BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Phosphagenics to start opioid pain patch study

December 3, 2012 | News | By BioSpectrum Bureau



Singapore:Ã?Â Melbourne-based Phosphagenics has resolved all crystallisation issues associated with its opioid patch development program, including its oxycodone patch design and product formulation. The opioid pain patches incorporate the company's proprietary TPM platform drug delivery technology.

A multi-dose study of this first-in-class product is expected to begin in early 2013. Following the completion of the trial, which will take up to six weeks, an investigational new drug (IND) will be submitted for approval to the US FDA in order to commence phase III of the program.

The firm has been closely working closely with its US-based commercial advisers, Neura Therapeutik, as well as regulatory and clinical advisers, INC Research, to develop a detailed target product profile (TPP) to form part of the final product label.Ã?Â The clinical development plan (CDP) has also been prepared, which outlines clinical activities and study designs for successful product registration.

Phosphagenics' patches contain the opioid oxycodone that has very low bioavailability, which makes it an ideal candidate for transdermal delivery.Ã?Â Following the successful pre-clinical program with this compound, the company will proceed with a single-dose clinical trial of an oxymorphone patch early in 2013. The company is also looking to develop patches of the another opioid called oxymorphone and is expected to begin its clinical trials in early 2013.

Phosphagenics' CEO, Dr Esra Ogru, said that,Ã?Â "The prospect of having two major opioid projects entering the clinic simultaneously represents a significant increase in the value of the program. We remain focused and committed to commercializing our first-in-class pain patch technology."