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Relmada Therapeutics' d-Methadone Receives Orphan Drug Designation for Management of Postherpetic Neuralgia

Relmada advancing clinical development plans for d-Methadone in treatment of neuropathic pain and depression.

NEW YORK, June 7, 2016 /PRNewswire/ -- Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of chronic pain, announced today that d-Methadone (dextromethadone, REL-1017), a N-methyl-d-aspartate (NMDA) receptor antagonist in development as a treatment for both depression and chronic neuropathic pain, has received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for the management of postherpetic neuralgia. Postherpetic neuralgia (PHN) is a painful neuropathic condition resulting from an outbreak of the herpes zoster virus, otherwise known as shingles.

Orphan drug designation is granted by the FDA Office of Orphan Drug Products to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity if the drug is the first of its type approved for the specified indication or if it demonstrates superior safety, efficacy, or a major contribution to patient care versus another drug of its type previously granted the designation for the same indication, as well as with potential tax credits for clinical research costs, the potential to apply for annual grant funding, clinical research trial design assistance and waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

"The award of Orphan Drug designation for d-Methadone in the treatment of neuropathic pain is another important development in our ongoing efforts to advance this highly promising therapy to late stage clinical development and regulatory review," said Sergio Traversa, CEO of Relmada Therapeutics. "We continue to see promising results in our research with d-Methadone in neuropathic pain as we also work to advance our development plans for this compound in the treatment of depression."

In May 2016, Relmada reported positive results from an in vivo study to determine whether d-Methadone elicits antidepressant-like effects after a single administration in a well-validated animal model to predict antidepressant effects, the forced swim test. At all doses tested, d-Methadone significantly decreased immobility of the rats compared to the vehicle, suggesting antidepressant-like activity. In addition, the effect of d-Methadone on immobility at the two highest doses tested was larger than the effect seen with ketamine, a noncompetitive NMDA receptor antagonist that has been thoroughly characterized in this model and has demonstrated rapid onset of activity in several clinical studies targeting treatment of depression, but has also been shown in multiple studies to present a high risk of toxicity.

About d-Methadone (REL-1017)

As a single isomer, d-Methadone (dextromethadone, 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 used in the treatment of various pain states and as a substitution therapy in opioid addiction and associated with typical opioid side effects.

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 products at various stages of development, including d-Methadone (REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist for neuropathic pain; topical mepivacaine (REL-1021), an orphan drug designated topical formulation of the local anesthetic mepivacaine; oral buprenorphine (REL-1028), an oral dosage form of the opioid analgesic buprenorphine; and LevoCap ER (REL-1015), an 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 to address areas of high unmet medical needs. For more information, please visit Relmada's website at: www.relmada.com.

Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by us or on our behalf. We may from time to time make written or oral statements in this letter, the proxy statements filed with the SEC communications to stockholders and press releases which constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are based upon management's current expectations, estimates, assumptions and beliefs concerning future events and conditions and may discuss, among other things, anticipated future performance, expected product development, product potential, future business plans and costs. Any statement that is not historical in nature is a forward-looking statement and may be identified by the use of words and phrases such as "expects," "anticipates," "believes," "will," "will likely result," "will continue," "plans to" and similar expressions. 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. Readers are cautioned that it is not possible to predict or identify all of the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be considered to be a complete list.

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