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Relmada Therapeutics Set for Busy 2015 in Clinical Trials Developing Drugs for the Lucrative Pain Market

NEW YORK, NY -- (Marketwired) -- 04/02/15 -- Relmada Therapeutics, Inc.(OTCQB: RLMD) has quite a busy 2015 ahead of it in the clinic. The pharmaceutical company has stepped up its work in a big way, and the latest news out of Relmada has it continuing to apply its unique model of drug development to "repurposed drugs" in the largest prescription drug market in the world -- the pain market.

When Relmada received clearance from Health Canada to begin a Phase 1 clinical trial for its proprietary drug BuTab, a drug being developed for the treatment of both chronic pain and opioid dependence, the company officially had its fourth product set for clinical trials. BuTab joins the company's drug MepiGel, a topical dosage form of the local anesthetic mepivacaine being studied for the treatment of neuropathic pain, in human clinical trials. Now each of the novel drugs in the company's pipeline will be in clinical trials at various stages.

Health Canada has granted permission for Relmada to conduct the first pharmacokinetic study with novel formulations of oral, enteric-coated buprenorphine (BuTab, REL-1028). What this means is that Relmada will use the U.S. Food and Drug Administration's (FDA) 505(b)(2) regulatory approval pathway in its development of BuTab and two other repurposed pain drugs, LevoCap ER and MepiGel.

Relmada is producing novel versions of proven drug products together with new chemical entities that can potentially address areas of high-unmet medical need in the treatment of pain.

The 505(b)(2) process allows Relmada Therapeutics to take pain medicines that have already been approved and make small modifications to them, which are allowed by FDA, with the expectation that the company can significantly improve efficacy, patient safety and patient convenience.

This strategy will assist Relmada in bringing 3 of its 4 lead products to the multi-billion dollar pain market much faster and at a fraction of the cost of typical drug development.

The FDA pathway employed by Relmada is relatively low risk because the drugs being improved upon by the company have already been proven to be safe, and because Relmada will have to pay for fewer studies in order to develop its drugs, the company's process offers a low cost solution.

According to the company, it 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."

Sergio Traversa, CEO of Relmada, said of the news of getting his fourth pain treatment into clinical trials, "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."

Relmada Therapeutics has a diversified pain relief portfolio all at various stages of development including LevoCap ER, its abuse resistant, sustained release dosage form of the opioid analgesic levorphanol; d-Methadone, its N-methyl-D-aspartate (NMDA) receptor antagonist for neuropathic pain; BuTab ER, its oral dosage form of the opioid analgesic buprenorphine; and MepiGel, its orphan drug designated topical formulation of the local anesthetic mepivacaine.

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