*ASX Limited*
*Market Announcements Office*

# Phosphagenics Announces Successful Results from its Phase 2 TPM®/Tretinoin Gel Study on Acne Patients

- *TPM®/Tretinoin gel better than Retin-A® in treating inflammatory acne lesions*
- *TPM®/Tretinoin gel produces less erythema and dryness than Retin-A®*
- *TPM®/Vehicle gel shows encouraging anti-acne effects*

**7 October 2014, Melbourne:** Australian drug delivery company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY), today announced results from its Phase 2 study examining the effectiveness of its TPM®/Tretinoin topical gel formulation in the treatment of acne vulgaris. The study demonstrated that the Company's proprietary TPM® technology provides a topical tretinoin formulation with several key advantages in overcoming limitations of the market leading topical formulation for acne, Retin-A®.

This Phase 2 trial was a randomised, active and vehicle controlled, investigator blind study to evaluate the efficacy, safety and tolerability of topically applied tretinoin formulated with TPM® as an anti-acne preparation (containing 0.05% w/w tretinion). The active control formulation was Retin-A® (0.05% w/w tretinoin; Valeant) and the negative control formulation was a vehicle containing TPM® alone. The trial was conducted at three sites across Australia and New Zealand on 53 patients suffering mild to moderate acne vulgaris. The trial examined the reduction in acne lesions (total, inflammatory and non-inflammatory) from baseline and the percentage of subjects with a successful outcome on the Investigator's Global Assessment (IGA) score after 12 weeks of treatment. The IGA is a 5-point scale that differentiates acne by its severity, with success defined as a reduction by two points.

There are two major types of acne lesions: non-inflammatory and inflammatory. Non-inflammatory lesions of acne are the open (blackheads) or closed (whiteheads) comedones. These lesions, especially closed comedones, may be precursors to the larger inflammatory lesions and, therefore, are of clinical importance. Inflammatory lesions are divided into papules, pustules and nodules/nodulocystic lesions, depending on the severity and location of the inflammation within the dermis.

Whilst the trial was not powered for significance, all three formulations (TPM®/Tretinoin, Retin-A® and the TPM® Vehicle) demonstrated a statistically significant ($p$<0.05) mean reduction in total (inflammatory and non-inflammatory) lesion counts over the 12-week treatment period. The TPM®/Tretinoin formulation produced the highest mean reduction in number of acne lesions (-76.6 lesions), followed by Retin-A® (-68.9 lesions) and the TPM® Vehicle (-51.6 lesions). At 12 weeks, the percentage reduction in total lesion counts comparing the TPM®/Tretinoin gel and the TPM® Vehicle gel was statistically significant ($p$<0.05). The difference between Retin-A® and TPM® Vehicle was not statistically significant.

All three formulations displayed a mean reduction in IGA scores over the 12-week period corresponding to an improvement in acne, but there was no significant difference between treatment groups in the number of patients that had a successful outcome on the IGA scale (ie 2 point reduction). However, when assessing the number of subjects that had an improvement in IGA scores, the TPM®/Tretinoin formulation performed better than both Retin-A® and the TPM® Vehicle. Seventy percent (70%) of patients treated with the TPM®/Tretinoin formulation showed a reduction of 1 or 2 points in IGA scores, versus 42% of patients treated with Retin-A® and 46% treated with the TPM® Vehicle gel. The mean percentage reduction in IGA scores was 28.2% (TPM®/Tretinoin), 15.3% (Retin-A®) and 17.9% (TPM® Vehicle). On the IGA scale, the TPM® vehicle was equivalent to the Retin-A® in this study.

The performance of the TPM® Vehicle in this study was extremely interesting. Positive vehicle effects are commonplace in acne reduction studies due to the rigorous cleaning and treatment regime to which patients must adhere. The degree of acne reduction produced by the TPM® Vehicle in this study is, however, greater than typical vehicle effects and may be attributed to the enhanced vitamin E properties of TPM® which has been demonstrated in earlier *in vitro* and *in vivo* studies. Phosphagenics has long known that TPM® has inherent acne reducing properties, with a related product (Vital-ET®) being sold into the personal care space (by Ashland Inc., our global distributor) with data supporting this effect. In the current study, the TPM® Vehicle gel also showed positive effects in reducing inflammatory acne, in line with the data generated on Vital ET®.

Phosphagenics Director, Dr Geert Cauwenbergh, the former head of R&D for skin care and dermatology products at Johnson and Johnson said, “The results of this study are very encouraging considering the relatively small number of patients, and confirm that tretinoin when combined with our TPM® formulation produced directional trends indicative of better performance than Retin-A® against inflammatory lesions in particular. This seems to be a result of our TPM® technology which is corroborated by effects seen in the vehicle formulation containing TPM®. As a result of these findings, the Company will continue development of TPM®/Tretinoin for the prescription market in addition to assessment of a topical formulation containing TPM® as an over-the-counter product”.

In addition to the effects on acne reduction, the study monitored erythema and dryness, common adverse effects of tretinoin treatment that can limit patient compliance. In this study, after two weeks of treatment with Retin-A®, the number of patients suffering erythema and dryness was significantly increased ($p<0.05$) and remained above baseline measures for 8-12 weeks of treatment. Treatment with TPM®/Tretinoin over the same period produced only a minor increase (not significant) in the number of patients with erythema and no increase in the number of patients reporting dryness. The small number of patients precludes a statistically significant difference between the formulations, but the results clearly support previous findings that the TPM® imparts a protective effect on the skin.

Harry Rosen, CEO of Phosphagenics, said, “These results will be of significant interest to companies who have been in discussion with us about the potential of TPM® in the delivery of dermatological products.”

The global market for products to treat acne is around US$3.5 billion per annum of which retinoids represent around $500 million per annum in the prescription market.

**ENDS**

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## About Phosphagenics

Phosphagenics Limited is a drug delivery company that is commercialising various products within the pharmaceutical, cosmetics and animal health sectors, using its proprietary drug delivery system called TPM® (Targeted Penetration Matrix). TPM® is a patient friendly and cost effective system, based on Vitamin E, that enhances the topical or transdermal delivery of active molecules. The lead products advancing through clinical trials are oxymorphone and oxycodone patches for the relief of chronic pain.

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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