June 27, 2016

Relmada Therapeutics Announces Notice of Allowance for U.S. Patent Covering d-Methadone, an NMDA Receptor Antagonist, for the Treatment of Depression

Patent contains claims that provide broad coverage for d-Methadone as a treatment for psychological and psychiatric disorders, including depression, anxiety, fatigue, and mood instability including pseudo-bulbar affect (PBA).

Clinical development plans for Phase II d-Methadone proof-of-concept study are underway.

NEW YORK, June 27, 2016 /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 its patent application relating to d-Methadone (dextromethadone, REL-1017), a N-methyl-d-aspartate (NMDA) receptor antagonist in development as a treatment for both depression and chronic neuropathic pain, was allowed for issuance as a new patent by the U.S. Patent and Trademark Office (USPTO).

The new d-Methadone patent application is entitled "d-Methadone for the Treatment of Psychiatric Symptoms." The patent is expected to be valid until 2033 upon granting. The patent contains claims that provide broad coverage for d-Methadone as a treatment for psychological and psychiatric disorders, including depression, anxiety, fatigue, and mood instability including pseudo-bulbar affect (PBA) for which there is currently only one U.S. Food and Drug Administration (FDA) approved treatment.

"This is a key milestone for Relmada that significantly strengthen Relmada's positon overall patent portfolio and support our continuing development program for d-Methadone, which has shown the potential to offer efficacy benefits similar to ketamine in the treatment of depression and other psychiatric disorders, but with significantly reduced risk of toxicity based on three completed Phase I studies," said Sergio Traversa, CEO of Relmada Therapeutics. "We look forward to initiating a Phase II proof-of-concept study with d-Methadone in depression as soon as feasible."

In May 2016, Relmada reported positive results from an in vivo study to determine whether d-Methadone elicits antidepressant-like effects after a single administration based on results of the forced swim test, a well-validated animal model to predict antidepressant effects. At all doses tested, d-Methadone significantly decreased immobility of rats compared to the vehicle, suggesting antidepressant-like activity. In addition, the effect of d-Methadone on immobility at the two highest doses tested was larger than the effect seen with ketamine, a noncompetitive NMDA receptor antagonist that has been thoroughly characterized in this model and has demonstrated rapid onset of activity in several clinical studies targeting treatment of depression, but has also been shown in multiple studies to present a high risk of toxicity.

About d-Methadone (dextromethadone, REL-1017)

As a single isomer, orally available d-Methadone 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 d-Methadone 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 associated with typical opioid side effects.

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.

Contact

Investor Contact:
Michael Becker, Chief Financial Officer
Relmada Therapeutics Inc.
Tel: 646-677-3857
mbecker@relmada.com

Media Contact:
Lynn Granito
Berry & Company Public Relations
Tel: 212-253-8881
lgranito@berrypr.com

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/relmada-therapeutics-announces-notice-of-allowance-for-us-patent-covering-d-methadone-an-nmda-receptor-antagonist-for-the-treatment-of-depression-300290343.html

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