ASX Limited
Market Announcements Office

Phosphagenics Announces Results of TPM®/Oxycodone Phase 2a Trial

29 January 2016, Melbourne: Australian drug delivery company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY) today reported the results of its Phase 2a proof of concept clinical trial examining its topical TPM®/Oxycodone patch for the treatment of pain caused by postherpetic neuralgia (PHN). The study did not meet the indication specific primary endpoint of demonstrating that locally delivered oxycodone can significantly ($p<0.05$) reduce PHN related pain scores compared to placebo. However importantly, the trial did achieve key pharmacokinetic, performance and safety objectives including demonstrating that the TPM®/Oxycodone patch can effectively deliver drug to the targeted site in the skin while maintaining sub-therapeutic blood levels and maintaining a safety and side effect profile in line with that of placebo. These positive findings support the company's current partnering discussions and support the applicability of the patch for other pain indications.

The Phase 2a trial was a randomised, double-blind, vehicle-controlled crossover study designed to assess the efficacy, safety and patch performance of Phosphagenics' topical TPM®/Oxycodone patch. Twenty-eight PHN patients suffering moderate-to-severe pain were randomised to the study, with 25 patients meeting the criteria for assessment in the primary endpoint.

Each patient received a three-day treatment with both the TPM®/Oxycodone patch and the equivalent TPM®/vehicle control patch, separated by a washout period of 10 days. The primary endpoint compared the mean reduction in average Numeric Pain Rating Scale (NPRS) score over days two and three of each patch application period. The NPRS is an 11-point scale (0-10) that allows patients to grade the intensity of pain they have experienced over the past 24 hours.

The trial demonstrated that the TPM®/Oxycodone patch itself performed well in the older PHN patient population, maintaining the oxycodone delivery profile established in prior Phase I clinical studies on healthy volunteers, with;

- Good three-day adhesion characteristics in line with expectations for a commercial patch;
- Excellent skin tolerability, with minimal dermal irritation;
- Good drug delivery with minimal (sub-therapeutic) systemic exposure to avoid opioid side effects; and
- An attractive side effect profile similar to the placebo/vehicle patch, without evidence of classical opioid side effects associated with oral dosage forms (ie: nausea, constipation, sedation, etc).

Despite the patch performing well and delivering oxycodone directly to the site of perceived pain, no statistically significant difference in pain relief was observed between the treatment and vehicle patch across the test population. The mean reduction from baseline in average NPRS was -0.39 (+/- 0.347) for the TPM®/Oxycodone patch and -0.53 (+/- 0.353) for the vehicle control.

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PHN is recognised as a complex and problematic disease to treat and recent population studies in patients with PHN have shown that specific patient sub-groups can display different pain patterns and different responses to common therapies. This may explain why in a broad patient population a drug with a single specific mechanism of action may only show benefit in a subset of patients. In the current study, a post-hoc subgroup analysis suggests that the TPM®/Oxycodone patch may in fact provide greater analgesia for a specific sub-group of PHN patients - with resultant reductions in NPRS scores of -1.17 (+/- 0.540) for the TPM®/Oxycodone patch and -0.11 (+/- 0.320) for the vehicle control. The Company is continuing to analyse the data to more fully understand this result and this subgroup, and is working with key opinion leaders to determine the implications of this finding for the management of pain in specific PHN sufferers, as well as other, non-neuropathic models of local pain.

Dr Ross Murdoch, Phosphagenics' CEO, said: "It is disappointing to be reporting a study that did not meet its primary endpoint. Phosphagenics designed this exploratory, proof of concept Phase 2a trial to answer two separate, but equally important questions related to the potential use for the topical TPM®/Oxycodone patch;

- Does the patch perform as designed in patients; delivering oxycodone to local tissue at the site of application with minimal blood concentrations and an appropriate safety and side effect profile? and
- Can oxycodone delivered topically to the primary perceived site of PHN pain effectively manage the neuropathic pain experienced by patients?

"It is very encouraging that the TPM®/Oxycodone patch successfully met its performance objective; delivering oxycodone into the local tissue with minimal systemic exposure and an adverse effects profile similar to placebo. This is very important as it supports the commercial potential of our technology and the patch itself. PHN is a notoriously difficult indication to treat topically or systemically and regrettably, the results of this study do not support the contention that topical oxycodone delivered to the primary site of PHN pain can effectively manage the neuropathic pain experienced by the majority of PHN patients. Given the results of this trial we are re-evaluating our plans for further development of the TPM®/Oxycodone patch.

Dr Murdoch concluded: "Although the primary end-point was missed, the learning derived from this study confirms that we have produced a viable patch that can deliver drug to a local site in the desired quantities without significant systemic exposure and with user friendly characteristics (side effect and skin adhesion profiles). The Company remains confident that the patch has applications for other local pain indications and believes that it has a compelling product profile that opens the way for partnering the technology for other indications. The positive performance of the TPM®/Oxycodone patch also bodes well for the ongoing refinement of our TPM®/Oxymorphone product by tesa Labtec. We remain focused on delivering the short to medium term opportunities previously communicated including the continued development of our TPM®/Oxymorphone patch, the future commercialisation of the TPM®/Daptomycin product in collaboration with Mylan and the completion of our ongoing Animal Health and Nutrition studies."

On the following page are the teleconference details at 12PM AEDT today for interested parties.

Enquiries

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Phosphagenics
Conference ID:
938702
Conference Call

29 January, 2016 – 12:00PM (AEDT)

- **Participant Dial-in Numbers**

All Participants will be asked to provide the Conference ID when joining the Call. Please provide the following Conference ID, and Dial In Number/s to all Participants.

- Conference ID: ***938702***

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- **Q&A Instructions**

In order to ask a question during the Live Question and Answer Session: Press **** then 1 on your telephone keypad*** *to enter the Q&A queue Press* **** then 2 on your telephone keypad*** *to withdraw your question*

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).