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Relmada Announces FDA Acceptance of IND and Authorization to Commence Phase 2a Clinical Trial for d-Methadone

Proof of concept study to assess rapid onset of action and safety of N-methyl-D-aspartate (NMDA) receptor antagonist in patients affected by treatment resistant depression.

NEW YORK, Jan. 25, 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 Investigational New Drug (IND) application for d-Methadone (REL-1017 dextromethadone), the company's novel, N-methyl-D-aspartate (NMDA) receptor antagonist, has been cleared by the U.S. Food and Drug Administration (FDA). The company is now authorized to advance the development program for d-Methadone to a Phase 2a proof of concept clinical study in patients with treatment resistant depression (TRD).

"FDA acceptance of our IND for d-Methadone represents a very significant milestone for Relmada and further validation of our efforts to develop innovative therapies with the potential to address some of the most challenging unmet needs in the treatment of depression," said Richard Mangano, Ph.D., chief scientific officer of Relmada. "Building on

the findings from our single- and multiple-ascending dose studies that demonstrated a targeted dose range without the side effects associated with racemic methadone and ketamine, d-Methadone has the potential to represent a paradigm shift in the treatment of major depressive disorder in the years ahead."

The planned phase 2a, randomized, double-blind, placebo-controlled study will include 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 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/or 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. In contrast, racemic methadone is a long-acting narcotic used in the treatment of various pain states and as a substitution therapy in opioid addiction and is associated with typical opioid side effects.

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 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/relmada-announces-fda-acceptance-of-ind-and-authorization-to-commence-phase-2a-clinical-trial-for-d-methadone-300396997.html

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