ASX Limited
Market Announcements Office

Phosphagenics Receives Ethics Approval to Commence Topical Phase 2 TPM®/Oxycodone Patch Trial

- ***Proof of concept Phase 2 human trial at multiple sites in Australia***
- ***Targeting neuropathic pain (Post-herpetic neuralgia indication)***
- ***Successful topical delivery of oxycodone via patch would be a world-first***

8 December 2014, Melbourne: Australian drug delivery company, Phosphagenics Limited (ASX: POH; OTCQX:PPGNY), has received ethics approval to commence a proof of concept Phase 2 trial in Australia for its TPM®/Oxycodone patch.

As indicated in the November 2014 newsletter, the trial will examine the effectiveness of the patch to reduce pain in patients suffering from post-herpetic neuralgia (PHN) by delivering oxycodone topically with little systemic exposure.

PHN is a well-accepted neuropathic pain model. The US FDA has commonly granted orphan drug status to drugs being developed to treat PHN. The grant of orphan status would have very positive implications for the Company by reducing the time, the number of patients and the expense required to obtain US FDA regulatory approval of the patch.

While several studies have demonstrated that inflammation in peripheral tissues causes the up-regulation of opioid receptors, opioids delivered into the skin via a patch have never before been successfully applied to treat peripheral pain, including neuropathic pain, in humans. Positive results in this trial will open up new market opportunities and indications for oxycodone.

Phosphagenics has demonstrated that TPM® can transport oxycodone across intact skin in a rodent model and act directly on inflamed tissue to provide local pain relief. This work will be submitted this month for peer-reviewed publication.

Dr Paul Gavin, CSO of Phosphagenics, said, "It is very exciting to get our first opioid patch into formal Phase 2 pain studies, especially as we are trialing a new application for this existing drug. Clearly, an opioid product with little or no systemic delivery that greatly reduces most of the common adverse side effects caused by opioids while providing localised pain relief would be a unique and extremely valuable product."

Ends

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

About Phosphagenics Phase 2 TPM®/Oxycodone Patch Trial

Trial design	Randomised, double blind, vehicle controlled, single dose crossover study
Sites	Multiple sites around Australia
Number of patients	~28
Duration	For each patient about 38 days from initial screening and selection through to post treatment assessment
Administration	Each patient will receive a single 3-day treatment with the TPM®/Oxycodone patch and a vehicle control
Primary endpoint	Assessment of the analgesic efficacy of TPM®/Oxycodone when applied to the painful area for PHN patients
Patch manufacture	Manufactured by our US-based contract manufacturer, which has recently completed technology transfer and manufacturing scale-up of the TPM®/Oxycodone patch. Patches are expected to be shipped from the US this month
Commencement	January 2015
Trial Completion	Expected early in the third quarter 2015, depending on recruitment

About PHN and Neuropathic Pain

Neuropathic pain is caused by lesion or disease of the somatosensory nervous system. There are many causes of neuropathic pain, including diabetes, cancer, infectious diseases, multiple sclerosis, stroke and many other diseases.

According to IMS Health Disease Insights 2014, sales of the key products to treat neuropathic pain in the US alone were approximately US$4 billion in 2013. Its findings also suggest that, while the US has an extremely large prevalence of neuropathic pain, only about 25% is treated with pharmaceutical agents. This opens up a significant commercial opportunity for the entry of new therapies such as the Company's TPM®/Oxycodone patch.

PHN, one of the many causes of neuropathic pain, is triggered by a complication of the herpes zoster virus, commonly called shingles. It affects the nerve endings in the skin and is accompanied by burning or stabbing chronic pain. If the TPM®/Oxycodone patch is shown to effectively reduce pain caused by PHN, it is very likely to be effective in treating many other neuropathic pain conditions, especially those where topical treatment could provide a therapeutic advantage (e.g., diabetic peripheral neuropathy, HIV induced neuropathy).

Enquiries

Harry Rosen
Chief Executive Officer
Phosphagenics Limited
+61 3 9565 1119

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

Rudi Michelson
Monsoon Communications
+61 3 9620 3333

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.

www.phosphagenics.com
www.bioelixia.com