



ASX Limited
Market Announcements Office

Reformulation of Phosphagenics' Transdermal TPM®/Oxymorphone Patch Complete

12 December 2016, Melbourne: Australian drug delivery company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY), announced today that tesa Labtec GmbH, the German transdermal formulation specialists, have successfully completed reformulation of its transdermal TPM®/Oxymorphone patch.

Phosphagenics has previously developed prototype transdermal TPM®/Oxymorphone patches capable of delivering therapeutic amounts of oxymorphone over three days in human clinical Phase 1 trials. tesa Labtec was tasked with finalising the patch composition to develop a commercial product with enhanced physical aspects while maintaining or surpassing the established delivery profile.

The reformulation work also took into account Phosphagenics' growing relationship with Terumo Corporation, a leading Japanese healthcare company investigating the potential use of the TPM®/Oxymorphone patch for the Japanese market. Key technical differences were identified in the requirements for the Japanese market compared to those required for North America. Consequently, tesa Labtec was tasked with developing a reformulated patch that takes account of the separate technical requirements of both markets.

Over the course of the reformulation program, tesa Labtec produced over 200 different variants of the TPM®/Oxymorphone patch to ensure they identified the optimal composition. The most promising of these new TPM®/Oxymorphone patches has increased transdermal flux in-vitro compared to the previous clinical patch, as well as enhanced physical and chemical stability across a range of standard stress tests. The performance of the patch in these assessments met or exceeded Phosphagenics' expectations towards a commercial product. Importantly, the reformulation program produced TPM®/Oxymorphone patches appropriate for commercialisation in either the Japanese or US market. These TPM®/Oxymorphone patches have now been submitted for final stability assessments.

Dr Ross Murdoch, CEO, said, "We are extremely happy with the outcome of the tesa Labtec reformulation. Not only have we emerged from the program with an enhanced TPM®/Oxymorphone patch, but now we have multiple patch candidates that appear to have all the attributes needed for commercialisation in either Japan or the USA. We see this as achieving one of the key steps in partnering this asset. We look forward to continuing the development of the product and progressing negotiations with Terumo in respect of an exclusive license for Phosphagenics' TPM®/Oxymorphone patch in Japan."

At the conclusion of the final stability study, Phosphagenics will resume development of the TPM®/Oxymorphone patch, the exact course of which will be determined once the outcome of the negotiations with Terumo are finalised.

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Enquiries

Dr Ross Murdoch
CEO
Phosphagenics Limited
+61 3 9565 1119

Kyahn Williamson
WE Buchan
+61 3 9866 4722 / +61 401 018 828
kwilliamson@buchanwe.com.au

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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