



ASX Limited  
Market Announcements Office

## **Phosphagenics/Terumo R&D alliance to focus on TPM<sup>®</sup> Injectables: TPM<sup>®</sup>/Oxymorphone Patch Development to move outside Agreement**

20 March 2018, Melbourne: Australian drug delivery company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY), announced today that its research and development alliance with Terumo Corporation, initially designed to broadly explore TPM<sup>®</sup> utility, will now focus on TPM<sup>®</sup>-injectable candidates. The shift in focus is the result of a number of alliance projects achieving key decision points; most notably the success of the TPM<sup>®</sup>/Propofol program and the challenges Terumo believe exist for a TPM<sup>®</sup>/Oxymorphone patch entering the unique Japanese market. The two companies have initiated discussions around TPM<sup>®</sup>-injectables within Phosphagenics' internal R&D program and Terumo has terminated the development agreement associated with the development of a 1-day TPM<sup>®</sup>/Oxymorphone patch specifically designed for the Japanese market.

All rights and obligations associated with the TPM<sup>®</sup>/Oxymorphone patch program will revert to Phosphagenics and all patch activities will now be directed towards the requirements of the broader global market.

In a statement to Phosphagenics, Mr Masahito Takahashi, General Manager of the Pharmaceutical Group, Hospital Systems Division, General Hospital Company, Terumo Corporation, said:

*"...the technical hurdles we set to ensure the commercial success of an opioid patch in Japan are very high. Terumo remains committed to the TPM<sup>®</sup> technology, TPM<sup>®</sup>/Propofol and our R&D alliance with Phosphagenics. We are interested in Phosphagenics' growing portfolio of early stage TPM<sup>®</sup>-based injectables and are actively investigating the potential to take on additional projects."*

Dr Ross Murdoch, CEO of Phosphagenics, said,

*"...Our R&D alliance with Terumo is strong and productive. This is most notably demonstrated in the success and rapid progression of the TPM<sup>®</sup>/Propofol injectable program which has already entered the formal preclinical/toxicology phase. I believe that the mutual decision to shift the primary focus of our agreement towards injectables is sensible and pragmatic, particularly given Terumo's strong portfolio of injectable technologies."*

*"...The R&D alliance has been very beneficial to our patch program. Redirecting all patch activities back to a 3-day TPM<sup>®</sup>/Oxymorphone patch so as to address the requirements of the broader market will be relatively seamless and has already begun. The demands and investment put towards the 1-day Japanese patch have benefited us and enabled a number of technical improvements. Improvements that should result in our 3-day patch being much better suited to address the requirements of the global pain market. Plans to initiate discussion with the FDA for progression of this patch into an IND are being formulated."*

Discussions with Terumo over potential injectable projects are ongoing and Phosphagenics will advise the market of progress when applicable.

## **Background**

In April 2016 Phosphagenics and Terumo entered into an agreement relating to the development of up to four parallel projects utilising TPM<sup>®</sup>. Projects specified for initial evaluation were the TPM<sup>®</sup>/Oxycodone patch, the TPM<sup>®</sup>/Oxymorphone patch, the TPM<sup>®</sup>/Propofol injectable and a number of novel concepts including gels and sprays. The agreement allows for sharing of R&D responsibilities, territories and revenues. Since signing over AUD \$2.5 million has already been invested into projects associated with this R&D alliance and the collaboration has produced multiple potential products including:

- a novel clear TPM<sup>®</sup>/ Propofol injectable protected by a new provisional patent application and entering preclinical development;
- improved TPM<sup>®</sup>/Oxymorphone patches and
- multiple formulations for a novel TPM<sup>®</sup> gel specifically targeting pain now available for global licensing.

On 22 August 2017 Phosphagenics and Terumo entered into a further development agreement to develop a 1-day TPM<sup>®</sup>/Oxymorphone patch for the Japanese market, pursuant to which Terumo had the right to take up an exclusion option and move forward to a full license agreement. Terumo set requirements specific for the Japanese market, a single day design and a size that could compete with the highly potent fentanyl patch already approved in Japan. The collaboration has resulted in multiple new TPM<sup>®</sup>/Oxymorphone patches that are more robust and higher performing than previous prototypes, with potential for both 1 and 3-day use across the broader global market. However, after considerable discussion, both companies share the view that production of a patch that satisfies all of Terumo's specific requirements for the Japanese market, including the desired size, is unlikely within a mutually acceptable timeframe.

## **Enquiries**

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## **About Phosphagenics**

Phosphagenics Limited is focused on developing and commercialising innovative Human Health, Animal Health and Personal Care products using its proprietary drug delivery system called TPM<sup>®</sup> (Tocopheryl Phosphate Mixture). TPM<sup>®</sup> is derived from Vitamin E using a unique, proprietary and patented process and has been proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients.

Amongst its major projects, Phosphagenics' is developing TPM<sup>®</sup> enhanced patches, gels and injectable products for the human health market and is also developing TPM<sup>®</sup> to enhance the feed efficiency and health of livestock.

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).

### **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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