Relmada Therapeutics Announces Outcome of End-of-Phase 2 Meeting with FDA for REL-1017 for Adjunctive Treatment of Patients with Major Depressive Disorder

Description

Phase 3 Program Can Advance and the Company Plans to Initiate Registration Studies in the Fourth Quarter of 2020

NEW YORK, May 27, 2020 /PRNewswire/ — Relmada Therapeutics, Inc. (Nasdaq: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, today announced the completion of its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) on its development program of REL-1017 (dextromethadone) for the adjunctive treatment of major depressive disorder (MDD) patients. The Company can proceed into Phase 3 without conducting additional clinical studies, and the FDA and Relmada are aligned on all key aspects of this planned Phase 3 program. Key points of the Phase 3 program discussed and agreed upon by the FDA and the Company include:

Relmada Therapeutics Corporate Logo

- The Company can proceed to Phase 3 registration studies. The program will consist of two placebo-controlled clinical trials with the first trial expected to commence in the fourth quarter of this year.
- The indication to be assessed will be adjunctive treatment in MDD patients who have failed at least one prior treatment in the current depression episode.
- The primary endpoint to be evaluated in the Phase 3 program will be the change from baseline on the Montgomery and Asberg Depression Rating Scale (MADRS) at day-28 for REL-1017 compared to placebo. Success on this endpoint would support the use of REL-1017 for chronic treatment, with the collection of sufficient safety data, if approved.
- The change from baseline on the 7-day MADRS will serve as a key secondary endpoint to provide data on the time to 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 concluded in 2019.
- The REL-1017 dose tested in the Phase 3 program will be 25mg once a day. The pharmacodynamic relationship in the Phase 2 trial support equivalence of the 25 mg and 50 mg doses. As such, each of the Phase 3 registration trials will be designed as a two-arm study.
- No PK bridging studies are required to support the transition from the powder-in-solution formulation of REL-1017 utilized in the Phase 2 trial to the tablet formulation that will be used in the Phase 3 program.
- Abuse liability studies to determine the scheduling of the drug are not required before starting the Phase 3 program and, as previously planned, will be conducted prior to the submission of a potential New Drug Application.

“The End-of-Phase 2 meeting with the Division provided valuable guidance for the Phase 3 program of REL-1017. Of significance, there was agreement on the primary endpoint of the MADRS score at day-28, after continuous daily administration, as the primary efficacy endpoint for regulatory approval for continuous chronic use. The MADRS score reduction at day-7 would capture the rapid onset of action as the key secondary endpoint,” said Maurizio Fava, MD, Chief of the Department of Psychiatry at Massachusetts General Hospital, who will serve as the lead Principal Investigator for upcoming Phase 3 studies.

Dr. Marc de Somer, medical lead at Relmada Therapeutics, added: “We have a unique opportunity to demonstrate the rapid and sustained effect of REL-1017 in the treatment of major depressive disorder. Our team aims to initiate twin pivotal studies in the United States and in Europe as quickly as possible.”

“We are determined to work closely with the FDA and complete the Phase 3 program to submit our NDA dossier for this initial indication. Based on the compelling clinical data generated to-date, we believe REL-1017 has the potential to be a paradigm changing treatment option for patients who suffer from MDD, and we look forward to the further clinical evaluation of this promising drug candidate,” commented Dr. Thomas Wessel, Head of R&D at Relmada.

About dextromethadone (REL-1017)

REL-1017 is a non-competitive N-methyl-D-aspartate Receptor (NMDAR) antagonist with the potential to be the first oral single agent NMDAR antagonist approved for the adjunctive treatment of MDD. In a Phase 2 trial, REL-1017 demonstrated rapid onset and sustained antidepressant effects with statistically significant improvements as compared to placebo on efficacy measures. 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 dextromethadone for the adjunctive treatment of major depressive disorder.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage, publicly traded biotechnology company developing novel medicines to address areas of high unmet medical need in the treatment of central nervous system (CNS) diseases. Relmada’s lead program, dextromethadone (REL-1017), is an N-methyl-D-aspartate (NMDA) receptor antagonist in development for the treatment of depression. NMDA receptor antagonists may have utility in the treatment of a range of psychiatric and neurological disorders associated with a variety of cognitive, neurological and behavioral symptoms.

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.

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