

Relmada Therapeutics Presents Development Program of REL1017 for Treatment of Depression at the 2019 American Society of Clinical Psychopharmacology Meeting

Description

Findings related to clinical safety and pharmacodynamic response together with evidence of activity in behavioral model of depression outlined in poster presentation

NEW YORK, May 31, 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 a review of the company progress in the development of REL1017 (d-methadone, dextromethadone) for the treatment of depression and other CNS disorders was presented this week during the 2019 American Society of Clinical Psychopharmacology meeting in Scottsdale, AZ.

Relmada Therapeutics Corporate Logo

“We are very pleased to outline the breadth of promising results from our pre-clinical and clinical research demonstrating that REL1017 has the potential to offer significant benefits to patients suffering from depression and other CNS disorders without the psychotomimetic and dissociative adverse events associated with ketamine and esketamine,” said Dr. Ottavio Vitolo, SVP, head of R&D and chief medical officer of Relmada. “Findings to date related to both the safety and activity of REL1017 provide strong support for our efforts to advance this promising program into late stages of clinical development as rapidly as possible.”

The poster presentation entitled, *“Development of the N-Methyl-D-Aspartate Receptor (NMDAR) Antagonist d-Methadone (REL 1017) for the Treatment of Depression and Other CNS Disorders”*, reported previously announced results from multiple pre-clinical studies comparing the effects of d-methadone and ketamine in different behavioral animal models used to assess antidepressant activity. Results showed that d-methadone produced improvements similar to ketamine across a range of key tests, including Forced Swim Test, Female Urine Sniffing Test, Novelty Suppressed Feeding Test, and a Chronic Unpredictable Stress protocol. In addition, d-methadone increased the expression of synaptic proteins and receptors critically involved in synaptic plasticity.

The poster presentation also highlighted results from two phase 1 studies showing that d-methadone exhibited a linear pharmacokinetic profile for a range of single dose and multiple dose parameters with no serious adverse events reported. Treatment with d-methadone was also shown to have a pharmacodynamic effect on levels of brain-derived neurotrophic factor (BDNF) plasma, with six of the six subjects in the treatment arm demonstrating statistically significant increases in BDNF levels, while levels

remained unchanged for the two patients in the placebo arm.

“Depression continues to represent a major area of unmet need in global health, and current standard of care involving treatment with ketamine presents a sub-optimal risk-benefit profile to patients,” Dr. Vitolo added. “Relmada is currently conducting a phase 2a multicenter, randomized, placebo controlled 3-arm study to further assess the safety, tolerability and antidepressant effect of d-methadone in patients with major depressive disorder, and we look forward to presenting top-line data from that study this summer.”

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 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 asset, 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

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