December 4, 2024

Relmada Therapeutics Reports That Data Monitoring Committee (DMC) Assessment Indicates That the Phase 3 Reliance II Trial is Futile at its Interim Analysis and is Unlikely to Meet the Primary Efficacy Endpoint with Statistical Significance

The DMC did not identify any new safety concerns

Relmada to evaluate potential next steps for the REL-1017 program

Relmada to continue to focus on the development of REL-P11 for metabolic disease

Relmada is well capitalized with approximately $54.1 million in cash and cash equivalents as of September 30, 2024

CORAL GABLES, Fla., Dec. 04, 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 that the pre-planned interim analysis of Reliance II, conducted by the Independent Data Monitoring Committee (DMC), indicated that the Reliance II Phase 3 study is futile and is unlikely to meet the primary efficacy endpoint with statistical significance. Reliance II is designed to evaluate REL-1017 as an adjunctive treatment for major depressive disorder (MDD), to be used in combination with other approved anti-depressants. No new safety signals were reported.

“We are disappointed with the outcome of this interim analysis,” said**Sergio Traversa, Chief Executive Officer** of Relmada. “Based on these results, Relmada will evaluate the full dataset to determine next steps for the REL-1017 program. The Company will continue to advance the Phase 1 study of REL-P11, an investigational agent for the treatment of metabolic disease, currently in a Phase 1 first-in-human study. We are grateful to the investigative sites and patients who participated in the REL-1017 program."

About REL-1017
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.

About REL-P11
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) and metabolic disorders. Relmada's experienced and dedicated team is committed to making a difference in the lives of patients and their families. 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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