



## ASX AND MEDIA RELEASE

### Further positive results of phase IIa AK trial

**BRISBANE, Australia, 9 May 2006: Peplin Limited** (ASX:PEP) today announced a 70% complete clearance rate in its US phase IIa dose escalation clinical trial of its proprietary drug PEP005 Topical in actinic (or solar) keratosis (AK) a skin lesion which can progress into skin cancer.

The preliminary result of this study (PEP005-004) was announced in February 2006 in which the maximum tolerated dose (MTD) was established at 0.05%. Subjects were then followed for four weeks (or until all local skin responses had resolved) post treatment. In the 10 patients who were treated at the MTD, two applications of PEP005 Topical (0.05%) gel on two consecutive days completely cleared 70% of AK lesions.

Managing Director & CEO Michael Aldridge said these positive results were further confirmation of the ability of PEP005 Topical to clear actinic keratosis lesions following just two treatments, and indicate that a well tolerated dose is also effective.

"The primary goal of the trial was to establish the maximum tolerated dose for PEP005 Topical in treating an area of skin. We announced that in February 2006.

"Today's announcement is very pleasing because it correlates closely with the clearance rates we have seen in previous studies. Interestingly we saw the clearance rates in this study just four to six weeks after treatment. That is very rapid," Mr Aldridge said.

AKs are the most common pre-cancerous skin lesions worldwide and the treatment of AK is the most common dermatologic procedure performed in an out-patient setting. Based on a 2005 study by The Lewin Group, Inc. in the US there were 8.2 million treatments of AK in 2004 and 58 million Americans have AK.

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**The following additional information is provided in accordance with the Code of Best Practice for Reporting by Life Science Companies.**

**Trial PEP005-004**

The AK dose escalation clinical trial was an open-label, dose escalation, cohort study to determine the maximum tolerated dose (MTD) of PEP005 Topical gel, administered once daily for two consecutive days to patients with AK with a four week follow-up period or until all local skin responses had resolved. A secondary goal was to determine the clearance rate of AKs at the final follow-up. This clinical trial treated 22 patients at a single centre in the US and was conducted under Peplin's open IND application with FDA.

The dose limit was determined by the investigator on the occurrence of severe (on a mild, moderate, severe scale) local skin reactions either prior to treatment on day 2 (following treatment on day 1) or on day 8 (following treatment on days 1 and 2).

Each cohort comprised three patients and a total of 10 patients were treated at the MTD to confirm the MTD and to characterise the safety profile. All patients completed the full course of therapy and there were no drop-outs.

Ten patients were treated at 0.05% PEP005 Topical and no severe side effects were observed. This established the MTD for PEP005 Topical gel, administered once daily for two consecutive days to an area of skin containing AK. In addition, blood samples were taken and confirmed no absorption of PEP005 into the blood stream.

A clinical assessment of lesion clearance in the treatment area was made at the final follow-up visit. Of the patients treated at the 0.05% concentration, 70% cleared the AK lesion.

The results of this study in conjunction with its Australian phase IIa study support the view that PEP005 Topical at 0.05% concentration has a favourable side effect profile and is effective in clearing AK lesions when applied to an area of skin containing AK.

## **ABOUT PEPLIN**

Peplin is focused on the development and commercialisation of prescription human therapeutic products for the treatment of cancer. Its lead compound is PEP005, the first in a new class of investigational agents. Peplin's lead product is PEP005 Topical, which is being studied in clinical trials for the treatment of actinic keratosis (AK) (a pre-cancerous lesion) and non-melanoma skin cancer (NMSC). PEP005 Topical works by a powerful mode of action, directly killing most cancer cells and then recruiting and activating the local immune system to clean-up these dead cancer cells and kill any remaining cancer cells. PEP005 Topical is potentially a rapidly acting and cosmetically attractive non-surgical topical treatment for AK and NMSC. Peplin's product development activities are supported by the Australian Federal Government under its Pharmaceuticals Partnerships Program.

Peplin's earlier stage pipeline is targeted at leukemia (a blood borne cancer) using its lead compound PEP005 in an intravenous formulation (PEP005 IV) and bladder cancer using an intra-cavitary or intravesical formulation (PEP005 IC). PEP005 has demonstrated selective and potent anti-leukemia activity in pre-clinical disease models. PEP005 induces apoptosis in leukemia cells via the activation of PKC delta. Peplin holds global proprietary rights for PEP005 Topical and other oncology applications of PEP005. Its research portfolio of EPUFA compounds opens additional potential opportunities in cancer and pain.

## **ABOUT ACTINIC KERATOSIS**

AK is a common skin condition characterised by rough, red, scaly patches, crusts or sores on the top layer of skin. If left untreated AKs can progress to squamous cell carcinoma, an invasive skin cancer that can be fatal. AKs usually develop on the face, lips, ears, scalp, neck, forearms and back of hands - areas that are most commonly exposed to the sun.

AKs are the most common pre-cancerous skin lesions worldwide affecting 50% of Caucasians over the age of 40 years with the average patient having 6-8 lesions. The treatment of AKs is the most common dermatologic procedure performed in the out-patient setting. Based on a 2005 study by The Lewin Group, Inc. for The Society for Investigative Dermatology and The American Academy of Dermatology Association, in the US there were 8.2 million treatments of AK in 2004. According to this study 58 million Americans have AK. The worldwide prevalence of AK is highest in Australia.

Current treatment alternatives comprise surgical techniques (primarily cryotherapy) and topical medications (e.g. 5-fluorouracil, imiquimod and diclofenac). Current treatment approaches can cause scarring and hypopigmentation at the treatment site, can be inconvenient or may require long treatment duration for effect.