

30 April 2008



## Company Announcement

# Phosphagenics Reports Positive Pre-clinical Results for Targeted Delivery of Lidocaine

## **- Company's TPM Drug Delivery Technology Demonstrates Substantial Increase in Lidocaine Penetration Compared to a Leading Marketed Product -**

Phosphagenics Limited ("Phosphagenics") (ASX: POH, AIM: PSG, OTCQX: PPGNY) today announced positive results of a pre-clinical study using TPM, the Company's patented drug deliver system, for the targeted delivery of lidocaine, demonstrating increased efficacy while restricting systemic exposure. A phase 1 human clinical trial is scheduled to commence in the third quarter of 2008.

### **Study Design**

The study was designed to demonstrate the ability of TPM to deliver lidocaine (5%) to a targeted local site after a single topical application, while restricting systemic exposure. Lidocaine concentrations were measured in the skin at the site of application as well as in the underlying muscle and tissue. The studies were performed in parallel using a leading commercial form of lidocaine, Xylocaine<sup>®</sup> 5%, to assess the relative efficacy of the TPM/Lidocaine formulation.

TPM/Lidocaine or Xylocaine<sup>®</sup> (20µl) were applied to a 2x2 cm<sup>2</sup> area of shaved skin on the thigh of the treatment, or control animals (n=10). Blood samples were taken at 0 (before application), 1, 2, 3, and 5 hours after application. Lidocaine concentrations were measured in the skin at the site of application as well as in the underlying muscle to determine the amount of lidocaine delivered to the local area of application. Plasma lidocaine concentration was quantified to evaluate systemic exposure.

### **Study Results**

Phosphagenics' TPM/Lidocaine increased, by a statistically significant margin ( $p \leq 0.001$ ), the amount of lidocaine delivered to the skin at the site of application as compared to Xylocaine<sup>®</sup> 5%. The lidocaine concentration in skin was approximately 900% higher 5 hours after topical application of TPM/Lidocaine, compared to Xylocaine<sup>®</sup> alone (see table 1).

In addition, TPM/Lidocaine was able to increase the depth of lidocaine penetration. A significant ( $p < 0.001$ ) increase of approximately 500% in lidocaine was detected in the thigh muscle of animals treated with TPM/Lidocaine over Xylocaine<sup>®</sup> alone.

Importantly, the increases in lidocaine delivery to both skin and muscle, did not lead to a significant increase in systemic exposure. The average plasma lidocaine concentration peaked 1 hour after the topical application for both TPM/Lidocaine and Xylocaine®. The differences in plasma concentration were not statistically significant. This is particularly impressive given the magnitude of the differences in the lidocaine concentrations in both skin and muscle.

These results show that TPM has the potential to be used as a targeted, localised delivery system, capable of increased delivery of therapeutic levels of lidocaine, and very likely other products, to targeted areas while minimising exposure to the rest of the body.

**Mean lidocaine levels in tissue and plasma following treatment**

Treatment	Skin (µg)	Thigh (µg)	Plasma Concentration (ng/ml)
Xylocaine® 5%	1.47 ± 0.65	0.11 ± 0.03	54.17 ± 26.22
TPM/Lidocaine 5%	13.46 ± 2.23	0.59 ± 0.10	77.46 ± 38.38

*Table 1*

Dr. Esra Ogru, Executive Vice President of Research and Development at Phosphagenics, said: “We are excited by the prospect of being a global competitor in such a large market, with global sales of topical local anesthetics for the year ended 30 June 2007 reaching US\$ 1.2 billion. Our technology has shown the potential to substantially enhance the current standard of care.”

Harry Rosen, President and CEO at Phosphagenics said; “Commercially, a portfolio of topically delivered products offers a number of advantages compared to transdermal products delivering actives into the bloodstream, including a faster time to market, a relatively easier path to regulatory approval, a cost effective development program, and, most importantly, significant markets and unmet medical needs. These unmet needs include dentistry, as our lidocaine formulation may potentially replace the need to inject patients with lidocaine, as well as possible use as a spray pain reliever for certain types of burns.”

“The results of this study were outstanding and clearly demonstrate the superiority of our formulation over existing products. Our extensive experience with the TPM platform delivery system suggests the strong possibility of obtaining similar results when our product is administered to humans,” Mr. Rosen said.

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## **APPENDIX AND NOTES TO EDITORS**

### **About Lidocaine**

Lidocaine is a widely used local anesthetic and antiarrhythmic drug. It is used topically to relieve itching, burning and pain from skin inflammations, injected as a dental anesthetic, and in minor surgery.

The most commonly encountered lidocaine preparations are marketed by Abraxis Pharmaceutical Products under the brand names Xylocaine® and Xylocard®, and as 'Lanacane' topical ointment in the UK, though lidocaine is also found in many other proprietary preparations. It is available as an ointment, jelly, patch, or aerosol for topical use, as an oral solution, and as an injection for local anesthesia.

### **About Phosphagenics Limited**

Phosphagenics is a Melbourne-based, globally driven biotechnology company focused on the discovery of new and cost effective ways to enhance the bioavailability, activity, safety and delivery of proven pharmaceutical and nutraceutical products.

Phosphagenics' core technology is built around the science and application of phosphorylation, a process where the addition of a phosphate group has been found to enhance the bioavailability, activity and safety of existing pharmaceuticals and nutraceuticals, as well as to assist in the production of drug delivery platforms.

Phosphagenics' shares are listed on the Australian Stock Exchange (POH) and the London Stock Exchange's Alternative Investment Market (PSG). An ADR – Level 1 program was established in the U.S. with The Bank of New York Mellon (PPGNY) for U.S. investors to trade in Phosphagenics' stock on the 'over-the-counter' market. In July 2007, this was upgraded to the International OTCQX, a new premium market tier in the U.S. for international exchange-listed companies, operated by Pink Sheets, LLC.

For more information, please visit Phosphagenics' web site at [www.phosphagenics.com](http://www.phosphagenics.com)

### **Safe Harbor Statement**

This press release contains forward-looking statements based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialise, actual results could vary materially from the Phosphagenics' expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations.

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