Relmada Announces FDA Fast Track Designation for d-Methadone for Adjunctive Treatment of Major Depressive Disorder

Description

NEW YORK, April 13, 2017 /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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation for d-Methadone (REL-1017 dextromethadone), the company's novel N-methyl-D-aspartate (NMDA) receptor antagonist in development for the adjunctive treatment of major depressive disorder.

Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose, according to the FDA, is to get important new drugs to the patient earlier. Drugs that receive Fast Track designation may be eligible for more frequent meetings and written communications with the FDA, accelerated review and priority approval, and rolling New Drug Application review.

"Treatment of depression continues to be a significant challenge in healthcare affecting millions of patients around the world," said Richard Mangano, Ph.D., chief scientific officer of Relmada. "The designation of Fast Track status by the FDA is further validation of the potential for d-Methadone to represent a major advance in treatment that can help patients with inadequate response to the current standard of care. We look forward to working with the FDA to advance the development program for d-Methadone and an expedited regulatory process."

Relmada is planning to advance the development program for REL-1017 to a phase 2a randomized, double-blind, placebo-controlled study in patients with major depressive disorder. The study will assess changes in depressive symptoms as well as the safety, tolerability and pharmacokinetics of two dose levels of REL-1017 as rapid acting adjunctive treatment in patients during a seven-day dosing period and 14-day observation period.

About d-Methadone (dextromethadone, REL-1017)

Relmada's lead product candidate, REL-1017, is a new chemical entity (NCE) being developed as a rapid acting, oral agent for the treatment of depression, neuropathic pain, and other potential CNS pathological conditions. The Company has completed Phase I single and multiple ascending dose studies and has confirmed safety, tolerability and dose range for planned Phase II studies in treatment-resistant depression (TRD).

As an enantiomer of racemic methadone, REL-1017 has been shown to possess NMDA antagonist properties with virtually no opioid activity at the expected therapeutic doses. The activation of NMDA receptors has been associated with both depression and neuropathic pain and it is expected that REL-1017 will have a role in depression and pain management by blocking this activity.

REL-1017's mechanism of action, as a non-competitive NMDA channel blocker or antagonist, is fundamentally differentiated from all commercially available antidepressants as well as from all atypical antipsychotics used adjunctively with standard FDA-approved antidepressants.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage, publicly traded biotechnology company developing novel versions of proven drug products together with new chemical entities that potentially address areas of high unmet medical need in the treatment of central nervous system (CNS) diseases. The Company has a diversified portfolio of four products at various stages of development, including d-Methadone (dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist for depression and neuropathic pain; LevoCap ER (REL-1015), an abuse resistant, sustained release dosage form of the opioid analgesic levorphanol; oral buprenorphine (BuTab, REL-1028), an oral dosage form of the opioid analgesic buprenorphine; and topical mepivacaine (MepiGel, REL-1021), an orphan drug designated topical formulation of the local anesthetic mepivacaine. The Company's product development efforts are guided by the internationally recognized scientific expertise of its research team. The Company's approach is expected to reduce clinical development risks and costs while potentially delivering valuable products to address areas of high unmet medical needs. 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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