

March 17, 2015

# **Relmada Therapeutics Reports Positive Phase 1 Results for NMDA Receptor Antagonist d-Methadone**

**Novel product candidate being developed for the treatment of neuropathic pain demonstrates good safety profile even at higher doses**

NEW YORK, March 17, 2015 /PRNewswire/ -- Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of chronic pain, announced today positive clinical results with d-Methadone, the company's N-methyl-D-aspartate (NMDA) receptor antagonist being developed for the treatment of neuropathic pain. In the Phase 1 pharmacokinetic and pharmacodynamic study in healthy volunteers not exposed to opioid therapy, d-Methadone demonstrated a good safety profile with no dose-limiting side effects after four cohorts were exposed to increasingly higher doses.

"We are pleased by the lack of dose limiting side effects in this initial study – even at the higher dose levels – which reinforces the different pharmacological profile of d-Methadone," stated Sergio Traversa, chief executive officer of Relmada Therapeutics. "Based on these important findings, we are requesting authorization from Health Canada to explore higher doses of d-Methadone in our planned clinical trials."

The aim of the initial Phase 1 study was to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of oral single ascending doses of d-Methadone in healthy subjects. In a planned second part of the study, healthy subjects will receive multiple daily doses of d-Methadone in order to determine a maximum tolerated dose. The data from these studies will inform the design of a subsequent Phase 2 proof of concept study in neuropathic pain.

## **About d-Methadone**

Racemic methadone is a long-acting opioid used in the treatment of various pain states and as a substitution therapy in opioid addiction. It is constituted by a 50/50 combination of two isomers: an l-isomer that is a potent opioid agonist, and a d-isomer that has virtually no opioid activity at the proposed doses and that has also been shown to possess NMDA antagonist properties. The activation of NMDA receptors has been associated with neuropathic pain and d-Methadone may have a role in pain management by blocking this activity.

## **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, its N-methyl-D-aspartate (NMDA) receptor antagonist for neuropathic pain; MepiGel, its orphan drug designated topical formulation of the local anesthetic mepivacaine; BuTab, its oral dosage form of the opioid analgesic buprenorphine; and LevoCap ER, 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](http://www.relmada.com).

### **Forward-Looking Statements**

This news release contains "forward-looking statements." These statements are based on management's current expectations and involve risks and uncertainties, which may cause actual results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, or financial performance. 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.

### **Contact**

Investor Contact:

Michael Becker, SVP of Finance and Corporate Development

Relmada Therapeutics Inc.

Tel: 212-702-7169

[mbecker@relmada.com](mailto:mbecker@relmada.com)

Media Contact:

David Salisbury

Berry & Company Public Relations

Tel: 212-253-8881

[dsalisbury@berrypr.com](mailto:dsalisbury@berrypr.com)

Logo - <https://photos.prnewswire.com/prnh/20150113/168770LOGO>

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news->

[releases/relmada-therapeutics-reports-positive-phase-1-results-for-nmda-receptor-antagonist-d-methadone-300051429.html](https://www.relmada.com/press-releases/relmada-therapeutics-reports-positive-phase-1-results-for-nmda-receptor-antagonist-d-methadone-300051429.html)

SOURCE Relmada Therapeutics, Inc.