ASX Limited
Market Announcements Office

Phosphagenics Completes First IND Enabling Study for TPM®/Oxymorphone Patch

- ***Single dose pharmacokinetic (PK) study reproduces earlier results***
- ***Therapeutic oxymorphone blood levels achieved in all 15 subjects***
- ***Drug elimination indicates favourable safety profile***

11 August 2014, Melbourne: Australian drug delivery company, Phosphagenics Limited (the Company) (ASX: POH, OTCQX: PPGNY), announces that the first of its additional studies designed to further characterise the TPM®/Oxymorphone patch, in support of an Investigational New Drug (IND) application with the FDA, has been completed. The study was conducted on 15 healthy volunteers at Linear Clinical Research's facility in Perth. It assessed additional pharmacokinetic parameters associated with the safety and elimination profile that were not addressed in the previous multiple dose Phase 1 study. The data generated will be used to help design the upcoming Phase 2 study, support the IND application and inform the eventual product label.

This single dose study unequivocally reproduced the outstanding results obtained in the previous Phase 1 study, both in terms of the oxymorphone delivery profile from the patch and the oxymorphone blood concentration in subjects. All 15 subjects achieved an oxymorphone blood concentration that was well above the minimum therapeutic blood level for the drug. The total number of subjects exposed to the TPM®/Oxymorphone patch now stands at 27 with all patients attaining therapeutic oxymorphone blood levels.

Dr Paul Gavin, Chief Scientific Officer, said, "The TPM®/Oxymorphone patch has demonstrated reproducibility in two independent manufacturing and clinical trial campaigns with all subjects tested demonstrating blood concentrations equivalent to those produced by the commercially available oral dosage form. These studies clearly establish that the TPM®/Oxymorphone patch has significant potential to be a remarkable product."

"The latest study also provides new information regarding the elimination phase of oxymorphone after patch removal, an important variable in patient safety that is needed to determine the Phase 2 study design. As with any transdermal system, drug delivery ceased upon patch removal and residual drug in the body was eliminated steadily over time. This represents one of the key safety advantages of a transdermal opioid system compared to the oral dosage form. Accidental overdose (i.e. due to the application of multiple simultaneous patches) rarely occurs with a transdermal patch because of the ease of intervention (i.e. removal of the unintended patches and immediate cessation of delivery)," said Dr Gavin.

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

Phosphagenics' TPM®/Oxymorphone patch development program for the next 18 months was previously described at this year's Annual General Meeting and reiterated in an announcement to the market on 28 July 2014. This result represents the successful and timely completion of the first stage of additional research that was communicated to the market. Phosphagenics will shortly commence the second planned study which will compare the transdermal absorption of oxymorphone from application of the patch to different parts of the body. That study will inform the selection of appropriate sites for application of patches during Phase 2. Both characterisation studies have been designed to provide valuable information for potential licensees as well as various global regulatory bodies.

Phosphagenics expects to begin the Phase 2 trial in the USA during the first half of 2015 following the submission of an IND with the FDA.

Enquiries

Australia:
David Segal
Investor Relations Manager
Phosphagenics Limited
+61 3 9565 1119

Rudi Michelson
Monsoon Communications
+61 3 9620 3333

USA:
Matthew Selinger
MZ North America
+ 1 949-298-4319

About Phosphagenics

Phosphagenics Limited is a drug delivery company that is commercialising various products within the pharmaceutical, cosmetics and animal health sectors, using its proprietary drug delivery system called TPM® (Targeted Penetration Matrix). TPM® is a patient friendly and cost effective system, based on Vitamin E, that enhances the topical or transdermal delivery of active molecules. The lead products advancing through clinical trials are oxymorphone and oxycodone patches 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).

Inherent Risks of Investment in Biotechnology Companies

There are a number of inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology.

Forward-looking Statements

Certain statements in this announcement may contain forward-looking statements regarding Company business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavour of building a business around such products and services.

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