Relmada Therapeutics Announces Initiation of Phase 3 Program for REL-1017 as Adjunctive Treatment for Patients with Major Depressive Disorder

Description

NEW YORK, Dec. 7, 2020 /PRNewswire/ — Relmada Therapeutics, Inc. (Nasdaq: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today announced that the first patient has been enrolled in the first Phase 3 clinical trial (RELIANCE I) for the Company's lead product candidate, REL-1017, as an adjunctive treatment for major depressive disorder (MDD).

Relmada Therapeutics Corporate Logo

"The initiation of our Phase 3 program for REL-1017 represents a significant operational milestone for our company," said Sergio Traversa, CEO of Relmada Therapeutics. "Importantly, the design of the Phase 3 program incorporates valuable guidance from the U.S. Food and Drug Administration (FDA) obtained in our successfully completed End-of-Phase 2 meeting. We believe that the reported positive Phase 2 results are indicative of the potential of REL-1017 to treat patients suffering from MDD. We look forward to the availability of top-line results from RELIANCE I in the first half of 2022."

"A significant unmet medical need continues to exist for therapeutics that demonstrate a rapid and robust antidepressant effect in patients with MDD, especially for patients who do not respond adequately to their first line of treatment. We are hopeful for the results of the RELIANCE trials and that in the near future physicians will have access to this novel treatment in their armamentarium " said Maurizio Fava, M.D., Chief of the Department of Psychiatry at Massachusetts General Hospital, and Principal Investigator for the REL-1017 Phase 3 program. "This important Phase 3 program provides us with an opportunity to confirm and further show the effect of REL-1017 in the treatment of MDD, a devastating and life altering condition with many sequelae. I am inspired and excited to continue evaluating this promising product candidate in late-stage clinical trials" said Marco Pappagallo, M.D. acting Chief Medical Officer of Relmada Therapeutics.

Key points of the Phase 3 program agreed upon in discussions with FDA include:

- The Phase 3 program will consist of two sister, two-arm, placebo-controlled clinical trials. Each trial will be conducted in 55 clinical sites in the United States and will include approximately 400 MDD patients with inadequate response to standard antidepressants in their current depression episode. Patients will add either a 25 mg oral dose of REL-1017 once per day or placebo to their ongoing antidepressant treatment.
- The primary endpoint to be evaluated will be the change from baseline on the Montgomery and Asberg Depression Rating Scale (MADRS) score at day-28 for REL-1017 compared to placebo. Success on this endpoint with the collection of sufficient safety data would support the use of REL-1017 for chronic treatment, if approved.

- The change from baseline and the 7-day MADRS score will serve as a key secondary endpoint and will provide data on the rapid onset of treatment effect; statistically significant separation between REL-1017 and the control group was achieved by day 4 in the Phase 2 proof-of-principle trial completed in 2019.
- The Company expects to initiate the second Phase 3 trial, RELIANCE II, in the first half of 2021. Patients who complete RELIANCE I and RELIANCE II will be eligible to rollover into the long-term, open-label study, which is also expected to include subjects who had not previously participated in a REL-1017 clinical trial.

Upcoming anticipated milestones for REL-1017 include:

- 1H21 – Start of RELIANCE II, the second pivotal Phase III adjunctive MDD trial
- 1H21 – Start of Phase II monotherapy MDD trial
- 2Q21 – Results of human abuse potential studies
- 4Q21 – Results of Phase II monotherapy MDD trial
- 1H22 – Results of RELIANCE I and RELIANCE II adjunctive MDD trials

About REL-1017

REL-1017, a novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is entering late-stage studies as an adjunctive treatment for MDD in adults. Our clinical program for REL-1017 will evaluate its potential as the first rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated rapid onset and sustained antidepressant effects with statistically significant improvements as compared to placebo. The Phase 2 study also confirmed the favorable safety and tolerability profile of REL-1017 observed in previously completed Phase 1 studies. In April 2017, the FDA granted Fast Track designation for REL-1017 for the adjunctive treatment of major depressive disorder.

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). Our 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 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 treatment for MDD in adults.

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, including but not limited to statements regarding the expected use of the proceeds from the offering. 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 the 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
212-915-2564
tim@lifesciadvisors.com

Media Inquiries:
FischTank PR
relmada@fischtankpr.com

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