Relmada Therapeutics Announces Filing of Clinical Trial Application in Canada for Novel Oral Formulations of Buprenorphine

Description

BuTab, an Enteric-Coated Buprenorphine Product Candidate, to be Compared with Marketed Intravenous and Sublingual Formulations

NEW YORK, Feb. 24, 2015 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), 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 a pharmacokinetic study with novel formulations of oral, enteric-coated buprenorphine (BuTab) being developed for the treatment of both chronic moderate to moderately severe pain and opioid dependence.

Relmada Therapeutics Corporate Logo

“We continue to make progress with the development of our chronic pain relief portfolio,” stated Sergio Traversa, CEO of Relmada Therapeutics. “If we can demonstrate that BuTab compares favorably with currently marketed formulations of buprenorphine, we believe that it has significant commercial potential.”

The Company is planning a Phase 1 study designed to assess the safety, tolerability, and pharmacokinetics of BuTab in healthy subjects. The safety and pharmacokinetic data from this study will inform the design of subsequent clinical pharmacology studies for opioid dependence and potential regulatory filing for this indication along with the design of a Phase 3 study in chronic pain under the abbreviated 505(b)(2) regulatory pathway.

About Buprenorphine

Buprenorphine has been widely used in several different formulations, but not by the more traditional oral capsule/tablet route due to poor oral bioavailability. Buprenorphine is a Schedule III controlled substance, meaning that it has been designated as having lower abuse potential than Schedule II drugs, a category that includes most opioid analgesics. Buprenorphine is a mu-opioid receptor partial agonist and a potent analgesic with a relatively long duration of action.

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, its N-methyl-D-aspartate (NMDA) receptor antagonist for neuropathic pain; MepiGel, its orphan drug designated topical formulation of the local anesthetic mepivacaine; BuTab, its oral dosage form of the opioid analgesic buprenorphine; and

LevoCap ER, 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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