Phosphagenics Initiates Arbitration Against Mylan

• Claims for alleged breaches of agreements related to the development and commercialisation of Phosphagenics’ TPM® formulation of the injectable antibiotic daptomycin

6 January 2016, Melbourne: Australian biotechnology company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY), announced today that it has commenced legal action against Mylan Laboratories Limited (Mylan), a wholly-owned subsidiary of Mylan Incorporated, by filing notices of arbitration at the Singapore International Arbitration Centre.

Phosphagenics and Agila Specialties Private Limited (Agila) entered into a Master Research Agreement (in 2011) and a Licensing Agreement (in 2012) to develop and ultimately commercialise a formulation combining Phosphagenics’ proprietary TPM® technology with the injectable antibiotic daptomycin, which is indicated for the treatment of complicated skin and skin structure infections, and staphylococcus aureus bloodstream infections. In 2013 Mylan acquired Agila. A lead TPM®/Daptomycin formulation is in the final stages of development by Mylan and, based on a patent filed by Agila, is expected to have commercial advantages over the existing formulation of daptomycin. Daptomycin is currently marketed by Merck under the brand name Cubicin, and is expected to have generic competition in the United States in June 2016.

The arbitration notices assert that Mylan is liable for breaches of several provisions under the two relevant agreements, fraudulent or negligent misrepresentations, breaches of confidence and/or unjust enrichment in relation to intellectual property and commercial licensing terms, amongst others. The dispute has been referred to arbitration in Singapore, in accordance with the relevant agreements. The substantive hearing is expected to take place in late 2016. Meanwhile, the Licensing Agreement continues in full force and effect pending the Arbitrator’s decision.

Phosphagenics has already planned for the legal costs associated with the arbitration proceedings in its 2016 budget. There is no assurance in respect of the outcome of the arbitration proceedings and Phosphagenics will, in accordance with its continuous disclosure obligations, notify the market of any material events as and when they occur.

Enquiries

Dr Ross Murdoch
Phosphagenics Limited
+61 3 9565 1119
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 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 a TPM® enhanced oxycodone patch for the treatment of pain associated with Postherpetic neuralgia (presently completing Phase 2a) and is also developing TPM® 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 (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