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Relmada Therapeutics Announces Publication of REL1017 Phase 1 Studies Results

Research Findings Accepted for Publication in Journal of Clinical Psychopharmacology

NEW YORK, April 16, 2019 /PRNewswire/ -- Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, today announced that results of its N-methyl-D-aspartate receptor (NMDAR) antagonist REL1017 (dextromethadone) single ascending dose and multiple ascending dose studies were accepted for publication in the peer reviewed Journal of Clinical Psychopharmacology. REL1017 is Relmada's lead product candidate currently in a Phase 2 study in individuals with major depressive disorder (MDD) who have not responded to traditional antidepressants.

"Results from our Phase 1 studies indicate that REL1017 has the potential to offer a favorable safety and tolerability profile in the treatment of MDD as an oral NMDAR antagonist without the psychotomimetic and dissociative adverse events associated with ketamine and its recently approved stereoisomer esketamine. These studies also confirm that the pharmacological profile of REL1017 is different from that of its racemic form methadone," said Dr. Ottavio Vitolo, SVP, head or R&D and chief medical officer of Relmada. "We look forward to completion of our Phase 2 trial in the first half of 2019 and the opportunity to learn more about the potential for REL1017 to be a significant advance in the treatment of individuals with depression."

The article is available online at:
https://journals.lww.com/psychopharmacology/Abstract/2019/05000/Characterization_of_the_Safety_and_Pharmacokinetic.8.aspx

Citation:
Bernstein, G., Davis, K., Mills, C., Wang, L., McDonnell, M., Oldenhof, J., et al. (2019). Characterization of the Safety and Pharmacokinetic Profile of D-Methadone, a Novel N-Methyl-D-Aspartate Receptor Antagonist in Healthy, Opioid-Naive Subjects: Results of Two Phase 1 Studies. Journal of Clinical Psychopharmacology. http://doi.org/10.1097/JCP.0000000000001035

About the Phase 2 study of dextromethadone in treatment resistant depression

The Phase 2, multicenter, randomized, double-blind, placebo-controlled, three 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 one 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. The study results are expected in mid-2019.

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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