

Relmada Therapeutics Inc. Announces First Patient Dosed in Phase 2 Study of REL-1017 in Patients with Major Depressive Disorder

Description

Top-line Data Expected in First Half of 2019

NEW YORK, June 27, 2018 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, today announced the dosing of the first patient in the Company's Phase 2 clinical study to evaluate the safety and efficacy of REL-1017 (dextromethadone) as an adjunctive treatment in patients affected by Major Depressive Disorder (MDD) that did not respond to currently marketed antidepressants.

Relmada Therapeutics Corporate Logo

"We are very pleased to have achieved this important milestone in the development of REL-1017 for major depressive disorder" said Dr. Ottavio Vitolo, Relmada Head of R&D and CMO. "REL-1017 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. REL-1017 has the potential of becoming the first orally available fast acting agent for the treatment of major depressive disorder and to improve the lives of individuals with depression not responding to standard antidepressant therapies."

"This study will add information on the safety and efficacy of REL-1017 in patients with major depressive disorder. Due to its oral bioavailability, its NMDAR antagonism, and the absence of psychotomimetic effects observed in previous studies, REL-1017 may have the potential to provide fast acting antidepressant activity and to alleviate the symptoms of depressed patients who are not responding to standard therapies," said Professor Maurizio Fava, M.D., Executive Vice Chair, Department of Psychiatry, Massachusetts General Hospital (MGH) and Associate Dean for Clinical & Translational Research, Harvard Medical School.

About the Phase 2 study of dextromethadone in Treatment Resistant Depression

This is a Phase 2, multicenter, randomized, double-blind, placebo-controlled, 3-arm study to assess the safety, tolerability and efficacy of multiple oral doses of REL-1017 25 mg and 50 mg as adjunctive therapy in the treatment of patients diagnosed with major depressive disorder (MDD). Participating subjects are adults with 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. The top line report is expected in the first half of 2019.

About dextromethadone (REL 1017)

Relmada is currently developing dextromethadone as a rapidly acting oral agent for the treatment of depression. Working as an NMDA receptor antagonist and on the same binding site as ketamine but having shown no ketamine psychotomimetics side effects, dextromethadone is fundamentally differentiated from all currently FDA-approved antidepressants, as well as all atypical antipsychotics used adjunctively. 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 that potentially address areas of high unmet medical need in the treatment of central nervous system (CNS) diseases. The Company has a diversified portfolio of products at various stages of development. 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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