Relmada Therapeutics Receives Health Canada Clearance to Commence First Clinical Study of d-Methadone

Description

*Novel Product Virtually Devoid of Opioid Activity Being Studied in Neuropathic Pain***.**

NEW YORK, Dec. 2, 2014 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of chronic pain, announced today that it has received a No Objection Letter ("NOL") from Health Canada to conduct the first pharmacokinetic and pharmacodynamic study with d-Methadone, its N-methyl-D-aspartate (NMDA) receptor antagonist for neuropathic pain, in Canada.

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

"In view of the public health crisis of opioid drug abuse in the United States, we believe that the development of a novel product that is nearly devoid of opioid activity and related side effects may help reduce abuse and misuse," stated Sergio Traversa, chief executive officer of Relmada Therapeutics. "If we can demonstrate that d-Methadone has efficacy in treating neuropathic pain conditions, we believe the product has the potential to be a significant drug in this large and unsatisfied market."

The company is planning two initial studies designed to assess the safety, tolerability, pharmacodynamics and pharmacokinetics of d-Methadone in healthy subjects. The first study will investigate the safety and tolerability of single escalating oral doses of d-Methadone and determine the maximum tolerated dose for single drug administration. In the second study, healthy subjects will receive daily multiple escalating oral doses of d-Methadone for the assessment of safety and tolerability. The safety, pharmacodynamic and pharmacokinetic data from these studies will inform the design of a subsequent Phase 2 proof of concept study in neuropathic pain.

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. The main classes of drugs used to treat these neuropathic pain conditions are anticonvulsants, antidepressants, opioids, and topical treatments. However, despite the availability of multiple pain medications only 50% of patients respond to any given drug and there are numerous side effects associated particularly with systemically administered drugs 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 LevoCap ER, its abuse resistant, sustained release dosage form of the opioid analgesic levorphanol; d-Methadone, its N-methyl-D-aspartate (NMDA) receptor antagonist for neuropathic pain; BuTab ER, its oral dosage form of the opioid analgesic buprenorphine; and MepiGel, its 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 in areas of high unmet medical needs. For more information, please visit Relmada's website at: www.relmada.com.

Forward-Looking Statements

This news release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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.

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