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Relmada Therapeutics Announces Completion of Dosing with REL-1017 in Phase 2 Study of Individuals with Treatment Resistant Depression

REL-1017 is a novel NMDA receptor antagonist in development as a rapidly acting oral agent for the treatment of depression

NEW YORK, July 29, 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 the last subject has completed dosing with REL-1017 (dextromethadone) in the company's double-blind, placebo-controlled Phase 2 clinical study evaluating the safety and efficacy of REL-1017 as an adjunctive treatment in patients affected by treatment-resistant depression. The company expects to announce topline results from the study in Q3 2019.

"We are very excited to have achieved this important milestone in the clinical development of REL-1017 for major depressive disorder," said Dr. Ottavio Vitolo, Relmada Head of R&D and CMO. "A total of 62 subjects were randomized and received treatment with REL-1017. None of the subjects experienced either serious adverse events or psychotomimetic adverse events, and no subject discontinued treatment because of safety or tolerability issues. Thus far, the blinded data confirms the favorable safety and tolerability profile of REL-1017 previously observed in the Phase 1 studies. We look forward to presenting top line data from this study by the end of Q3 2019."

REL-1017 is an orally administered NMDA receptor (NMDAR) antagonist shown to be active on the NMDAR ketamine binding site. Two Phase 1 studies previously demonstrated an overall favorable safety profile with no psychotomimetic adverse reactions, which are commonly associated with ketamine treatment. In preclinical studies, RLMD-1017 showed antidepressant efficacy and effects on neuronal activity similar to that of ketamine. REL-1017 has the potential to be the first orally available fast acting agent for the treatment of major depressive disorder for patients with depression not responding to standard antidepressant therapies.

"The completion of dosing of the last subject in our landmark Phase 2 study highlights the significant progress we are making at Relmada in our effort to bring a new treatment option

to patients around the world who suffer from depression," said Sergio Traversa, CEO of Relmada. "This study will provide important information on the antidepressant activity of REL-1017, which will enable Relmada to critically advance its clinical development."

About the Phase 2 study of REL-1017 in treatment resistant depression

This is a Phase 2, multicenter, randomized, double-blind, placebo-controlled 3-arm study to assess the safety and tolerability 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). Subjects in the study are adults with MDD who have experienced an inadequate response to one to three courses of treatment with an antidepressant medication. The study enrolled 62 subjects at approximately 10 sites in the United States. Relmada expects to report top line data from this study before the end of Q3 2019.

About REL-1017 (dextromethadone)

REL 1017 (dextromethadone) is an NMDA receptor antagonist targeting the same binding site as ketamine. Thus far, REL 1017 appears to be devoid of the psychotomimetic side effects associated with ketamine treatment and is fundamentally differentiated from all currently FDA-approved antidepressants and atypical antipsychotics used adjunctively to treat depression. In April 2017, the FDA granted Fast Track designation for dextromethadone for the adjunctive treatment of major depressive disorder. The availability of a daily oral therapy that demonstrates efficacy more rapidly and offers an advantageous safety profile would represent a major advance in patient care in the treatment of depression.

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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