



PHOSPHAGENICS

Company Announcement

Phosphagenics on Track: Pivotal TPM/oxycodone Patch Trials Begin

- *Precursor to Pivotal Phase 3 Trial*
- *Optimised Patch to be used in Clinical Trials*
- *Clinical Trial Results to be included in IND Application*

21 November 2011, Melbourne, Australia: Australian drug delivery technology company Phosphagenics Limited (ASX: POH, OTCQX: PPGNY) has been granted ethics approval to begin clinical trials on its leading pharmaceutical product, a TPM/oxycodone patch to manage chronic pain. The trials will start at the end of November 2011.

This pharmacokinetic study will examine the safety and tolerability of the patch, which has been optimised in collaboration with global company 3M, and builds on Phosphagenics' proprietary transdermal TPM® platform delivery technology.

Sixty-five healthy subjects will participate in the trials at the CMAX facilities at the Royal Adelaide Hospital. The trials are designed to examine the oxycodone delivery profile of the newly developed patch. In the first stage of the trial subjects will be administered a single dose patch; the second stage will examine repeat dosing.

Results from this study will be used to design the upcoming Phase 3 trial scheduled to commence in the third quarter of 2012.

Phosphagenics CEO, Dr Esra Ogru, said the new patch was far superior to the original in-house developed prototype. In a series of *in vitro* studies the newly developed patch delivered greater amounts of oxycodone over a longer period of time resulting in a reduction of the size of the patch and a commercial finish.

Dr Ogru said the trials were designed to capture the pivotal data that would form the basis of the IND regulatory submission to the FDA and to ensure the upcoming Phase 3 trials proceed as seamlessly as possible.

"We expect this trial will confirm the superior efficacy of the optimised commercial product and demonstrate a sustained drug delivery appropriate for the treatment of chronic pain. Our aim is to ensure Phase 3 trials are accelerated which will result in the swiftest path to market."

Phosphagenics recently announced a successful capital raising to fund trials and continue product commercialisation.

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Dr Ogru noted: “This is a first-in-class product and a revolutionary way of transdermally delivering the powerful painkiller oxycodone which we believe will address many of the abuse issues related to this drug. According to a recently completed Physicians’ Survey projected demand for this product is expected to exceed \$1 billion per annum.”

Ends

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About Phosphagenics

Phosphagenics is commercialising drug delivery applications based on its novel transdermal (drugs administered via skin) TPM® – Targeted Penetration Matrix technology. TPM® is a patient friendly and cost effective system used to deliver proven pharmaceutical and nutraceutical products.

The lead product advancing through clinical trials is an oxycodone matrix system for the relief of chronic pain.

Phosphagenics’ shares are listed on the Australian Securities Exchange (POH) and its ADR – Level 1 program in the US is with The Bank of New York Mellon (PPGNY).

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