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Relmada Therapeutics Initiates Phase 1 Dosing with REL-P11 for Metabolic Disease

REL-P11 is a proprietary, low-dose, modified-release psilocybin formulation

Single-Ascending Dosing (SAD) study to evaluate safety and pharmacokinetics in obese and normal weight subjects

With positive results, Phase 2a proof-of-concept study expected to begin in H1 2025

CORAL GABLES, Fla., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Relmada Therapeutics, Inc. (Nasdaq: RLMD, "Relmada", "the Company"), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today announced the initiation of dosing in a Phase 1 SAD study of REL-P11, an investigational agent for metabolic disease.

"Dosing of the first subjects in the Phase 1 study is an important milestone for REL-P11, a low-dose, modified-release psilocybin formulation. Preclinical rodent studies, published at the American Association for the Study of Liver Disease in 2023 (AASLD 2023), showed that treatment with REL-P11 improved multiple metabolic parameters with no detrimental CNS effects, and suggest that REL-P11 could have potential to become a valuable therapeutic option in the evolving obesity and metabolic syndrome space," said **Sergio Traversa, Chief Executive Officer** of Relmada. "We expect the Phase 1 study to help define the pharmacokinetic, safety and tolerability profile of REL-P11 and, with positive data, pave the way for a Phase 2a proof-of-concept study to begin in H1 2025."

About REL-P11 and the Phase 1 Study
Relmada acquired the development and commercial rights to a novel psilocybin and derivatives program in July of 2021. Psilocybin has neuroplastogen™ effects that have the potential to ameliorate neurodegenerative conditions. Relmada identified the potential to use low-dose psilocybin as a treatment for metabolic diseases and published the data at the American Society for the Study of Liver Disease (AASLD 2023).

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a late-stage biotechnology company addressing diseases of the central nervous system (CNS), with a focus on major depressive disorder (MDD). Relmada's experienced and dedicated team is committed to making a difference in the lives of patients and their families. Relmada's lead program, REL-1017, is a new chemical entity (NCE) and novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission. REL-1017 is in late-stage development as an adjunctive treatment for MDD in adults. Learn more at www.relmada.com.

Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by us or on our behalf. This press release contains statements which constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Any statement that is not historical in nature is a forward-looking statement and may be identified by the use of words and phrases such as "expects", "anticipates", "believes", "will", "will likely result", "will continue", "plans to", "potential", "promising", and similar expressions. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including potential failure of clinical trial results to demonstrate statistically and/or clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure of the Reliance-OLS (study 310) to accurately reflect the results of the ongoing Reliance II (study 302) and Relight (study 304) blinded, randomized and controlled studies of REL-1017, failure of the ongoing Phase 1 and planned Phase 2a trials of REL-P11, the Company's low-dose, modified release formulation of psilocybin, to be successfully carried out, failure to obtain regulatory approval of REL-1017 for the treatment of major depressive disorder, and the other risk factors described under the heading "Risk Factors" set forth in the Company's reports filed with the SEC from time to time. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Relmada undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned that it is not possible to predict or identify all the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be a complete list.

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