August 23, 2023

Relmada Therapeutics Announces Dosing of First Patient in Relight, a Phase 3 Trial of REL-1017 for the Adjunctive Treatment of Major Depressive Disorder

CORAL GABLES, Fla., Aug. 23, 2023 /PRNewswire/ -- Relmada Therapeutics, Inc. (Nasdaq: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today announced the dosing of the first patient in the Relight (study 304) Phase 3, randomized, double-blind, placebo-controlled trial evaluating REL-1017 as an adjunctive treatment of Major Depressive Disorder (MDD).

"The dosing of the first patient in this important study represents a significant milestone in the ongoing late-stage development program of REL-1017 for the adjunctive treatment of MDD," said Cedric O'Gorman, Relmada's Chief Medical Officer. "Relight has been designed to better control placebo response by reducing the time spent by patients at sites and to prioritize the quality of subject enrollment and overall data. Our recent investigator meetings with participating sites focused on providing intensive training on appropriate subject enrollment, data quality, strategies for controlling placebo response and rater training. We are confident that the optimized study protocol will enhance the potential for success in the Relight trial."

The Relight Phase 3 trial has a planned enrollment of approximately 300 patients. Relight is a randomized, double-blind, placebo-controlled, four-week trial, evaluating the efficacy and safety of REL-1017 as an adjunctive treatment of MDD in patients experiencing inadequate response to an ongoing background antidepressant treatment. The primary endpoint is the change in the MADRS total score from baseline to Day 28 for REL-1017 compared to placebo.

The Phase 3 development program for REL-1017 as an adjunctive treatment for MDD also includes the ongoing Reliance II (study 302) trial, which includes the same key study design parameters as Relight. Enrollment in the Reliance II study is expected to be completed in the first half of 2024. In addition, results from the recently completed Reliance-OLS (study 310), a long-term, open-label study of REL-1017 in MDD, are anticipated in the current quarter.

The Reliance and Relight Phase 3 clinical trials advance the clinical development of REL-1017 as an adjunctive treatment for MDD which, if approved, would be mechanistically different to treatments currently available for this indication.

Further information on the Relight Phase 3 trial can be found at https://www.relightstudies.com/the-relight-study

About REL-1017

REL-1017, a new chemical entity (NCE) and novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is currently in late-stage development for the adjunctive treatment of major depressive disorder (MDD). The ongoing Clinical Research Program is designed to evaluate the potential for REL-1017 as a rapid-acting, oral, once-daily antidepressant treatment.

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 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.

Investor Contact:
Tim McCarthy
LifeSci Advisors

tim@lifesciadvisors.com

Media Inquiries:
Corporate Communications
media@relmada.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/relmada-therapeutics-announces-dosing-of-first-patient-in-relight-a-phase-3-trial-of-rel-1017-for-the-adjunctive-treatment-of-major-depressive-disorder-301907423.html

SOURCE Relmada Therapeutics, Inc.