ASX Limited
Market Announcements Office

Phosphagenics' Oxymorphone Patch Success

- *Oxymorphone patch achieves world first therapeutic plasma concentrations in all subjects in clinical trial*
- *Results from Phase 1 oxymorphone patch clinical trial demonstrates excellent drug delivery profile*
- *Most commercially significant trial result ever achieved by Phosphagenics as it proves the concept for an estimated $1 billion annual sales*
- *Phase 2 study to proceed focusing on optimising commercial appeal of the patch*

24 October 2013, Melbourne: Australian drug delivery technology company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY), today announced results from its multi-dose oxymorphone Phase 1 trial. In a world first, the Company's proprietary TPM®/oxymorphone patch delivered therapeutic plasma concentrations of oxymorphone to all 12 subjects.

The Phase 1 trial was conducted at Linear Clinical Research Limited's facility in Perth on 12 healthy volunteers. The trial was designed to characterise the oxymorphone delivery profile from repeated applications of a three day patch that mimicked a real life pain medication regime.

All 12 subjects demonstrated oxymorphone plasma concentrations well above the threshold therapeutic concentrations produced by the oral long-acting or extended release dosage form (Opana® ER) within the first application period of three days. Oxymorphone plasma concentrations increased with repeated patch application, while maintaining the profile desirable for transdermal products. Results demonstrate that the maximum plasma concentration in subjects can be as high as that produced by a single oral dose of the highest strength Opana® ER tablet (40 mg).

Oxymorphone is a drug that has been approved and used for a long time in oral and injectable dosage forms. Consequently, the relationship between oxymorphone plasma concentration and analgesic effect are well established. Exceeding these well-defined target plasma concentrations ensures the product will be therapeutic.

Overall, the pharmacokinetic profile of oxymorphone resulting from the multiple-dosing regime exceeded expectations and showed plasma concentrations equivalent to those attained by oral dosages used to treat moderate-to-severe chronic pain.

"The importance of the success of this trial cannot be overstated. While we were confident going into the trial, the magnitude of the oxymorphone concentration in plasma surpassed our expectations," said Dr Paul Gavin, Chief Scientific Officer of Phosphagenics."

The result is also significant with respect to abuse potential, a major concern of the FDA and a significant hurdle for product registration of any opioids. The TPM®/oxymorphone patch contained about 25% of the amount of the drug normally used in high dosage strengths of Opana® ER over the same 72-hour dosage period, thereby significantly reducing the amount of dispensed opioid that could be the target of abuse. This should be viewed very favourably as part of the risk minimisation component of regulatory submissions.

Dr Gavin said, "Not only can the patch deliver therapeutic amounts of oxymorphone, the results suggest that the patch can compete with the therapeutic value of the higher dosage strengths of the oral product and surpass them with respect to bioavailability."

Based on these positive results, Phosphagenics will proceed to a Phase 2 trial, although its emphasis will now shift. Previously it was envisaged that the Phase 2 trial would need to prove that the product was capable of providing analgesia for patients with chronic pain conditions. As the Phase 1 result emphatically answers that question, the focus of the upcoming Phase 2 will now shift to defining the dosage regimes to be used with the product and enhancing its commercial value, rather than demonstrating therapeutic effect.

"The FDA is currently conducting an aggressive review of the prescribing and utilisation practices of opioids in the United States. An oxymorphone patch that is a viable alternative to the oral product, that reduces adverse effects associated with oral delivery while containing less drug, ought to be very attractive to the FDA. If approved, this product has the potential to capture significant market share in the extended release opioid market," said John LaLota, CEO of US-based Neura Therapeutik, Phosphagenics' commercialisation partner. "We expect to attract significant interest from potential licensees. The Phase 1 results for the oxymorphone patch will enable serious discussions with big pharma to commence. Similar results at Phase 2 will likely lead to Phosphagenics partnering its oxymorphone patch," he added.

Harry Rosen, CEO of Phosphagenics, said, "This result represents the biggest milestone in the Company's history. It is a world class achievement by Australian researchers. I cannot speak more highly about their efforts and tenacity. While we had previously demonstrated the capability of TPM®, for the first time we have delivered a drug that has never before been delivered through the skin at a level comparable to dosing by other means. Additionally, we are tackling a very substantial market opportunity."

"The questions as to whether our opioid patch technology works have been categorically answered by these results. The task now is to work with our pain experts and regulatory consultants to progress the project through the next phases of the clinical trial and regulatory process, as well as licensing discussions. We have to ensure that all boxes are ticked, including dialogue with the FDA, as we progress towards partnering our products. We anticipate that the Phase 2 trial for our transdermal oxymorphone patch will begin around the middle of CY2014."

The extended release opioid market for the treatment of chronic pain, which is the target market for the oxymorphone patch, is approximately $6 billion per annum. Surveys undertaken on behalf of Phosphagenics have indicated that a successfully commercialised oxymorphone patch could achieve peak annual sales of between $700 million - $1.4 billion.

In another significant development, Phosphagenics was recently notified of the allowance of a very broad patent in the United States for its proprietary patch by the United States Patent and Trademark Office.

In the current regulatory and social environment with serious concerns about the use and abuse of opioids, a commercial oxymorphone patch will likely have significant competitive advantages.

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About Phosphagenics

Phosphagenics Limited 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 products advancing through clinical trials are an oxymorphone and 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).

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 ASX 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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