Relmada Therapeutics Announces Completion of Treatment in Company's Registrational Phase 3 RELIANCE III Trial for REL-1017 as a Monotherapy for Major Depressive Disorder

Description

CORAL GABLES, Fla., Sept. 20, 2022 /PRNewswire/ — Relmada Therapeutics, Inc. (Nasdaq: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today announced the completion of patient treatment in RELIANCE III, a monotherapy registrational Phase 3 trial evaluating REL-1017, the Company's novel NMDA receptor (NMDAR) channel blocker, for major depressive disorder (MDD). Relmada expects to report top-line data from the RELIANCE III trial early next quarter.

Relmada Therapeutics Corporate Logo (PRNewsFoto/Relmada Therapeutics, Inc.)

"We are pleased to continue to expeditiously advance our late-stage REL-1017 development program with the completion of treatment in RELIANCE III," said Sergio Traversa, Relmada's Chief Executive Officer. "We have multiple significant catalysts anticipated over the next few quarters, beginning with top-line data from RELIANCE III, which is expected early next quarter. Based on REL-1017's product profile and the data generated from the Phase 2 study, we believe that REL-1017 has the potential to help address the substantial unmet need in MDD, a therapeutic area in which new treatment options are beginning to emerge after several decades of little innovation." The FDA has recently granted Fast Track Designation for REL-1017 as a monotherapy for the treatment of major depressive disorder.

Relmada's late-stage development program for REL-1017 includes RELIANCE III, the Phase 3 two-arm, placebo-controlled registrational study for REL-1017 as a potential monotherapy treatment of MDD, as well as RELIANCE I and RELIANCE II, two ongoing Phase 3, two-arm, placebo-controlled, pivotal studies evaluating REL-1017 as a potential adjunctive treatment for MDD. The RELIANCE development program also includes Reliance-OLS, a long-term open-label safety study that is enrolling rollover participants from all three pivotal studies, as well as de novo participants.

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 treatment of major depressive disorder (MDD). The ongoing Reliance Clinical Research Program is designed to evaluate the potential for REL-1017 as a rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated rapid, robust, and sustained antidepressant effects with statistically significant improvements compared to placebo. The Phase 2 study also showed a favorable pharmacokinetic, safety, and tolerability profile of REL-1017 consistent with results observed in previously completed Phase 1 studies.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a late-stage biotechnology company addressing diseases of the central nervous system (CNS), with 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 has entered late-stage development as an adjunctive and monotherapy treatment for MDD in adults. In addition, Relmada is advancing a clinical-stage program in neurodegenerative diseases based on psilocybin and select derivative molecules. 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 the RELIANCE III trial top-line results to demonstrate 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 as a monotherapy 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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