

ASX AND MEDIA RELEASE

Start of US dose escalation clinical trial

BRISBANE, Australia, 1 September 2005: Peplin Limited (ASX:PEP) announced it had initiated its US-based phase IIa clinical trial to study increasing doses of its proprietary product PEP005 Topical on an area of skin with actinic keratosis (AK) – a skin lesion which can lead to skin cancer and which affects more people per capita in Australia than anywhere else in the world.

Peplin Managing Director and CEO Michael Aldridge said the US trial would seek to expand the market opportunity for PEP005 Topical in the treatment of AK and is a key component in both the development of the product profile for PEP005 Topical and planning for more advanced clinical trials expected to start in the first half of 2006.

“Our current Australian 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 impact on AK affected areas of skin,” Mr Aldridge said.

“We believe there is a significant market opportunity for a product which is a rapidly acting and cosmetically attractive non-surgical treatment and applicable to both a discrete AK lesion and an area of sun damaged skin with AK. Such a product would address particular challenges dermatologists face treating this disease,” he said.

“AKs are generally treated using two quite different approaches. Cryotherapy and other ablation techniques work quickly but are generally only used to treat discrete AK lesions and are sometimes painful and have the potential for a poor cosmetic outcome. In the case of sun damaged skin with multiple or contiguous AK lesions, multi-week courses of prescription pharmaceutical products, mainly creams, are the typical form of treatment,” Mr Aldridge said.

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

The following additional information is provided in accordance with the draft ASX and AusBiotech Code of Best Practice for Reporting by Biotechnology, Medical Device and other Life Science Companies.

The clinical trial is 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. This clinical trial will recruit between 13 and 34 patients at a single centre in the US and be conducted under Peplin’s open IND application with the US Food and Drug Administration (FDA).

The initial dose level is 0.01% PEP005 Topical, the same concentration that was administered (as a single application) in Peplin’s phase I clinical trial. The dose limit will be 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

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on days 1 and 2). The most common local skin reaction reported in Peplin's US phase I clinical trial was localised erythema (redness and irritation) and all local skin reactions were reported as mild.

Each cohort comprises three patients and a total of 10 patients will be treated at the MTD to confirm the MTD and to characterise the safety profile. The dose is escalated when no dose limiting toxicity is observed in all three patients. If dose limiting toxicity is seen in one patient of three a further three are enrolled into that cohort; the dose is escalated if only one patient of six exhibits dose limiting toxicity. The dose limit is reached when either two out of three or two out of six patients exhibit dose limiting toxicity.

The trial will enrol male or female patients at least 18 years of age with an AK lesion selected for treatment on the shoulders, chest, back or arms and will exclude females of child bearing potential.

Secondary objectives of the clinical trial are to evaluate the clinical efficacy of PEP005 Topical gel in clearing AK lesions and to assess any systemic absorption of PEP005 Topical gel at the MTD.

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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 (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 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 intracavitary 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.

Market opportunity

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. AKs typically occur on sun damaged skin of Caucasians older than 40 years.

NMSC 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 AK and NMSC.