Relmada Therapeutics Successfully Completes Multiple Ascending Dose Study of d-Methadone for Neuropathic Pain

Description

Second Successful Clinical Trial to Pave the Way to the Proof of Concept Phase II Study for this Novel Drug with Blockbuster Potential

NEW YORK, Jan. 4, 2016 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD) (“Relmada” or the “Company), a clinical-stage company developing novel therapies for the treatment of chronic pain, announced today that it completed its multiple ascending dose (“MAD”) study with d-Methadone (dextromethadone, REL-1017), its novel, N-methyl-D-aspartate (“NMDA”) receptor antagonist being developed for the treatment of neuropathic pain. Relmada previously completed a single ascending dose (“SAD”) study in March 2015. The design of the Company’s Phase II proof-of-concept study in neuropathic pain, anticipated to start in the first half of 2016, will be based on this study’s findings.

Relmada Therapeutics Corporate Logo

“The results from the MAD study further build on the positive results seen in the previous clinical trial of d-Methadone, as they confirm and extend the safety and tolerability observed in our previously completed SAD study,” said Sergio Traversa, CEO of Relmada Therapeutics. “Given the high level of need for more effective and better-tolerated therapies for chronic neuropathic pain, we remain committed to advancing d-Methadone with the goal of providing a novel treatment option with virtually no opioid-related adverse effects for patients suffering from a wide range of pain syndromes.”

The aim of the MAD study was to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of oral multiple ascending doses of d-Methadone in healthy subjects. In this study, healthy subjects received daily doses of d-Methadone over ten days based on the dose range and maximum tolerated dose established in the Company’s Phase I SAD study. The results successfully demonstrated a potential therapeutic dosing regimen for d-Methadone with a very favorable side effect and tolerability profile.

Continued Dr. Traversa, “The d-Methadone findings announced today, together with the recently announced positive BuTab results, strongly affirm Relmada’s robust product development pipeline and the many value creation opportunities that are possible over the next 12 to 24 months. We believe that we have the right Board, management team and strategy in place to realize these opportunities and remain focused on the continued development of our product portfolio, which we expect to create benefits for patients and Relmada stockholders alike.”

About d-Methadone (REL-1017)

As a single isomer, d-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 neuropathic pain and it is expected that REL-1017 will have a role in pain management by blocking this activity. In contrast, racemic methadone is a long-acting narcotic producing typical opioid side effects used in the treatment of various pain states and as a substitution therapy in opioid addiction.

About Neuropathic Pain

Neuropathic pain is defined as a disorder of the sensorimotor system and is distinctly different from nociceptive pain, which is a consequence of trauma, injury, or inflammation. The term neuropathic pain is used to describe a wide range of pain syndromes, including painful diabetic neuropathy, postherpetic neuralgia, and trigeminal neuralgia. According to the Neuropathy Association, neuropathic pain is estimated to affect more than 20 million people in the United States alone. The main classes of drugs used to treat neuropathic pain conditions are anticonvulsants, antidepressants, opioids, and topical treatments. However, despite the availability of multiple pain medications only about 50% of patients respond to treatment with currently available therapy options, and they present the risk of numerous side effects that reduce their tolerability.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage, publicly traded specialty pharmaceutical 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 pain. The Company has a diversified portfolio of four lead products at various stages of development including d-Methadone (REL-1017) its N-methyl-D-aspartate (NMDA) receptor antagonist for neuropathic pain; topical mepivacaine (REL-1021), its orphan drug designated topical formulation of the local anesthetic mepivacaine; oral buprenorphine (REL-1028) its oral dosage form of the opioid analgesic buprenorphine; and LevoCap ER (REL-1015), its abuse resistant, sustained release dosage form of the opioid analgesic levorphanol. 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 in 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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