Relmada Therapeutics Announces Initiation of Second Pivotal Phase 3 Study of REL-1017 as Adjunctive Treatment for Patients with Major Depressive Disorder

Description

Long-Term Safety Study Also Underway

Top-line Data from Both Pivotal Studies Expected in First Half of 2022

NEW YORK, April 1, 2021 /PRNewswire/ — Relmada Therapeutics, Inc. (Nasdaq: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today announced the initiation of the second of the two sister pivotal Phase 3 clinical trials (RELIANCE I and RELIANCE II) for the Company's lead product candidate, REL-1017, as an adjunctive treatment for major depressive disorder (MDD).

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

"We are pleased to begin enrolling patients into the second Phase 3 clinical trial of REL-1017 in MDD, a condition impacting more than 17 million individuals in the U.S., with limited safe and effective therapeutic options currently available," said Sergio Traversa, Relmada's Chief Executive Officer. "The first Phase 3 trial, RELIANCE I, which was initiated in December 2020, continues to enroll patients as planned, and additional sites are coming online. Importantly, the pivotal Phase 3 studies in the RELIANCE program are optimized to reduce the risk of placebo effect associated with depression trials due to the two-arm design, strong focus on site selection and training as well as the multiple levels of screening to ensure accurate patient diagnosis. We continue to anticipate the availability of top-line data from RELIANCE I and RELIANCE II in the first half of 2022."

The company also confirmed that RELIANCE-OLS, the long-term, open-label safety study for REL-1017, is underway. RELIANCE-OLS will include both patients continuing from the pivotal studies as well as *de novo* patients.

Key Aspects of the RELIANCE Clinical Studies Program for REL-1017 in MDD:

- The Phase 3 program consists of two sister, two-arm, placebo-controlled clinical trials, RELIANCE I and RELIANCE II. Each trial will be conducted at up to 55 clinical sites in the United States and will include 364 MDD patients with inadequate response to one up to three standard antidepressants in their current depression episode. Patients will add either a 25 mg oral dose of REL-1017 or placebo once per day to their ongoing antidepressant treatment.
- The primary endpoint is the change from baseline on the Montgomery and Asberg Depression Rating Scale (MADRS) score, a well-established measure of the severity of depression, at day-28 for REL-1017 compared to placebo. Success on this endpoint, in addition to sufficient safety data,

will support, if approved by the FDA, the use of REL-1017 for chronic treatment.
- The change from baseline at the day 7 MADRS score will serve as a key secondary endpoint and will provide data on the rapid onset of treatment effect. In the Phase 2 proof-of-principle trial completed in late 2019, statistically significant separation between REL-1017 and the control group was achieved by day 4.
- Patients who complete either RELIANCE I or RELIANCE II will be eligible to roll over into the long-term, open-label study, RELIANCE-OLS. The RELIANCE-OLS program will also enroll patients with MDD who have not participated in either of the pivotal programs.

Upcoming Anticipated Milestones for REL-1017

- 1H21 – Start of the monotherapy MDD trial
- 2Q21 – Results of oxycodone human abuse potential study
- 2H21 – Results of ketamine human abuse potential study
- 4Q21 – Results of the monotherapy MDD trial
- 1H22 – Results of RELIANCE I and RELIANCE II adjunctive MDD trials

About REL-1017
REL-1017, a novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is entering late-stage studies as an adjunctive treatment for MDD in adults. Our clinical program for REL-1017 will evaluate its potential as the first rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated rapid onset and sustained antidepressant effects with statistically significant improvements as compared to placebo. The Phase 2 study also confirmed the favorable safety and tolerability profile of REL-1017 observed in previously completed Phase 1 studies. In April 2017, the FDA granted Fast Track designation for REL-1017 for the adjunctive treatment of major depressive disorder.

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). Our 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 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 for MDD in adults.

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.

Investor Contact:
Tim McCarthy
LifeSci Advisors
212-915-2564
Tim@LifeSciAdvisors.com

Media Inquiries:
FischTank PR
Relmada@FischTankPR.com

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SOURCE Relmada Therapeutics, Inc.

Released April 1, 2021

Date Created
2021/04/01