



PHOSPHAGENICS

Company Announcement

Phosphagenics Delivers Further Positive Oxycodone Patch Trial Results

- Latest trial demonstrates excellent patch characteristics
- Development of viable commercial product
- 4.5 x more oxycodone delivered

15 February 2012, Melbourne, Australia: Australian drug delivery technology company Phosphagenics Limited (ASX: POH, OTCQX: PPGNY) today announced positive results from the clinical trial using its new TPM/oxycodone patch.

The patch developed for commercial application in collaboration with global partner 3M, was trialed on 45 subjects at the Royal Adelaide Hospital's CMAX facility.

The trial was designed to characterise and assess the oxycodone delivery profile from a single 3-day application of the 3M developed TPM/oxycodone patch system.

Results have demonstrated that the new patch delivered 4.5 times more oxycodone over 72 hours into the blood compared to the original prototype developed by Phosphagenics more than a year ago.

Further, the patch was half the size of the original prototype and had the characteristics of a commercial patch.

Phosphagenics' CEO, Dr Esra Ogru said: "The trial results confirm we have a viable product. While minor improvements will be undertaken to further optimise the patch, we will address these comfortably in the knowledge that we have produced a commercial patch with potential global impact."

Dr Ogru said the patch exhibited superior delivery of oxycodone compared to the original prototype.

"The rate of oxycodone delivery from this new patch was exceptional and has the potential to provide longer-term pain relief from a single patch", she said.

"Clinically the new patch is of significant benefit from a safety and anti-abuse perspective in comparison to current oral dosage forms. Our patch with the sustained delivery profile will minimise the potential for overdose, reduce the rate at which drug tolerance develops and improve patient compliance.

Phosphagenics Limited

ACN 056 482 403 ABN 32 056 482 403

11 Duerdin Street, Clayton VIC 3168

PO Box 1415, Clayton South MDC VIC 3169 Australia

Tel: +61 (0)3 9565 1119 Fax: +61 (0)3 9565 1151

Web: www.phosphagenics.com Email: info@phosphagenics.com

“We believe that this result will be looked upon positively by both clinicians and the regulatory agencies.”

Phosphagenics’ top-level regulatory advisors have responded favourably to the trial results. Our senior advisor, Lee S Simon MD, a former Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products (DAAODP) at the FDA commented: “The delivery profile from this patch is extremely interesting and points to the need to engage with the FDA as soon as is practically possible. These results indicate that Phosphagenics is well on the way to creating a unique product.”

Dr Ogru said minor formulation changes will be undertaken to improve the final commercial product.

“Phosphagenics has chosen to address these changes now before progressing into the multiple dosing component of the clinical program, which will lead into the fully funded Phase 3 program expected to start later this year”, she said.

Prior to starting the Phase 3 program Phosphagenics will meet with the US FDA to get clinical study sign-off.

Based on a previously announced Physician’s Survey, projected demand for the TPM/oxycodone patch is expected to exceed \$1 billion per annum. The current global oxycodone market exceeds \$3 billion per annum.

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Enquiries:

Dr Esra Ogru
Chief Executive Officer
Phosphagenics Limited
+61 3 9565 1119

David Segal
Investor Relations Manger
Phosphagenics Limited
+61 3 9565 1103

Rudi Michelson
Monsoon Communications
+61 3 9620 3333

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 (PPGY).

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