



9 September 2009

## **PHOSPHAGENICS TO COMMENCE PHASE 2/3 TOPICAL DICLOFENAC TRIAL**

***Phosphagenics announced today that in the first quarter of 2010 it intends to start a Phase 2/3 trial of its patented TPM delivery system using the drug diclofenac, a leading anti-inflammatory drug.***

***Phosphagenics' successful studies of diclofenac, including the Phase 1B study completed this week, have shown that TPM-delivered diclofenac permeates the skin substantially more effectively than the currently available Voltaren® gel, thereby increasing drug concentrations in local tissues while maintaining similar levels of systemic exposure.***

***Diclofenac is one of the leading products of a class of drugs known as NSAIDs (non-steroidal anti-inflammatory drugs) with global sales approximately US \$1 billion.***

Phosphagenics Limited ("Phosphagenics") (ASX: POH; OTCQX: PPGNY) today announced it will start a Phase 2/3 trial of its patented TPM delivery system with the anti-inflammatory drug, diclofenac, in the first quarter of 2010.

The successful completion of the Phase 1B trial this week demonstrated that Phosphagenics' TPM delivery system was able to safely deliver a significantly greater amount of diclofenac into the skin compared to a leading commercial product, Voltaren®.

Diclofenac is one of the leading products of a class of drugs known as NSAIDs (non-steroidal anti-inflammatory drugs) with global sales approximately US \$1 billion. It is used to reduce inflammation and pain associated with inflammation of tendons or joints (tendonitis or arthritis) and acute injuries, such as sport injuries.

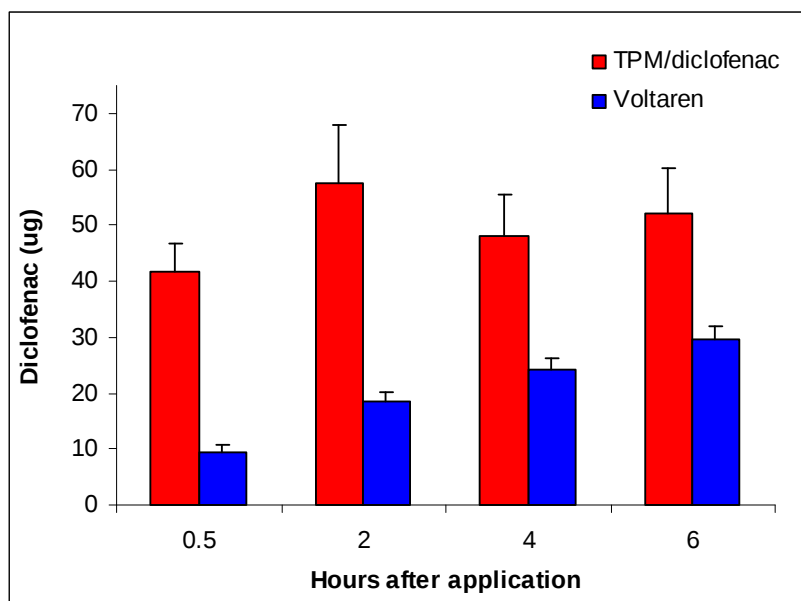
In the Phase 1B trial, diclofenac absorption was assessed by tape stripping, a standard, non-invasive procedure used to measure the amount of a diclofenac or other drugs found in the various layers of the stratum corneum, the outer layer of the skin.

Thirty minutes after application, TPM/diclofenac delivered on average over 400 percent more diclofenac into the stratum corneum, than the commercial product, Voltaren® ( $p < 0.001$ ; Figure 1). Phosphagenics' TPM/diclofenac also significantly augmented the depth of penetration, with 380 percent ( $p < 0.001$ ) more diclofenac found in the deepest layers of the skin sampled.

The trial clearly demonstrated that the TPM/diclofenac formulation had a quicker onset and greater magnitude of diclofenac delivery than Voltaren®, with increased delivery maintained for at least six hours, the duration of the trial.

The open label, single centre study was conducted under the guidance of Principal Investigator Dr Alex Veldman. Twelve healthy adult volunteers enrolled in the bioavailability trial of dermal delivery.

Figure 1. Dermal absorption of diclofenac after topical application of the TPM/diclofenac and Voltaren® formulations



Dr Paul Gavin, Vice President of Research and Development at Phosphagenics said; “The results obtained from our Phase I programs have provided the conclusive evidence needed for the company to progress diclofenac into a Phase 2 or 3 clinical trial. We are in the process of designing the parameters of the study and preparing the paperwork required to initiate an efficacy trial during Q1 2010. The human study will assess the efficacy of TPM/diclofenac for the reduction of pain in selected relevant indications such as arthritis or sports injuries.”

“We are also in the process of preparing an IND package for filing with the US FDA. We aim to submit our IND Q1 2010. We have had significant commercial enquires for this product and believe that these results will further these discussions.”

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## **APPENDIX AND NOTES TO EDITORS**

### **About Phosphagenics Limited**

Phosphagenics is a Melbourne-based, globally driven biotechnology company focused on the discovery of new and cost effective ways to enhance the bioavailability, activity, safety and delivery of proven pharmaceutical and nutraceutical products. Phosphagenics' core technology is built around the science and application of phosphorylation, a process where the addition of a phosphate group has been found to enhance the bioavailability, activity and safety of existing pharmaceuticals and nutraceuticals, as well as to assist in the production of drug delivery platforms. Phosphagenics' shares are listed on the Australian Stock Exchange (POH) and its ADR – Level 1 program was established in the U.S. with The Bank of New York Mellon (PPGNY) for U.S. investors to trade in Phosphagenics' stock on the 'over-the-counter' market. In July 2007, this was upgraded to the International OTCQX, a new premium market tier in the U.S. for international exchange-listed companies, operated by Pink Sheets, LLC. For more information, please visit Phosphagenics' web site at [www.phosphagenics.com](http://www.phosphagenics.com).

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