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# **Relmada Therapeutics Receives Health Canada Clearance to Commence First Clinical Study for Novel Oral Formulations of Buprenorphine**

## **Enteric-Coated Buprenorphine Product Candidates (BuTab, REL-1028) to be Compared with Marketed Intravenous and Sublingual Formulations**

NEW YORK, March 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 received a No Objection Letter ("NOL") from Health Canada to conduct the first pharmacokinetic study with novel formulations of oral, enteric-coated buprenorphine (BuTab, REL-1028) being developed for the treatment of both chronic pain and opioid dependence.

"Following Health Canada clearance, our second product candidate is about to enter clinical trials during the second quarter of 2015," stated Sergio Traversa, CEO of Relmada Therapeutics. "The rapid progress of our pain relief portfolio this year is a testament to the experienced and talented team we have in place at Relmada Therapeutics. If we can demonstrate that oral BuTab compares favorably with currently marketed sublingual 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 historically poor oral bioavailability. Relmada's BuTab product candidate is designed 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. 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](http://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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