Relmada Therapeutics Presents Clinical Data on Increased BDNF Plasma Levels in Subjects Treated with REL-1017

Description

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

NEW YORK, Dec. 12, 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 clinical data demonstrating increased plasma levels of brain derived neurotrophic factor (BDNF) in healthy subjects treated with REL-1017 (dextromethadone) were presented at the annual American College of Neuropsychopharmacology meeting. BDNF has been shown to play an important role in the pathophysiology of depression and has been investigated as a biomarker for depression.

Relmada Therapeutics Corporate Logo

REL-1017 is an orally available N-methyl-D-aspartate (NMDA) receptor antagonist with potential rapid onset efficacy in individuals with depression and treatment resistant depression. The U.S. Food and Drug Administration (FDA) has granted REL-1017 Fast Track designation for the adjunctive treatment of major depressive disorder (MDD). Relmada is currently evaluating REL-1017 in a Phase 2 clinical trial assessing tolerability, safety and antidepressant efficacy in patients with MDD.

The BDNF plasma level data presented were derived from a single-site, randomized, double-blind, placebo-controlled Phase 1 clinical trial of REL-1017 administered orally for 10 days to healthy volunteers admitted for 14 days to a Clinical Research Unit (CRU) (NCT03638869). The study findings showed that the administration of REL-1017 significantly increased BDNF plasma levels in healthy subjects compared to placebo, ranging from twice to 17 times the pre-treatment BDNF levels. The increase began as early as day two and persisted through day 10. These findings further support and are consistent with the results of preclinical studies demonstrating that REL-1017 exerts an antidepressant-like activity in animal models of depressed behavior comparable to that of ketamine.

“These findings are indicative of both the potential antidepressant effect of REL-1017 and its neurotrophic effects that could be beneficial in the treatment of multiple central nervous system conditions. Considering the oral administration, the lack of psychotomimetic side effects and the overall acceptable tolerability and safety profile observed in two Phase 1 studies in healthy volunteers, REL-1017 has the potential to be a safer and equally efficacious treatment alternative to ketamine,” 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 MDD patients and expect top-line data from this trial in the first half of 2019.”

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 MDD who have experienced an inadequate response to up to three 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 results 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

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