ASX Limited
Market Announcements Office

Phosphagenics' FDA meeting provides guidance for TPM®/Oxymorphone patch.

17 January 2019, Melbourne: Australian drug delivery company, Phosphagenics Limited (Phosphagenics) (ASX: POH) is pleased to announce that it has received and now accepted the final minutes of the Pre-IND meeting with the U.S. Food and Drug Administration (FDA) for its 3-day TPM®/Oxymorphone patch conducted on 13 December 2018. The purpose of the meeting was to obtain regulatory guidance and agreement on the preclinical, CMC and regulatory information to be included in an IND for Phosphagenics' 3-day TPM®/Oxymorphone patch as part of an eventual NDA filing in the USA.

Phosphagenics submitted a request for a Type B, PIND meeting in mid-June 2018 for regulatory guidance on its 3-day TPM®/Oxymorphone patch. The FDA scheduled a face-to-face meeting for 13 December 2018. Dr Paul Gavin and Dr Ross Murdoch (Phosphagenics CSO and CEO respectively), together with two external experts, met with a 15 member panel of the FDA Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) in Washington DC for the pre-IND meeting. The meeting topics were broad, allowing discussion and providing feedback on the number, nature, scope and design of studies required for IND and NDA. Topics included the anticipated clinical indication, the approvability of a transdermal opioid patch in the current US environment, and the potential for abuse deterrent label claims.

Dr Paul Gavin, CSO of Phosphagenics said "We have reached a crucial point in the development of the TPM®/Oxymorphone patch. We needed to be sure of the approvability of the patch in the current environment and that the regulatory and development plan we had established would address any concerns the FDA may have around a novel transdermal oxymorphone patch. The relatively recent withdrawal of Opana ER from the market reinforced this need. Pleasingly, the FDA agreed that, despite the withdrawal of Opana ER, the "less resource intensive" 505(b)(2) pathway remains a feasible path for approval of the patch and that a broad chronic indication/label similar to that granted to Opana ER is potentially achievable. The Agency did note however growing concern around the use of chronic opioids in opioid-naive patients and that access to the opioid-naive population may require further specific justification. The meeting discussion and minutes provided guidance for an IND submission and for an NDA including the need for a minimum safety database of at least 750 patients. Of particular note, the Agency also suggested some additional studies (not required for product approval) for Phosphagenics to consider, that could potentially enable the TPM®/Oxymorphone patch to gain valuable abuse deterrent label claims."

Dr Ross Murdoch, CEO of Phosphagenics commented "We believe that the TPM®/Oxymorphone patch can provide real value to patients and the community and can address the short-comings of many currently marketed oral opioids. The approvability of a

novel opioid patch in the USA has however remained an open question, particularly in the mind of potential partners. Whilst approval obviously requires a full FDA review of all data developed up to the time of NDA, I believe the outcome from this meeting to be very useful in providing further confidence in our blueprint for moving forward. This is important not only for future planning but also as a lever to reinvigorate partnering discussions around the TPM®/Oxymorphone (and potentially the TPM®/Oxycodone) patch."

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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® (Targeted Penetration Matrix). TPM® is derived from Vitamin E using a unique, proprietary and patented processes and has been proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients.

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

Phosphagenics' shares are listed on the Australian Securities Exchange (POH).

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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