Relmada Therapeutics Commences Proof-of-Concept Clinical Study for Novel Oral Formulations of Buprenorphine

Description

Oral Buprenorphine Product Candidates (BuTab, REL-1028) to be Compared with Marketed Sublingual and Intravenous Formulations

NEW YORK, April 21, 2015 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of chronic pain, today announced the commencement of a proof-of-concept pharmacokinetic study with its novel formulations of oral, enteric-coated buprenorphine (collectively BuTab, or REL-1028) being developed for both chronic pain and opioid dependence indications.

Relmada Therapeutics Corporate Logo

“We are pleased to announce the start of this clinical trial evaluating the safety and pharmacokinetics of BuTab,” stated Sergio Traversa, CEO of Relmada Therapeutics. “Our team is working to advance an oral formulation of BuTab that will compare favorably with currently marketed sublingual formulations of buprenorphine. With this advantage, BuTab would represent an important advance in patient care and a significant commercial opportunity for Relmada. We look forward to reporting results from this study during the second half of 2015. “

The clinical study is designed to assess the safety, tolerability, and pharmacokinetics of BuTab in healthy subjects. Based on the underlying scientific rationale and the company’s previously conducted successful preclinical work, the key objective of this study is to assess if buprenorphine can be delivered orally and reach safe and effective blood levels through the gastrointestinal route of administration. There are currently no commercially available oral formulations of buprenorphine that result in gastro-intestinal absorption. The data generated by 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 researchers have previously been unable to develop an effective oral formulation of buprenorphine that results in gastro-intestinal absorption due to the drug’s poor oral bioavailability. Relmada has identified a reformulation of BuTab with the potential to overcome this limitation by avoiding the metabolism that normally occurs in the upper gastrointestinal tract, therefore allowing it to be absorbed into the bloodstream more effectively. 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 (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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