Relmada Therapeutics Announces Publication of REL-1017 Phase 2 Study Results in The American Journal of Psychiatry

Description

– Manuscript further details findings from study assessing REL-1017 as adjunctive treatment for MDD

– Primary endpoint results included rapid, significant, and sustained efficacy vs. placebo

– Safety analysis showed adverse event profile comparable to placebo, with no signs or symptoms of withdrawal or psychotomimetic effects associated with NMDAR blocking

CORAL GABLES, Fla., Dec. 22, 2021 /PRNewswire/ — Relmada Therapeutics, Inc. (NASDAQ: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today announced the publication of Phase 2 data from the clinical study of REL-1017 as adjunctive treatment for patients with major depressive disorder (MDD) in the peer-reviewed *American Journal of Psychiatry*, the most widely read psychiatric journal in the world. The article is titled, "*REL-1017 (Esmethadone) as Adjunctive Treatment in Patients with Major Depressive Disorder: a Phase 2a Double-Blind Randomized Trial,*" and is available online at: https://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2021.21020197.

Relmada Therapeutics Corporate Logo (PRNewsFoto/Relmada Therapeutics, Inc.)

"These compelling data confirm the favorable safety and tolerability profile of REL-1017 without opioid, dissociative, or psychotomimetic effects" said Paolo L. Manfredi, M.D., Chief Scientific Officer of Relmada.

The objectives of the Phase 2, randomized, double-blind, placebo-controlled clinical study were to evaluate the safety, tolerability, and efficacy of two doses of REL-1017 tablets, 25 mg once a day and 50 mg once a day, when given as an adjunctive treatment for MDD in patients with inadequate response to standard antidepressants. A total of 62 patients were randomized to one of three arms: placebo, REL-1017 25 mg, or REL-1017 50 mg. The primary efficacy endpoint was the Montgomery–Asberg Depression Scale (MADRS) score. The trial was conducted at ten centers in the United States from May 2018 to August 2019.

"We look forward to seeing esmethadone potentially helping millions of depressed patients with inadequate response to antidepressants if these efficacy and safety results are replicated in the ongoing Phase 3 trials" said Maurizio Fava, M.D., Principal Investigator and Chair of the Department of Psychiatry

at Massachusetts General Hospital (MGH).

Key Findings:

- These results confirmed the favorable safety, tolerability, and pharmacokinetic profile of REL-1017 and demonstrated that both doses of REL-1017 produced rapid, robust, and sustained antidepressant effects when compared to placebo in patients with MDD.
- The improvement on MADRS shown on Day 4 in both REL-1017 25mg and 50mg groups was sustained through Day 7 (last dose) and Day 14 (7 days after the last dose) with p ? 0.0308 and effect sizes (a measure of quantifying the difference between two groups), from 0.7 to 1.0.
- There were no serious adverse events and no patients experienced treatment-emergent adverse events (TEAEs) that resulted in treatment discontinuation. Patients experienced only transient mild or moderate transient adverse events comparable to placebo. Additionally, there were no opioid, dissociative or psychotomimetic symptoms or withdrawal effects upon treatment discontinuation.

“We are pleased to share these important Phase 2 data with the psychiatry community,” said Sergio Traversa, Relmada’s Chief Executive Officer. “Importantly, these Phase 2 findings enabled us to advance REL-1017 into the multiple clinical studies RELIANCE Phase 3 program for REL-1017 in MDD.”

About REL-1017

REL-1017, a new chemical entity (NCE) and novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is currently in late-stage development for the treatment of MDD in adjunctive and monotherapy Phase 3 studies. The ongoing RELIANCE Phase 3 Clinical Research Program is designed to evaluate the potential for REL-1017 as a rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated rapid, robust, and sustained antidepressant effects with statistically significant improvements compared to placebo in tested measures of depression. The Phase 2 study also showed a favorable safety, tolerability, and pharmacokinetics profile of REL-1017, consistent with observed in previously completed Phase 1 studies.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a late-stage biotechnology company addressing diseases of the central nervous system (CNS), with a focus on major depressive disorder (MDD). Relmada’s experienced and dedicated team is committed to making a difference in the lives of patients and their families. Relmada’s lead program, REL-1017, is a new chemical entity (NCE) and novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission. REL-1017 has entered late-stage development as an adjunctive treatment and monotherapy treatment for MDD in adults. In addition, Relmada is advancing a clinical-stage program in neurodegenerative diseases based on psilocybin and select derivative molecules. Learn more 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. This press release contains statements 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, including but not limited to statements regarding the expected use of the proceeds from the offering. 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,” “potential,” “promising,” and similar expressions. These statements are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including the risk factors described under the heading “Risk Factors” set forth in the Company’s reports filed with the SEC from time to time. 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 the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be a complete list.

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