



PHOSPHAGENICS

*Company Announcement*

## **Phosphagenics Ready to Commence Pivotal Oxycodone Clinical Trials**

- *Patch successfully completed with global development partner 3M*
- *First in class product to manage pain*
- *Top level steering committee appointed to oversee trials and FDA regulatory requirements*

**19 September 2011, Melbourne, Australia:** Australian drug delivery technology company Phosphagenics Limited (ASX: POH, OTCQX: PPGNY) has, in collaboration with 3M, completed the optimisation of the TPM/oxycodone patch. This milestone clears the way for the company to commence its pivotal oxycodone clinical trials.

Phosphagenics has previously shown that the prototype patches developed in-house were capable of delivering therapeutic amounts of oxycodone into the blood after daily application. The optimised final patch which will be produced by 3M for the upcoming pivotal trials, will be equivalent to the article of commerce. The patch represents an important advancement in the development of the TPM® patch technology, with significantly improved oxycodone delivery and an extended wear profile.

Phosphagenics CEO, Dr Esra Ogru, said that the performance of the finished patch was exceptional.

“We have developed a patch that delivers more oxycodone, at a faster rate, over a longer period of time. The commercial patch will not only provide flexibility for the treatment of a wider range of pain indications but will also be much smaller than our original prototype, an important element in patients’ compliance.”

Phosphagenics’ pivotal phase human trial program will begin in Australia in the next quarter and will be expanded next year into other countries including the United States. It is anticipated that Phase 3 will be completed by 2013.

Phosphagenics has appointed a prestigious steering committee to design and oversee the upcoming trials and to ensure that the strict regulatory requirements needed to obtain FDA approval are met. The four member committee consists of two clinical pain experts who are highly regarded internationally and two US based regulatory advisers.

Dr Ogru added, “The successful completion of the upcoming human trials will result in major commercial opportunities for the company and represents the culmination of many years of development.”

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### **Phosphagenics Limited**

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A TPM/oxycodone patch will have considerable advantages over other forms of pain medication, including the capability of diminishing breakthrough pain as well as avoiding GI tract inflammation and constipation, common consequences of administering oxycodone orally.

The patch should also reduce the onset of drug tolerance in patients, which normally results in a need for these patients to increase their oxycodone intake over time to maintain therapeutic benefits of opioids.

Dr Ogru noted that the patches will reduce opioid abuse as it is more difficult to extract the drug from a patch than from most oral forms of oxycodone. Additionally, applying multiple patches will not produce euphoria, the major reason for drug abuse.

“Our TPM/oxycodone patch has ticked all the boxes with respect to clinical efficacy, safety, abuse profile and market potential. We look forward to our upcoming trials and anticipate a swift path to market.”

Oxycodone is one of the most prescribed pain drugs by physicians and the current market for oral forms of the drug is more than \$3.5 billion.

## **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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