Innovations in Pain Medicine®

Relmada Therapeutics Announces Levocap ER Development Progress

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Relmada Therapeutics announces the approval of its CTA (Clinical Trial Authorization) by the MHRA (Medicines and Healthcare products Regulatory Agency) in the United Kingdom to conduct a Phase 1 pharmacokinetic study with LevoCap ER.

Blue Bell, PA – March 4, 2013 – Relmada Therapeutics Inc., a clinical-stage company developing novel therapies for the treatment of chronic pain, today announced the approval of the application of a Clinical Trial Authorization (CTA) that was submitted with the Medicine and Health Regulatory Agency (MHRA) to conduct a Phase I pharmacokinetic study with the development product abuse-deterrent LevoCap extended release (ER) capsules. The MHRA is the UK government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe.

This Phase I safety study is designed to assess the bioavailability and dose proportionality of three levorphanol extended release (ER) formulations, how these compare with a marketed IR (immediate release) product available in the US, and whether there are any differences under fed and fasted conditions.

"This significant progress is in line with the development plan of LevoCap ER. If this study shows positive results, then we will be on track to enter the phase III program in the fourth quarter," said Sergio Traversa, CEO of Relmada.

LevoCap ER, Relmada's lead product is intended to add a powerful new tool to treat pain where opioids alone or non-opioids alone do not provide adequate relief. Unlike other opioids, levorphanol, the active ingredient in LevoCap ER modulates pain through both opioid pathways and noradrenergic pathways thereby providing pain relief through multiple mechanisms in one capsule. Levorphanol has also been shown to partially reverse analgesic tolerance to morphine and may therefore benefit patients who are tolerant to the analgesic effects of their current opioid.

Based on its pharmacological profile, LevoCap alone should demonstrate improved efficacy in a broader patient population compared to other opioids. This includes the vast category of patients affected by chronic pain with combined nociceptive and neuropathic components, which frequently require treatment with two or more pain medications to achieve efficacy.