

ASX AND MEDIA RELEASE

Peplin progresses PEP005 Topical development

- **Completes enrolment in phase IIa AK clinical trial**
- **Announces plans for a US-based phase IIa clinical trial**

BRISBANE, Australia, 30 June 2005: Peplin Limited (ASX:PEP) today announced it had completed patient enrolment in its Australian phase IIa clinical trial of its proprietary product PEP005 Topical for actinic keratosis (AK). In addition Peplin announced plans to conduct a US based phase IIa clinical trial to study escalating doses of PEP005 Topical on an area of skin with AK.

Peplin Managing Director and CEO Michael Aldridge said completing patient enrolment late yesterday for the Australian phase IIa clinical trial and announcing plans for the US dose escalation study were major advances in the development of PEP005 Topical.

“Sixty patients, each with five AKs, complete treatment, follow-up and exit visits over a three month period at clinical centres in major metropolitan cities around Australia. We expect to announce the results of this Australian phase IIa AK trial in the fourth quarter of 2005,” said Mr Aldridge.

Mr Aldridge said Peplin’s current program of three Australian phase IIa clinical trials was running well within budget and ongoing progress of its two basal cell carcinoma trials was on schedule to report results in the first quarter of 2006.

“We intend to fund the planned US clinical trial from cash on hand and within the original budget for our program of phase IIa clinical trials. Our cash balance at 30 June 2005 is approximately \$9.2 million,” he said.

The planned US phase IIa clinical trial is an open label study of the safety and efficacy of escalating concentrations of PEP005 Topical when applied on two consecutive days to a large area of skin incorporating an AK lesion. This trial would recruit up to 30 patients at a single centre in the US and be conducted under Peplin’s open IND application with FDA.

The clinical trial is designed to evaluate both treatment area skin responses and the effect of the drug on AK lesions. A primary outcome will be to establish a maximum tolerated dose when treating an area of skin. Peplin expects to initiate the clinical trial in August 2005.

Mr Aldridge said the US trial would seek to maximise the market opportunity for PEP005 Topical in the treatment of AK and was a critical component of planning for more advanced clinical studies to start in the first half of 2006.

“We are comfortable with the safety profile of our drug for AK to now evaluate alternative treatment formats. The ability to use PEP005 Topical to treat multiple AK lesions over an area of skin would address challenges dermatologists face treating this disease,” he said.

Consultant dermatologist and Peplin’s coordinating investigator in its Australian clinical trials Dr Greg Siller said AKs were generally treated using two quite different approaches.

“Cryotherapy and other ablation techniques work quickly and are primarily used to treat a discrete AK lesion, while longer courses of treatment with various pharmaceutical products, which are mainly creams, are prescribed for the treatment of sun damaged skin with multiple or contiguous AK lesions,” he said.

Mr Aldridge said he believed there was a highly attractive and significant market opportunity for a product which could rapidly, conveniently and simultaneously treat both a discrete lesion and an area of sun damaged skin.

“Our current Australian phase IIa AK clinical trial is designed to study PEP005 Topical’s ability to treat a discrete lesion; this US clinical trial would evaluate the drug’s effect on an area of AK affected skin. We believe PEP005 Topical is a unique product with the potential to be a rapidly acting and cosmetically attractive non-surgical treatment for AK and non-melanoma skin cancer,” he said.

Peplin’s previously reported 16 patient US phase I clinical trial in patients with AK demonstrated a favourable safety profile for PEP005 Topical. It also indicated the ability of PEP005 Topical to have a clinically relevant impact on AK lesions within 21 days of a single treatment.

AKs are the most common pre-cancerous skin lesions worldwide and the treatment of AKs is the most common dermatologic procedure performed in the out-patient setting.

Based on a 2001 study, in the US each year there are 3.7 million office visits and about 5.2 million procedures for AK. According to the American Academy of Dermatology AK affects more than 10 million Americans. The worldwide prevalence of AK is highest in Australia.

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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 phase IIa clinical trials for the treatment of actinic keratosis (a pre-cancerous lesion) and non-melanoma skin cancer. 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 treatment for actinic keratosis and non-melanoma skin cancer. 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 particularly in cancer and pain.

Market opportunity

Actinic keratoses are the most common pre-cancerous skin lesions and typically occur on sun damaged skin of Caucasians older than 40 years. Non-melanoma skin cancer is the most common form of cancer worldwide. Peplin is developing PEP005 Topical to address the highly attractive and significant global market opportunity for non-surgical approaches to the treatment of actinic keratosis and non-melanoma skin cancer.