

Relmada Therapeutics Acquires Global Rights to Develop and Market Dextromethadone for Treatment of Disorders of the Nervous System

Description

Agreement positions company to advance dextromethadone program to its full potential targeting a wide range of neurological conditions including certain rare genetic diseases

NEW YORK, Jan. 17, 2018 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, announced today that it has acquired the global rights to develop and market dextromethadone (REL-1017), a novel N-methyl-D-aspartate (NMDA) receptor antagonist, for the treatment of neurological conditions including certain rare diseases with symptoms affecting the CNS.

Relmada Therapeutics Corporate Logo

The company expects to select and initiate development for additional indications in 2018. Relmada previously acquired the global rights to dextromethadone for the treatment of symptoms associated with a range of psychological and psychiatric disorders including depression, anxiety, fatigue, and mood instability and plans to start to enroll patients in a Phase 2a randomized, double-blind, placebo-controlled study of two dose levels of dextromethadone as a rapid acting adjunctive treatment in patients affected by major depression in the first half of 2018.

“The clinically proven mechanism of action of dextromethadone shows potential benefits in the treatment of a wide range of CNS diseases and conditions, including rare diseases that represent significant areas of unmet need in healthcare,” said Sergio Traversa, CEO of Relmada Therapeutics. “We believe that this new agreement is the most important transaction for Relmada since its inception, positioning us to target a wide range of development and global marketing opportunities for dextromethadone in the years ahead.”

The NMDA receptor is a therapeutic drug target for many CNS disorders and is a predominant molecular device for controlling synaptic plasticity and memory function, allowing for the transfer of electro-chemical signals between neurons. Based on this clinically proven mechanism of action, several NMDA receptor antagonists (chemicals that block overactive NMDA receptor), including dextromethadone are considered as therapeutic agents for CNS disorders.

In April 2017, Relmada announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for dextromethadone for the adjunctive treatment of major depressive disorder. The company plans to advance the development program of dextromethadone to a Phase 2a randomized, double-blind,

placebo-controlled study that will assess changes in depressive symptoms as well as the safety, tolerability and pharmacokinetics of two dose levels of dextromethadone as a rapid acting adjunctive treatment in patients affected by major depression. The company has also initiated a pre-clinical program to identify the most appropriate additional neurological indications for dextromethadone, including certain rare syndromes affecting the CNS.

About dextromethadone (REL 1017)

Relmada is currently developing dextromethadone as a rapidly acting oral agent for the treatment of depression. Working through the same brain mechanisms as ketamine, a non-competitive NMDA channel antagonist, but potentially lacking its adverse side effects, dextromethadone is fundamentally differentiated from all currently FDA-approved antidepressants, as well as all atypical antipsychotics used adjunctively. In April 2017, the FDA granted Fast Track designation for dextromethadone for the adjunctive treatment of major depressive disorder. With today's agreement we can expand the development to an array of additional neurologic disorders including certain rare diseases characterized by symptoms affecting the Central Nervous System.

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. The Company has a diversified portfolio of products at various stages of development. 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.

Contact

Media Contact:

Jenna Iacurci

Berry & Company Public Relations

Tel: 212-253-8881

jiacurci@berrypr.com

 View original content with multimedia: <http://www.prnewswire.com/news-releases/relmada-therapeutics-acquires-global-rights-to-develop-and-market-dextromethadone-for-treatment-of-disorders-of-the-nervous-system-300583736.html>

SOURCE Relmada Therapeutics, Inc.

Released January 17, 2018

Date Created

2018/01/17