Relmada Therapeutics Successfully Completes Phase 1 Single Ascending Dose Study with Promising NMDA Receptor Antagonist d-Methadone

Description

Multiple Ascending Dose Study to Begin in Second Half of 2015

NEW YORK, June 10, 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 successfully completed a Phase 1 single ascending dose (SAD) clinical study with d-Methadone (dextromethadone, REL-1017), its novel, N-methyl-D-aspartate (NMDA) receptor antagonist being developed for the treatment of neuropathic pain.

Relmada Therapeutics Corporate Logo

The study results indicate that d-Methadone was generally well tolerated and a maximum tolerated dose (MTD) was achieved. The planned multiple ascending dose (MAD) study with d-Methadone will begin in the second half of 2015. Assuming successful completion of the MAD study, d-Methadone could enter Phase 2 clinical development in the first half of 2016.

“Based on their unique mechanism of action, NMDA antagonists such as d-Methadone have the potential to provide relief of pain and other symptoms in patients suffering from chronic neuropathic pain, a debilitating disorder in which novel agents with improved tolerability, efficacy, and long-term safety profiles are needed,” said Richard Mangano, Ph.D., senior vice president of clinical development at Relmada Therapeutics.

The aim of the completed study was to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of oral single ascending doses of d-Methadone in healthy subjects in order to establish a MTD. In the 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 (dextromethadone, REL-1017)

As a single isomer, d-Methadone 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 many 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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