U.S. FDA to define the optimal regulatory pathway and accelerate NOVA's drug development program.

1. Vich Vila A, Imhann F, Collij V, et al. (December 2018). "Gut microbiota composition and functional changes in inflammatory bowel disease and irritable bowel syndrome." *Sci Transl Med.* 10(472):eaap8914.
2. McElhanon BO, McCracken C, Karpen S, Sharp WG (May 2013). "Gastrointestinal symptoms in autism spectrum disorder: a meta-analysis." *Pediatrics.* 133(5):872-83.
3. Mazurek MO, Vasa RA, Kalb LG, Kanne SM, et al. (January 2013). "Anxiety, sensory over-responsivity, and gastrointestinal problems in children with autism spectrum disorders." *J Abnorm Child Psychol.* 41(1):165-76.

About Nova Mentis Life Science Corp.

Nova Mentis Life Science Corp. is a Canadian-based biotechnology company that is focused on the emerging field of serotonergic psychedelic medicine, such as psilocybin and its related tryptamine derivatives. The Company is a global leader in this field by integrating the latest state-of-the-art medical and scientific technology into its drug development program. The goal is to diagnose and treat debilitating chronic conditions that have unmet medical needs, such as autism spectrum disorder (ASD).

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

On Behalf of the Board

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