Relmada Therapeutics to Present Clinical Data on the Effect of REL-1017 on BDNF Plasma Levels

Description

Findings of REL-1017 Effect on BDNF Plasma Levels to be Presented at the Annual Meeting of the American College of Neuropsychopharmacology

NEW YORK, Oct. 2, 2018 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, announced today that it will present clinical data demonstrating increased plasma levels of brain derived neurotrophic factor (BDNF) in healthy subjects treated with d-methadone (REL-1017). BDNF has been shown to play an important role in the pathophysiology of depression. Since its plasma levels appear to decrease in individuals with depression and increase with treatment response, BDNF has been investigated as a biomarker for response to antidepressant therapy.

REL-1017 is an orally available NMDA receptor antagonist with potential rapid onset efficacy in individuals with depression and treatment resistant depression. FDA has granted REL-1017 Fast Track designation for the adjunctive treatment of major depressive disorder.

The data will be presented in a poster presentation at the Annual Meeting of the American College of Neuropsychopharmacology (ACNP), which will take place December 9-13, 2018, in Hollywood, FL. These data were derived from the completed multiple ascending dose study of REL-1017 (NCT03638869).

“We are pleased that our poster was accepted for presentation at one of the world’s leading forums on neuropsychopharmacology, the ACNP Annual Meeting. These findings provide further confidence in the potential clinical efficacy of REL-1017 and its NMDAR antagonist activity and support the neurotrophic effects that have emerged to date from our pre-clinical studies of REL-1017,” said Dr. Ottavio Vitolo, SVP, Head of R&D and Chief Medical Officer of Relmada. “We look forward to the completion of our ongoing Phase 2 study in depressed patients to gain additional knowledge of the potential antidepressant effect of REL-1017. We expect top-line data from this trial in the first half of 2019.”

Presentation Details

Title: The NMDAR Antagonist Dextromethadone Increases Plasma BDNF Levels in Healthy Volunteers Undergoing a 14-Day In-Patient Phase 1 Study

Date/Time: Tuesday, December 11, 2018, from 5:30 PM – 7:30 PM
Abstract Number: 146
Poster Session: II

About the Phase 2 study of dextromethadone (REL–1017) 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. Relmada recently announced that 25% of the planned subjects have been dosed and that 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.

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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SOURCE Relmada Therapeutics, Inc.

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