Phosphagenics Announces Results of Dairy Trial

22 December 2017, Melbourne: Australian drug delivery company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY), today reported the results of its placebo-controlled, blinded trial assessing the effect of TPM® as an oral feed additive on milk quality and selected fertility end-points in dairy cattle. Despite the TPM® treated group having a numerically lower number of mastitis cases requiring treatment, no statistically significant improvements in milk quality and fertility end-points (p<0.05) were seen in treated cows compared to controls.

Previous smaller studies, where TPM® was formulated as an oral drench successfully demonstrated improvements in milk quality (i.e. somatic cell count reductions) and increased nutrient uptake in dairy cows with sub-clinical and clinical mastitis. Pelleted in-feed formulations are considered more commercially attractive for broad use in a commercial farm setting and therefore this latest trial was designed to assess if TPM® could provide similar benefits when delivered in a pelleted dairy ration.

This large, randomised, placebo-controlled study was conducted at two large commercial dairy farms in Victoria and monitored by independent dairy consultants. Unfortunately, when the selected dose of TPM® was included in a pelleted dairy ration with key nutrients, it did not replicate the successful outcomes seen when delivered as an oral drench.

The differences between the drench and pellet efficacy may be in-part explained by the two dosage forms experiencing a different gastric pathway. Oral drenches can by-pass the first three stomachs of the cow directly entering the final stomach: effectively changing the cow’s gastric pathway to more closely resemble a monogastric (single stomach) species such as pigs and poultry. TPM® delivered in an in-feed ration (as in this latest study), is exposed to the full fermentation process and four stomachs of the cow, potentially lowering the effective dose of TPM®. Functional differences between monogastric and ruminant species have been shown to be associated with different dosing responses in the past.

Phosphagenics’ General Manager of Animal Health and Nutrition, Dr Roksan Libinaki, said, “The results of this study differ from the successful outcomes seen with similar preparations in pigs and poultry, and previously seen with the oral drench in dairy cows. This indicates that more work is required to optimise the dose and delivery of TPM® in products for ruminants. This will need to be a focus of discussions with potential partners interested in the ruminant market.”

Phosphagenics’ Chief Executive Officer, Dr Ross Murdoch, added, “I believe our investment in the animal nutrition space to date has been a great success. We have always recognised the potential for differences in effectiveness of TPM® between species and between dosage forms - this is why Phosphagenics has maintain separate programs across multiple species (monogastric and ruminant). Our recent successful results with pigs and poultry had given me hope for a “clean sweep” of successful results across all species tested. We will now need to rethink how we will tackle the obvious opportunities for TPM® within the ruminant space. We remain encouraged by
discussion with a number of potential partners interested in exploiting TPM® for use in the Animal Nutrition sector."

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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® (Tocopheryl Phosphate Mixture). 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 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) 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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