



PHOSPHAGENICS

12<sup>th</sup> November 2008

## Company Announcement

### Transdermal Diclofenac enters Phase 1 Clinical Trial in Humans

Phosphagenics Limited ("Phosphagenics") (ASX: POH; OTCQX: PPGNY) announced today that it has initiated a phase 1 human clinical trial using its patented drug delivery system, TPM, for the targeted delivery of a leading non steroidal anti-inflammatory drug (NSAID), diclofenac. The trial will compare the bioavailability and penetration of the topically applied Voltaren<sup>®</sup> gel (1% diclofenac), one of the leading marketed products, and Phosphagenics' diclofenac (at 1% and 2% diclofenac concentrations).

Conducted at the Centre for Pharmaceutical Research, University of South Australia, the Principal Investigator is Professor Allan Evans. The trial is an open label, single centre bioavailability and penetration trial of dermal and systemic pharmacokinetics in 12 healthy adult volunteers, incorporating secondary endpoints of safety and tolerability. The Company expects to obtain and announce the results of this phase 1 trial in the first quarter of 2009.

Dr Esra Ogru, Executive Vice President of Research and Development at Phosphagenics, said; "Diclofenac is a well known topical anti-inflammatory drug most commonly used for sprains and strains. In our preclinical studies with TPM/diclofenac we have demonstrated significant increases in skin penetration of diclofenac compared to the market leader (Voltaren<sup>®</sup>); results we are confident we can replicate in human testing."

"The advantage of our formulated diclofenac is that it increases the amount of anti-inflammatory drug delivered to the site of action. Sales of Voltaren<sup>®</sup> in 2007 for both oral and topical application were around US\$700 million, so we are very pleased to be entering into the clinic with our new formulation as we believe its superior efficacy will prove it to be a very attractive product commercially," she said.

**Ends...**

## **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). An 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)

### **Safe Harbor Statement**

This press release contains forward-looking statements based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialise, actual results could vary materially from the Phosphagenics' expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations.

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