Relmada Therapeutics to Provide an Update on the Development Plan for LevoCap ER

Description

Dialog with FDA establishes defined path to phase III plans and NDA filing

NEW YORK, Jan. 24, 2017 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, is pleased to announce that after an exchange of correspondence and a recent meeting with the U.S. Food and Drug Administration (FDA), a path has been defined for the clinical development of LevoCap ER (REL-1015, levorphanol extended release, abuse deterrent capsules) and the objective of a new drug application (NDA) filing is achievable.



“The FDA’s input into the development plan for LevoCap ER was thorough and constructive, and will help ensure that the NDA meets current approval standards for opioid analgesics,” said Richard Mangano, Ph.D., chief scientific officer of Relmada Therapeutics. “This will benefit both patients and physicians by providing information about the safe and effective use of LevoCap ER.”

In recent weeks, Relmada exchanged correspondence and held a meeting with the FDA Division of Anesthesia, Analgesia, and Addiction Products. The interaction was constructive, with the FDA indicating interest in reviewing clinical protocols supporting an NDA filing for LevoCap ER in the U.S.

“Although details of the final development plan and phase III protocol have not yet been established, the required steps are realistic and the project is economically feasible,” said Mangano. “This development is a significant achievement that will help in the search for the optimal partner to bring LevoCap ER to market and make it a commercial success.”

About LevoCap ER (REL-1015)

Our most-advanced novel version of a proven drug product, LevoCap ER (REL-1015), is an extended release, abuse deterrent, and proprietary formulation of levorphanol (levo-3-hydroxy-N-methyl-morphinan), a unique, broad spectrum opioid with additional “nonopioid” mechanisms of action. In particular, levorphanol binds to all three opioid receptor subtypes involved in analgesia (mu, kappa, and delta), the NMDA receptor, and the norepinephrine and serotonin reuptake pumps, whereas morphine, oxycodone, hydrocodone, and other opioids are highly selective for the mu receptor subtype. Due to its multi-modal mechanism of action, levorphanol could achieve analgesia in patients resistant to other

strong opioids. In clinical studies, levorphanol has demonstrated a remarkably broad spectrum of analgesic activity against many different types of pain including neuropathic pain, post-surgical pain, and chronic pain in patients refractory to other opioids. To our knowledge, the analgesic tapentadol (Nucynta®) is the only other commercially available, multimodal opioid with nonopioid analgesic benefits. However, in contrast to levorphanol's strong opioid effects, tapentadol is a low affinity mu opioid receptor agonist and a norepinephrine reuptake inhibitor.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage, publicly traded biotechnology 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 central nervous system (CNS) diseases. The Company has a diversified portfolio of four products at various stages of development, including d-Methadone (dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist for depression and neuropathic pain; LevoCap ER (REL-1015), an abuse resistant, sustained release dosage form of the opioid analgesic levorphanol; oral buprenorphine (BuTab, REL-1028), an oral dosage form of the opioid analgesic buprenorphine; and topical mepivacaine (MepiGel, REL-1021), an 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 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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