

MYND Diagnostics Inc. Announces Participation in a Monash University (Australia) Proposal for \$3 Million Clinical Trial

Evaluating the efficacy of psilocybin-assisted psychotherapy in treatment resistant depression

VANCOUVER, BC, Oct. 13, 2021 /CNW/ - **MYND Diagnostics Inc.**, a wholly-owned subsidiary of MYND Life Sciences (CSE: MYND) (OTC: MYNDF) is pleased to announce that the Company's proprietary biomarker test technology will be a pivotal component of a proposed clinical trial seeking partial funds from a \$15 million fund allocated by the Australian government.

The proposed project will directly address the desired outcomes by conducting an adaptive dose finding single phase 2b clinical trial of the efficacy and safety of psilocybin assisted psychotherapy ("PAP") in the treatment of people diagnosed with treatment resistant depression ("TRD"). MYND Diagnostics' suite of proprietary biomarkers will be utilized in the trials to assess and then monitor blood indicators of trial subjects' response, progress, and any relapsing to the psilocybin treatments administered in the trials.

The project team will be led by Professor Paul Fitzgerald, of Monash University with 7 scientific collaborators from Monash University, Deakin University and the University of Sydney. Dr. Fitzgerald is Director of the Epworth Centre for Innovation in Mental Health ("ECIMH") and Professor of Psychiatry at the Epworth Clinic / Epworth Health Care in Camberwell. He is a qualified psychiatrist, has a Masters of Psychological Medicine and research PhD. Professor Fitzgerald has run over 20 clinical trials registered through this scheme over the last two decades.

The proposed study is titled *Evaluating the efficacy of psilocybin-assisted psychotherapy in treatment resistant depression* and MYND Diagnostics' will play an integral role in the "evaluate" component. If successful, it will lead, within 12 months of completion, to a multi-site phase 3 adaptive trial to take this treatment through to regulatory approval by the Therapeutic Goods Association ("TGA"), the Australian counterpart to Health Canada and the US Food and Drug Administration

Major Depressive Disorder ("MDD") is common and results in the greatest global burden of disease. Although there are established treatments for depression, people frequently do not respond to these treatments. At least 1/3 of patients with depression have an inadequate response to medication, many of whom remain persistently unwell. Psilocybin is a naturally derived psychedelic and is converted in the body to psilocin which is the psychoactive agent. The form and dose of drug and psychotherapeutic approach are all important considerations that will be refined through the trial.

Psilocybin has a number of characteristics which support its potential use in patients with depression. These patients often require a psychotherapeutic approach to treatment but struggle to successfully engage in therapy due to impairments of concentration, mood and motivation. Psilocybin has the potential to immediately boost mood enhancing engagement in therapy in addition to any direct physiological effects produced by the substance

"When Dr. Fitzgerald and I signed off on NDAs and entered into discussion back in May of this year, we were optimistic about the receptiveness for this trial within the Australian government's regulatory climate", stated Dr. Lyle Oberg MD, MYND Life Sciences CEO. "Depression, and other neuropsychiatric disorders are a plague on the human population that, unfortunately, know no borders. As such, our proposed solutions will require international collaborations within multiple government regulatory ecosystems. We are impressed with Dr. Fitzgerald's research and leadership in this space, the team he has assembled, and his eagerness to provide one of the very first opportunities to test our emerging suite of biomarker tests."

ABOUT MYND LIFE SCIENCES

MYND Life Sciences, the parent company of MYND Diagnostics INC., is a medical biotech drug research and development company focused on neuro-pharmaceutical and novel psilocybin drug development, diagnostics and vaccines. The Company is advancing pharmaceuticals through rigorous science and clinical trials, while diligently patenting and safeguarding its intellectual property. For more information and to subscribe to the Company's mailing list, please visit https://myndsciences.com/contact/

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