

Relmada Therapeutics Selects MepiGel Formulations to Advance Into Clinical Studies

Description

MepiGel, a topical dosage form of the local anesthetic mepivacaine, is being studied for the treatment of neuropathic pain

NEW YORK, Feb. 4, 2015 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD), a clinical-stage company developing novel therapies for the treatment of chronic pain, announced today that the company has selected the formulations to be advanced into clinical studies for MepiGel, the company's topical dosage form of the local anesthetic mepivacaine being studied for the treatment of neuropathic pain.

Relmada Therapeutics Corporate Logo

“MepiGel is designed to offer a number of advantages over existing patch forms of treatment, including greater skin penetration and retention along with application advantages in areas of poor adhesion,” stated Sergio Traversa, chief executive officer of Relmada Therapeutics. “We believe these are important product distinctions and support our plans to work towards the initiation of clinical studies.”

The MepiGel formulations were chosen after the evaluation of results from *in vitro* and *ex vivo* studies comparing various topical prototypes of mepivacaine that were conducted by MedPharm Ltd, a specialist formulation development company recognized internationally for its expertise in topical and transdermal products. Relmada is planning single and multiple dose Phase I studies in healthy subjects with the selected MepiGel formulations later this year. The data from these studies will inform the design of a subsequent Phase 2 proof of concept study in patients suffering from neuropathic pain.

About Mepivacaine and MepiGel

Mepivacaine is an anesthetic (numbing medicine) that blocks the nerve impulses that send pain signals to the brain. It is chemically related to bupivacaine but pharmacologically related to lidocaine. Mepivacaine is currently indicated for infiltration, nerve block and epidural anesthesia. The U.S. Food and Drug Administration (FDA) has granted orphan drug designation to Relmada for the use of mepivacaine in the treatment of after-shingles pain, or postherpetic neuralgia (PHN), and HIV-associated neuropathy, entitling Relmada to seven years of marketing exclusivity upon regulatory approval.

About Neuropathic Pain

Neuropathic pain is a disorder of the sensorimotor system and the term is used to describe a wide range of pain syndromes, including painful diabetic neuropathy, postherpetic neuralgia and trigeminal neuralgia. According to the Neuropathy Association, neuropathic pain is estimated to affect more than 20 million

people in the United States alone. The main classes of drugs used to treat these neuropathic pain conditions are anticonvulsants, antidepressants, opioids and topical treatments. However, despite the availability of multiple pain medications only about 50% of patients respond to treatment with currently available therapy options, and they present the risk of numerous side effects that reduce their tolerability.

About MedPharm Ltd

MedPharm is a specialist pharmaceutical development company that is recognized internationally for its expertise in transdermal and topical (skin, nail, nose, lungs and other mucosal membranes) drug delivery systems and formulations. Established in 1999, and with numerous high profile customers, MedPharm has built a worldwide reputation for its unique and highly specialized service in contract research and development; together with expert project management and focus on dermatology. Projects range from simple feasibility tests, formulation and dosage form design and optimization, through to preparation of GMP clinical supplies for Phase I/II trials with guaranteed subsequent smooth transfer through to commercial manufacturing sites. The company operates a hybrid business model, with a CRO business and a development program with a substantial patent portfolio of novel topical and transdermal drug delivery systems. These systems include MedSpray®, MedTherm® and AquaRMed™.

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 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. 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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