Relmada Therapeutics to Discontinue the Reliance II and Relight Phase 3 Studies of REL-1017

Description

Relmada Therapeutics has Commenced a Process to Explore Strategic Alternatives to Maximize Shareholder Value

CORAL GABLES, Fla., Dec. 09, 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 in light of the recent data monitoring committee (DMC) evaluation of the full dataset from the Reliance II Phase 3 study of the Company’s REL-1017 program, the Company will discontinue the Reliance II and Relight Phase 3 studies. 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.

In connection with this decision, the Company has commenced a process to explore strategic alternatives to maximize shareholder value. As part of this process, the Company plans to consider a wide range of options with a focus on maximizing shareholder value, including, but not limited to, the sale of Company assets, a sale of the Company, a merger or a reverse merger, the acquisition of assets or rights for the development of other products, or other strategic transaction(s). There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or as to the timing of any such agreements or transactions. The Company is in the process of engaging a financial advisor to assist in the strategic review process.

The Company has not set a timetable for completion of the evaluation process and does not intend to disclose further developments or guidance on the status of its exploration of strategic alternatives unless and until it is determined that further disclosure is appropriate or necessary.

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 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 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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