

Braxia Scientific Achieves Milestone as Landmark Psilocybin Clinical Trial Commences, Participants Receive First Doses of Psilocybin

- Patients receive first dose in first-ever Health Canada-approved, multi-dose psilocybin clinical trial conducted at Braxia Scientific's subsidiary CRTCE clinic
- Trial establishes psilocybin treatment framework for patients with TRD and opens new pathway for patients to access psychedelic treatment

TORONTO, Dec. 14, 2021 /CNW/ - Braxia Scientific Corp. ("Braxia", or the "Company"), (CSE: BRAX) (OTC: BRAXF) (FWB: 496), a medical research company with clinics providing innovative psychedelic treatments for persons with depression and related disorders, has reached a milestone as the first Health Canada-approved multiple-dose psilocybin clinical trial which commenced with first patients dosed in November 2021. The trial, which is being sponsored by the Brain and Cognition Discovery Foundation, is being conducted at the Canadian Rapid Treatment Center of Excellence (CRTCE), a wholly owned Braxia subsidiary, and includes adults with treatment-resistant depression (TRD) as part of bipolar or unipolar disorder, who have not benefited from multiple conventional treatments. This study is the only [Health-Canada approved psilocybin trial in Canada](#) that is actively recruiting participants at this time.

Of the more than 300 million people suffering with depression worldwide, it is estimated that up to two thirds of affected people receiving treatment will inadequately respond to currently approved treatments, making patients with TRD a very large population that disproportionately dominates the majority of mental health services.

"This is a historically significant occasion for our patients, for Braxia, and for other organizations that endeavour to discover and develop innovative rapid-acting psychedelic treatments for the mental health sector," said Braxia Scientific CEO Dr. Roger McIntyre.

"For patients who have undergone at least two – and possibly dozens of – unsuccessful conventional treatments for their depression, this remedy offers a potential and innovative treatment avenue for adults with TRD."

"For Braxia Scientific, it marks two very important milestones. First, this trial establishes a proprietary framework and positions our platform among the leading groups that endeavour to research and develop new psychedelic treatments for TRD. Second, our proprietary data from this landmark trial will enable us to continue our work developing potential new chemical entities in the future, while providing patients with TRD immediate access to new treatment."

Dr. Joshua Rosenblat, Braxia's Chief Medical and Scientific Officer and the Principal Investigator (PI) of the trial, added, "Outside of rare exemptions for a very small number of patients with terminal medical illnesses, the only way to legally access psilocybin treatment in Canada is through Health Canada-approved clinical trials. As we have the country's only open trial (e.g., only one actively recruiting, enrolling and treating participants with psilocybin),^[i] the CRTCE is currently the only place in Canada that can legally provide psilocybin for depression in the absence of any comorbid medical condition."

Building on management's extensive clinical and research expertise, the Company has expanded the necessary infrastructure to provide novel interventions that include ketamine, psilocybin and other potential future psychedelics that become available.

More specifically, the Company infrastructure has:

- Established access to a high-quality source of psilocybin that meets all regulatory requirements for human use in clinical research
- Received more than 150 referrals to date for psilocybin-assisted therapy for treatment resistant depression at our clinic in the first six weeks of opening recruitment
- Received Health Canada and Research Ethics approval for protocols to collect treatment outcome data to allow for further optimization of psilocybin treatment protocols and development of best practice guidelines
- Trained medical and research staff as part of Braxia Institute to provide psilocybin-assisted therapy with high quality safety monitoring. This program includes twenty (20) therapists licensed to practice in Ontario with specialized training in psilocybin-assisted therapy. All therapists were trained by the Braxia Institute and are serving as study therapists for the active psilocybin clinical trial. b
- Developed physical space to safely provide psilocybin treatment with a comfortable living room-like environment with appropriate medical and psychological monitoring and protocols

"This tremendous infrastructure enables Braxia Scientific to provide psilocybin-assisted therapy today, as part of the current clinical trial, and importantly, if psilocybin is approved in the future for use outside of clinical trials, Braxia Scientific is positioned to immediately provide access to psilocybin-assisted therapy treatment for eligible patients," commented Dr. Rosenblat.

The trial will also provide Braxia Scientific a chance to evaluate the psilocybin-assisted therapy training program launched earlier this year. Upon completion of the psilocybin study, this program, run by the Braxia Institute, the Company's training centre focused on advancing psychiatric clinical practice and health services of ketamine and psychedelic treatment therapy, is set to graduate its first cohort of medical professionals, a multidisciplinary group of 20 therapists from diverse psychiatry and psychotherapy backgrounds.

About Braxia Scientific Corp.

Braxia Scientific is a medical research company with clinics that provide innovative ketamine treatments for persons with depression and related disorders. Through its medical solutions, Braxia aims to reduce the illness burden of brain-based mental disorders such as major depressive disorder among others. Braxia is primarily focused on (i) owning and operating multidisciplinary clinics, providing treatment for mental health disorders, and (ii) research activities related to discovering and commercializing novel drugs and delivery methods. Braxia seeks to develop ketamine and derivatives and other psychedelic products from its IP development platform. Through its wholly owned subsidiary, the Canadian Rapid Treatment Center of Excellence Inc., Braxia currently operates multidisciplinary community-based clinics offering rapid-acting treatments for depression located in Mississauga, Toronto, Ottawa, and Montreal.

ON BEHALF OF THE BOARD

"Dr. Roger S. McIntyre"
Dr. Roger S. McIntyre
Chairman & CEO

The CSE has not reviewed and does not accept responsibility for the accuracy or adequacy of this release.

Forward-looking Information Cautionary Statement

This news release contains forward-looking statements within the meaning of applicable securities laws. All statements that are not historical facts, future estimates, plans, programs, forecasts, projections, objectives, assumptions, expectations, or beliefs of future performance are "forward-looking statements."

Forward-looking statements include statements about the intended promise of ketamine-based treatments for depression and the potential for ketamine to treat other emerging psychiatric disorders, such as Bipolar Depression. Such forward- looking statements involve known and unknown risks, uncertainties and other

factors that may cause actual results, events, or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such risks and uncertainties include, among others, the failure of ketamine, psilocybin and other psychedelics to provide the expected health benefits and unanticipated side effects, dependence on obtaining and maintaining regulatory approvals, including acquiring and renewing federal, provincial, municipal, local or other licenses and engaging in activities that could be later determined to be illegal under domestic or international laws. Ketamine and psilocybin are currently Schedule I and Schedule III controlled substances, respectively, under the Controlled Drugs and Substances Act, S.C. 1996, c. 19 (the "CDSA") and it is a criminal offence to possess such substances under the CDSA without a prescription or a legal exemption. Health Canada has not approved psilocybin as a drug for any indication, however ketamine is a legally permissible medication for the treatment of certain psychological conditions. It is illegal to possess such substances in Canada without a prescription.

These factors should be considered carefully, and readers are cautioned not to place undue reliance on such forward-looking statements.

Although the Company has attempted to identify important risk factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other risk factors that cause actions, events or results to differ from those anticipated, estimated or intended. Additional information identifying risks and uncertainties that could affect financial results is contained in the Company's filings with Canadian securities regulators, including the Amended and Restated Listing Statement dated April 15, 2021, which are available at www.sedar.com. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in forward-looking statements.

¹ Clinicaltrials.gov

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