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Relmada Therapeutics Announces Publication of Full Results from Phase I Study Showing Treatment with d-Methadone to be Safe and Well Tolerated

Results Indicate d-Methadone Tolerability Shows Potential in Treatment of Wide Spectrum of Pain Syndromes

NEW YORK, March 1, 2016 /PRNewswire/ -- Relmada Therapeutics, Inc. (OTCQB: RLMD) ("Relmada" or the "Company), a clinical-stage company developing novel therapies for the treatment of neuropathic and chronic pain, announced today the publication of the full results from a safety and tolerability Phase I trial of d-methadone (dextromethadone, REL-1017) in patients suffering from chronic pain. Results published in the *Journal of Opioid Management[1]*demonstrated that d-methadone appears to be safe and well tolerated. The design of the Company's Phase II proof-of-concept study in neuropathic pain will be based in part on this study's findings as well as Relmada's recently completed Phase I single and multiple ascending dose studies (SAD and MAD) conducted in healthy subjects.

"The publication of these data in a leading pain research journal reflects the importance of our planned proof of concept study for d-methadone," 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 effects for patients suffering from a wide range of pain syndromes."

The aim of the prospective Phase I open label study was to evaluate the safety of d-methadone 40mg PO BID administered to patients with chronic pain. The study was approved by the Memorial Sloan Kettering Cancer Center (MSKCC) Institutional Review Board (IRB#01-017) and performed at a comprehensive cancer center in New York City. Patients with chronic pain were screened in the Pain and Palliative Care and Anesthesia Pain outpatient clinics and, if found eligible, were offered enrollment in the study.

"Studies have suggested that NMDA receptor antagonists have the potential to treat many neurological and psychiatric disorders such as neuropathic pain and depression. Clinical trials have had limited success thus far because the antagonists evaluated have

demonstrated unacceptable neurobehavioral side effects," said Richard Mangano, CSO of Relmada Therapeutics. "This study and our recently conducted SAD and MAD studies in healthy subjects demonstrate that potentially therapeutic doses of d-methadone can be administered without eliciting mu-opioid or ketamine-like side effects."

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 used in the treatment of various pain states and as a substitution therapy in opioid addiction and associated with typical opioid side effects.

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 less than 50% of patients respond to treatment with currently available therapy options and currently available medications are poorly tolerated.

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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[1] A phase I study of D-methadone in patients with chronic pain.
Moryl N, et al. J Opioid Manag. 2016 Jan-Feb.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/relmada-therapeutics-announces-publication-of-full-results-from-phase-i-study-showing-treatment-with-d-methadone-to-be-safe-and-well-tolerated-300228350.html

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