15 December 2009

Company Announcement

PHOSPHAGENICS ANNOUNCES RESULTS OF ITS METABOLIC SYNDROME TRIAL

Phosphagenics Limited (Phosphagenics) (ASX: POH; OTCQX: PPGNY) today announced the results of its Phospha-E® clinical trial for the treatment of Metabolic Syndrome.

The human trial focussed on using orally administered Phospha-E® as a treatment for heart disease and diabetes. While not large enough to show statistical significance, the trial did show marked improvement in heart disease and diabetes risk factors - particularly in smokers receiving Phospha-E® treatment.

As the trial did not meet the primary end point, the reduction of hsCRP, Nestlé Nutrition has made the decision not to exercise its option to commercialise Phospha-E®.

Phosphagenics' core TPM™ technology delivering insulin and pain medication, oxycodone, transdermally remains the primary focus of the company, according to CEO, Harry Rosen. "Phospha-E® remains an area of interest to the company, but as has always been the case, the focus of the company remains very much on our key areas of the development and commercialisation of the TPM™ transdermal and topical delivery technology, which has successfully delivered insulin, oxycodone and many other actives into humans in trials conducted by the company," he said.

"Currently oxycodone and insulin can only be administered orally or intravenously, which make the global diabetes and pain markets for a transdermal patch potentially very large. Phosphagenics remains highly focussed on fast tracking both these products to Phase 2/3 clinical trials in 2010 and in getting these products to market."

The study trial results showed that orally administered Phospha-E® was safe and well tolerated in all patients. Phospha-E® administration led to a statistically significant improvement in some heart disease and diabetes risk factors – particularly in smokers.

In contrast to the preclinical trials which were aimed at preventing metabolic syndrome - a collection of disorders that occur together and increase the risk of developing type 2 diabetes, stroke or heart disease – this study specifically addressed the reduction of inflammation associated with these conditions.

Harry Rosen, CEO of Phosphagenics, said that the results from the previous animal studies were significant in the prevention of the disease. "While the human trial also showed some statistically significant reduction in patients already with the condition, the results did not match those achieved in animal studies. The primary endpoint, the reduction of hsCRP, was only observed to be statistically significant in smokers."

"Phosphagenics will continue to develop and commercialise Phospha-E® as a food and supplement product as the results of the clinical trial were sufficiently compelling to warrant this approach. These results are not contrary to the animal studies in which the aim was to demonstrate the prevention of the onset of metabolic syndrome."

Background to the Study

One hundred and seventy-four (174) patients were enrolled for the 12 week double-blinded, randomised, placebo-controlled trial, which was conducted at five sites across Australia. Of the patients enrolled, 144 completed the trial in accordance with the protocols. The trial consisted of four treatment arms: placebo, Vitamin E, Phospha-E® at 200IU and Phospha-E® at 400IU ("400IU"). Blood samples were taken at the 6-week mid-point and at the end of the study, for analysis.

The end-points of the study included safety and tolerability of Phospha-E® in humans, the effects on the important inflammatory biomarker, high sensitive C-reactive protein (hsCRP), and on plasma lipids. The study was not powered to show statistical significance, except when very large differences between treatments were observed. However, a number of trends emerged and unexpectedly, statistical significance was noted in some end points in patients who received the 400IU dose.

Summary of results:

The results of the human trial revealed that orally administered Phospha-E® had a positive effect on smokers, including:

- lowering hsCRP - an important inflammatory biomarker associated with increased risk of heart attack and
- increasing HDL or "good cholesterol".

The results also indicated that Phospha-E® could lower triglycerides with a statistically significant reduction in mean blood triglyceride concentration in subjects taking Phospha-E® when directly compared to patients administered normal Vitamin E. Reducing triglyceride levels is also a key factor correlating in reduction of the risk of stroke.

Detailed results:

Six weeks after administration commenced the following results were obtained in subjects receiving the 400IU dose:

- A statistically significant reduction in mean hsCRP amongst patients who were smokers when compared to smokers who received the placebo treatment (a 16% reduction in hsCRP). Smokers are under more oxidative stress than non-smokers.

- A statistically significant increase in plasma HDL-C or "good cholesterol" when compared to patients receiving the placebo treatment (an 8.6% increase in HDL).

- A statistically significant increase in the large HDL-C sub fraction (HLP) when compared to placebo treatment (an increase of 6.7% in HLP). An increased level of HLP is associated with the reduction of the severity of the onset of coronary heart disease.

- A statistically significant decrease in blood triglyceride concentrations when directly compared to patients receiving the standard Vitamin E treatment (a 5.9% decrease).

Total cholesterol and LDL-C were not changed in any of the treatment arms. Overall, these results indicate there was a statistical and biological improvement in the lipid profile in patients with metabolic syndrome following six weeks of treatment with Phospha-E® at 400IU. The improvement in lipid profile was less pronounced 12 weeks after commencement of treatment, with no statistical significant differences between any of the treatment groups being observed for the main end-points.

ENDS….

APPENDIX AND NOTES TO EDITORS

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 its 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.

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