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Relmada Announces The Filing Of Clinical Trial Application In Canada For d-methadone

Key Step Accomplished Signals the Initiation of Clinical Development for Potential Blockbuster d-methadone

NEW YORK, Sept. 10, 2014 /PRNewswire/ -- Relmada Therapeutics, Inc. (OTCBB: RLMD) ("Relmada" or the "Company"), a clinical stage company developing novel therapies for the treatment of chronic pain, today announced that it has filed a Clinical Trial Application (CTA) with Heath Canada to conduct 2 pharmacokinetic studies with d-methadone, its NMDA receptor antagonist for neuropathic pain. Health Canada has accepted the application that is now under review.

"We are extremely pleased to have completed this milestone as we continue to make progress with the development of our chronic pain relief solutions," stated Sergio Traversa, CEO of Relmada Therapeutics. "There is a huge potential market for a treatment that can address neuropathic pain. If we can demonstrate that d-methadone has analgesic efficacy in this painful condition, we strongly believe that it has the potential to be a blockbuster drug in this large and unsatisfied market".

The 2 studies are designed to assess the safety, tolerability 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 and pharmacokinetic data from these studies will inform the design of a subsequent Phase 2 proof of concept study in neuropathic pain.

Dr. Richard Mangano, Relmada's Senior VP of Clinical Development, stated "We are convinced that d-methadone has an enormous potential. Initiating the process for clinical trials is a key step to bring the drug to the market as quickly as possible. We believe that, unlike racemic methadone, d-methadone is nearly devoid of opioid activity and related side effects but maintains N-methyl-D-aspartate (NMDA) receptor antagonism. Evidence from non-clinical studies suggests that NMDA receptor antagonists can prevent the central nervous system changes that follow acute and chronic pain. Such changes are implicated in maintaining chronic pain states, especially neuropathic pain."

In addition to d-methadone, Relmada is currently developing LevoCap ER, its abuse resistant, sustained release dosage form of the opioid analgesic levorphanol; BuTab ER, its oral dosage form of the opioid analgesic buprenorphine; and MepiGel, its FDA Orphan Drug designated topical formulation of the local anesthetic mepivacaine.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical stage, public specialty pharmaceutical company, focused on 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 different stages of development and a deep early stage pipeline. The Company's product development efforts are guided by the internationally recognized scientific expertise of its research team with inputs from a world-class scientific advisory board. The Company's approach is expected to reduce overall clinical development risks and costs while potentially delivering valuable products in areas of high unmet medical needs.

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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