

Diamond Therapeutics initiates dosing in first-ever Phase 2a clinical trial evaluating low-dose psilocybin for anxiety

Double-blind, placebo-controlled study explores daily non-psychedelic doses of psilocybin for individuals with Generalized Anxiety Disorder

TORONTO, ONTARIO, CANADA, July 30, 2025 /EINPresswire.com/ -- Diamond Therapeutics Inc. ("Diamond"), a clinical-stage drug development company focused on non-hallucinogenic, psychedelic-based therapies for mental health conditions, in partnership with the Kingston Health Sciences Centre Research Institute (KHSC-RI), today announced the enrollment of the first participants in its Phase 2a clinical trial. This is the first Health Canada-approved trial evaluating daily, at-home, sub-perceptual doses of psilocybin for the treatment of Generalized Anxiety Disorder (GAD).



Diamond's trial site at Kingston General Hospital

The randomized, double-blind, placebo-controlled trial is designed to assess the safety, tolerability, and preliminary efficacy of sub-perceptual psilocybin administered daily over a four-week period. Participants will then be randomly assigned to receive either a placebo or continue treatment for an additional four weeks. Up to 60 individuals diagnosed with GAD will take part in the study.

The study is being conducted at KHSC-RI under the supervision of Principal Investigator Dr. Claudio Soares, Professor of Psychiatry at Queen's University and Director of the Centre for Psychedelic Health and Research (CPHR) at Providence Care.

"There are significant unmet needs among people living with GAD, and they are seeking effective, well-tolerated treatments," said Dr. Soares. "This study represents a paradigm shift—a different approach to target anxiety with a compound that may engage the brain in novel ways, without inducing hallucinogenic effects or causing daily sedation or emotional blunting like conventional pharmacotherapies."



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Generalized Anxiety Disorder affects approximately 5% of adults in Canada—more than 1.6 million people—with a disproportionate impact on women. Existing pharmacotherapies are often slow to act and may cause undesirable side effects.

“This trial represents a landmark moment in psychiatric drug development,” said Dr. Edward Sellers, Professor Emeritus of Pharmacology and Toxicology, Medicine and Psychiatry at the University of Toronto and Chair of the Clinical Advisory Board for Diamond Therapeutics. “If successful, it could redefine how we think about treating

Generalized Anxiety Disorder and other mental health conditions.”

“We are encouraged by the initiation of this trial,” added Dr. Michael McDonnell, Chief Medical Officer of Diamond Therapeutics. “This rigorous, evidence-based research will help inform the future of mental health treatment.”

Diamond Therapeutics has previously published preclinical research in **Frontiers in Pharmacology** demonstrating that very low, non-hallucinogenic doses of psilocybin and its active metabolite, psilocin, improved motivation and attention—suggesting that therapeutic benefits may be achievable without hallucinogenic effects.

Mental illness remains a leading cause of disability in Canada, with an annual economic burden estimated at \$51 billion. Novel therapeutic approaches are essential to address these ongoing and widespread challenges.

To learn more about the study, contact: cs.research@queensu.ca

About Diamond Therapeutics

Diamond Therapeutics is a clinical-stage drug development company based in Toronto, Canada and Birmingham, Alabama. The company is dedicated to developing new and better therapies for mental health conditions by unlocking the fundamental mechanisms underlying these disorders. Diamond’s focus is on safe, effective treatments suitable for broad patient populations. Learn more at: www.diamondthera.com

About KHSC-RI

Kingston Health Sciences Centre Research Institute (KHSC-RI) is a not-for-profit academic research institute affiliated with Kingston Health Sciences Centre, Providence Care, and Queen’s University. With over 350 investigators, KHSC-RI is a hub for cutting-edge research in brain, heart, neurological, and other complex disorders. Through multidisciplinary collaboration, KHSC-RI

drives innovation, discovery, and training of the next generation of research leaders.

Cautionary Statement Regarding Forward-Looking Information

This press release contains forward-looking information as defined under Canadian securities laws. Forward-looking statements are based on current expectations and include, without limitation, statements regarding the potential benefits of low-dose psilocybin, trial progress, and the potential impact on mental health treatment. Such information is subject to risks and uncertainties, including regulatory delays, market conditions, and scientific outcomes that may differ materially from those anticipated. Readers are cautioned not to place undue reliance on forward-looking statements. Diamond undertakes no obligation to revise or update such information except as required by law.

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