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Relmada Therapeutics Receives Health Canada Clearance to Further Explore Promising NMDA Receptor Antagonist d-Methadone (REL-1017)

Phase 1 study to include additional cohorts with novel product candidate being developed for the treatment of neuropathic pain

NEW YORK, April 16, 2015 /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 clearance from Health Canada to continue dose escalation and explore higher doses of d-Methadone (REL-1017), 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 previously exposed to opioid therapy, d-Methadone demonstrated a good safety profile with no dose-limiting side effects after the original four cohorts were exposed to increasingly higher doses. The trial will continue dose-escalation with the additional cohorts.

"The initial four cohorts of the Phase 1 study successfully demonstrated a lack of dose limiting side effects with d-Methadone – even when administered at doses several fold higher than conventionally used with racemic methadone in opioid naïve subjects – which reinforces the radically different pharmacological profile of the compound," stated Sergio Traversa, chief executive officer of Relmada Therapeutics. "While racemic methadone is a widely known synthetic opioid used to treat both pain and drug addiction, it suffers from poor safety and tolerability due to opioid side effects."

The aim of the initial Phase 1 study is to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of oral single ascending doses of d-Methadone (REL-1017) in healthy subjects in order to establish a Maximum Tolerated Dose (MTD). In a planned second study, healthy subjects will receive daily doses of the product over several days, based on the established MTD. The data from these studies will inform the design of a subsequent Phase 2 proof of concept study in neuropathic pain.

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

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.

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