Relmada Therapeutics Provides Enrollment Update in Phase 2 Study of REL-1017 in Patients with Major Depressive Disorder

Description

Trial Enrolling Well, with Approximately 25% of Targeted Subjects Recruited Top-line Data Expected in First Half of 2019

NEW YORK, Sept. 18, 2018 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, today announces that since dosing the first subject on June 27, 2017, 25% of the planned subjects received treatment in its Phase 2 study of dextromethadone (REL-1017) in depression. None of the treated subjects experienced either serious adverse events or psychotomimetic adverse events. Overall REL-1017 continues to show an acceptable safety and tolerability profile, which confirms what was previously observed in the Phase 1 single ascending dose and multiple ascending dose studies. The Phase 2 study is expected to be completed and top line results released in the first half of 2019.

Relmada Therapeutics Corporate Logo

“We are very pleased by the higher than expected enrollment rate that we have observed so far and by the emerging safety and tolerability data” said Dr. Ottavio Vitolo, CMO and Head of R&D of Relmada Therapeutics. “Based on this positive initial enrollment, we continue to expect top-line data from this trial in the first half of 2019. The recent New Drug Application submission for esketamine nasal spray, a potential first-in-class NMDA antagonist and rapidly acting antidepressant, is an important achievement for this new class of antidepressant drugs. We believe that dextromethadone has the potential to be best-in-class as a once-a-day oral tablet without ketamine-like psychotomimetic side effects.”

About the Phase 2 study of dextromethadone in Treatment Resistant Depression

The Phase 2, multicenter, randomized, double-blind, placebo-controlled, 3-arm study is designed to assess the safety, tolerability, and antidepressant effect of REL-1017 at two doses (25 mg QD and 50 mg QD) as an adjunctive therapy in the treatment of patients diagnosed with major depressive disorders. Participating subjects are adults with major depressive disorder (MDD) who have experienced an inadequate response to 1 to 3 adequate courses of treatment with an antidepressant medication during the current episode. The study will enroll 60 subjects at approximately 10 sites in the United States.

About dextromethadone (REL 1017)

REL-1017 (dextromethadone) is an orally administered NMDA receptor (NMDAR) antagonist, which is active on the NMDAR ketamine binding site and has demonstrated an overall favorable safety profile without ketamine psychotomimetic adverse reactions in two Phase 1 studies. In preclinical studies, REL-

1017 showed antidepressant efficacy and effects on neuronal activity similar to that of ketamine. The U.S. Food and Drug Administration previously granted Fast Track designation for dextromethadone for the adjunctive treatment of MDD.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage, publicly traded biotechnology company developing novel medicines that potentially 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. NMDA receptor antagonists may have potential in the treatment of a range of psychiatric and neurological disorders associated with a variety of cognitive, neurological and behavioral symptoms. For more information, please visit Relmada's website 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. We may from time to time make written or oral statements in this letter, the proxy statements filed with the SEC communications to stockholders and press releases 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. These forward-looking statements are based upon management's current expectations, estimates, assumptions and beliefs concerning future events and conditions and may discuss, among other things, anticipated future performance, expected product development, product potential, future business plans and costs. 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" and similar expressions. 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 of the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be considered to be a complete list.

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