Relmada Therapeutics Receives FDA Fast Track Designation for REL-1017 as a Monotherapy for the Treatment of Major Depressive Disorder

Description

CORAL GABLES, Fla., Aug. 9, 2022 /PRNewswire/ — Relmada Therapeutics, Inc. (Nasdaq: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to REL-1017, the Company's novel NMDA receptor (NMDAR) channel blocker, as a monotherapy for the treatment major depressive disorder (MDD).

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

"The receipt of Fast Track Designation represents a significant milestone for our promising late-stage REL-1017 development program," saidPaolo Manfredi, our Chief Scientific Officer. "This designation further supports the potential of REL-1017 as a paradigm shifting novel stand-alone treatment for MDD and highlights the significant unmet medical need in a therapeutic area where little has changed over the last several decades: available treatments remain inadequate for the majority of patients with MDD. We thank the FDA for this designation and we will continue to work closely with the Agency to bring this much needed potential new therapy to patients as expeditiously as possible".

The FDA's Fast Track designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. To qualify, a fast track drug must show some advantage over current therapy, such as superior effectiveness, effect on serious outcomes or improved effect on serious outcomes, and avoiding serious side effects of an available therapy. A Fast Track designation allows for more frequent meetings with the FDA to discuss the drug's development plan and the design of the proposed clinical trial to ensure collection of appropriate data needed to support drug approval. In addition, a drug that receives Fast Track designation is eligible for Accelerated Approval and Priority Review, if relevant criteria are met, as well as Rolling Review, which enables a drug company to submit portions of the New Drug Application to the FDA as they are completed.

Relmada's late-stage development program for REL-1017 includes Reliance III, an ongoing monotherapy registrational Phase 3 trial. In addition, Reliance I and Reliance II are two ongoing Phase 3 sister two-arm, placebo-controlled, pivotal studies evaluating REL-1017 as a potential adjunctive treatment for MDD. The Reliance development program also includes Reliance-OLS, the long-term open-label safety study that is enrolling rollover participants from all three pivotal studies, as well as de novo participants.

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 major depressive disorder

(MDD). The ongoing Reliance 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. The Phase 2 study also showed a favorable pharmacokinetic, safety, and tolerability profile of REL-1017 consistent with results 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 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 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. 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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SOURCE Relmada Therapeutics, Inc.

Released August 9, 2022

Date Created
2022/08/09