

Nova Mentis Expands Pre-Clinical Development Pipeline; Company Begins Fragile X Syndrome Treatment with its Proprietary Psilocybin Drug

VANCOUVER, BC, Feb. 18, 2021 /CNW/ - **Nova Mentis Life Science Corp.** (CSE: NOVA) (FSE: HN3Q) (OTCQB: NMLSF) ("**NOVA**" or the "**Company**"), a leader in the development of serotonergic psychedelic compounds, is pleased to announce that the Company is expanding its pre-clinical program to develop a novel diagnostic and treatment approach to fragile X syndrome (FXS), a persistent unmet medical need.

FXS is a rare genetic disorder characterized by mild-moderate intellectual disability along with behavioral and learning challenges and various physical characteristics. FXS is considered the most common cause of inherited mental disability and the most known genetic cause of autism spectrum disorder (ASD). There is currently no cure for FXS and early intervention is recommended, including special education, behavioral therapy, speech therapy, etc., as it provides the best opportunity for developing a range of skills (**Hall, 2008*). Medications are recommended for associated seizures, mood problems and aggressive behavior.

"My interest in developing the fragile X model used in my lab is to show how the behavioral treatment findings in a preclinical animal model can be translated into effective clinically meaningful therapy for people with ASD," stated Dr. Viviana Trezza, PhD, Department of Science, Roma Tre University, Rome, Italy.

Current pharmacological treatment centres on managing problem behaviors and psychiatric symptoms associated with FXS, however, as there has been little research done in this specific population, the evidence to support the use of these medications in individuals with FXS is poor (**Rueda, 2009*).

NOVA plans to conduct the FXS study alongside its currently ongoing prenatal valproic acid (VPA) rodent model of ASD with Dr. Trezza. During the treatment phase of the study, NOVA will administer its proprietary psilocybin drug, PLZ-1013 to test its potential efficacy in FXS and to determine therapeutic dosage parameters for planned human studies.

"We are delighted to have expanded our pre-clinical development pipeline to treat this unmet medical need, fragile X syndrome. Psilocybin, with its many mechanisms of action, has the potential to yield a multifaceted approach to treat this rare genetic disorder," stated Marvin S. Hausman MD, Chairman of NOVA's Scientific Advisory Board.

NOVA intends to collect fecal bacterial data from the FXS study to continue proving out its proprietary ASD Microbiome Diagnostic Index. It is the intent of NOVA to identify potential genetic subsets within the syndrome called fragile X that may specifically respond, with positive statistical results, to treatment with psilocybin and related tryptamine derivatives.

As there are no currently approved therapeutic treatments for FXS, novel investigational techniques may hold promise in managing and treating common symptoms. For example, Zynerba Pharmaceuticals Inc. has received U.S. FDA Orphan Drug designation for the use of cannabidiol (CBD) as a treatment of FXS via their pharmaceutically produced CBD formulation as a patent-protected permeation-enhanced transdermal gel.

About the Microbiome Diagnostic Index (MDI)

The MDI is based on identifying specific bacterial species within bodily tissues and fluids. Taxonomic profiling (diversity and abundance) is performed using a complex technique for parallel sequencing of DNA from the organisms present in the sample. NOVA intends to obtain data on the complex gut microbiome in healthy individuals and animals, and link changes in the microbiome to specific diseases and treatment.

This index is being developed with the assistance of Dr. Kyle H. Ambert, a member of NOVA's Scientific Advisory Board. Dr. Ambert is currently Director of Data Science at Nike Inc. and has extensive experience in data analytics, machine learning, artificial intelligence and applied analytics. It is the goal of the Company to utilize machine learning to create a statistically objective biomarker program to measure psychedelic treatment response. As drug design and discovery becomes more personalized, machine learning methods are poised to become a central component of the pharmaceutical development workflow.

**Hall SS, Burns DD, Lightbody AA, Reiss AL (August 2008).*

*["Longitudinal changes in intellectual development in children with Fragile X syndrome".](#) *Journal of Abnormal Child Psychology.* **36** (6): 927–39.*

**Rueda JR, Ballesteros J, Tejada MI (October 2009).*

*["Systematic review of pharmacological treatments in fragile X syndrome".](#) *BMC Neurology.* **9**: 53. [doi:10.1186/1471-2377-9-53](#). [PMC 2770029](#). [PMID 19822023](#)*

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

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

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