



PHOSPHAGENICS

29 June 2009

## Company Announcement

### ***Phosphagenics Announces the Successful Completion of a Phase 1 Clinical Trial using TPM/Oxycodone***

***- Data demonstrates that repeat applications of TPM/oxycodone formulation does not cause significant opioid induced erythema or sensitisation***

Phosphagenics Limited ("Phosphagenics") (ASX: POH; OTCQX: PPGNY) today announced the successful completion of its Phase 1 Repeat Insult Patch Test (RIPT) demonstrating that the repeated application of its patented TPM/oxycodone formulation did not cause any significant erythema or sensitisation in humans. Erythema (skin reddening) and sensitization can typically occur when opioids are exposed to the skin and have until now been a limiting factor in commercialising transdermal opioids.

With sales exceeding \$US 1.5 billion annually, oxycodone is one of the world's leading pain management drugs, being more potent than morphine with less adverse side effects. Currently it can be administered only orally or intravenously but Phosphagenics is working towards becoming the first company to offer patients suffering from chronic pain a gel or patch that will provide sustained-release of Oxycodone into the bloodstream.

Phosphagenics' previously completed pre-clinical research and demonstrated that oxycodone was delivered transdermally in therapeutic doses when formulated with TPM into a gel or patch. As part of these pre-clinical studies, the company conducted animal studies which established that its formula did not cause sensitisation. This was a crucial milestone in its opioid development program but it needed to be verified in humans before the compounds could be commercialised.

#### **About the Study**

RIPT is the standard method for assessing whether a compound is an irritant and/or sensitiser. During the three week induction phase of the study, TPM/Oxycodone was applied every second day to the same area of the subjects' back and covered with an occlusive dressing. The site of application was assessed every second day after patch removal, and scored for redness and erythema. During the challenge phase which occurred two weeks after the completion of the induction phase, the formulation was applied once to a new area of skin and assessed to determine whether an immune response had developed.

The open label, single centre study was conducted at the Royal Adelaide Hospital under the guidance of Principal Investigator, Dr Guy Ludbrook. Fifty healthy, adult volunteers participated in the RIPT trial. The endpoints were the assessment of erythema and sensitisation.

Over the three week induction phase, no patients exhibited erythema scores above 1 (on a scale of 0 - 4) with most scores registered as zero, demonstrating that TPM/Oxycodone does not cause irritation and therefore is not an irritant. Importantly, all patients during the

challenge phase had scores of zero establishing that TPM/Oxycodone is not a sensitiser. These results corroborate the previous clinical studies demonstrating that TPM significantly reduced erythema caused by tretinoin, also a known irritant.

These clinical results pave the way for an extensive Phase 1A pharmacokinetic study examining the transdermal delivery of Oxycodone from Phosphagenics' TPM/Oxycodone in the recently announced patch systems and also in gels. These studies are expected to commence Q3/09.

**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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