

ASX RELEASE

Details of phase IIb actinic keratosis trial

BRISBANE, Australia, 1 August 2006: Peplin Limited (ASX:PEP) announced today details of PEP005-006, its multi-centre, 200 patient phase IIb clinical trial in the United States to evaluate the safety and efficacy of PEP005 Topical, its proprietary product candidate for the treatment actinic (solar) keratosis (AK).

The clinical trial, which will be conducted in the US under Peplin's open IND with FDA, will seek to establish the safety and efficacy of PEP005 Topical gel as a patient-applied, take-home prescription medication and build on the positive results demonstrated in Peplin's earlier AK studies, in larger patient cohorts.

Details of the clinical trial are set out below

The clinical trial (PEP005-006) is a multi-centre, randomised, double-blind, double-dummy, vehicle-controlled study to determine the safety and efficacy of PEP005 Topical gel in patients with actinic keratosis lesions.

Treatment with PEP005 Topical at 0.025%, 0.05% or vehicle gel will be on either two or three consecutive days. Drug will be applied to a 25 cm² contiguous area containing 4 to 8 typical AK lesions on the arm, shoulder, chest, back or scalp.

The primary study objectives are to:

1. evaluate the safety and tolerability of PEP005 Topical; and
2. to evaluate the efficacy of PEP005 Topical

There is one primary and two secondary measures of efficacy:

- **Primary:** *complete AK lesion clearance rate* defined as the proportion of patients at the day 57 post treatment visit with no clinically visible AK lesions in the treatment area
- **Secondary:** *baseline AK lesion clearance rate* defined as the proportion of patients at the day 57 post treatment visit with 100% reduction in the number of AK lesions identified at baseline in the treatment area
- **Secondary:** *partial clearance rate* defined as the proportion of patients at the day 57 post treatment visit with a 75% or greater reduction in the number of AK lesions identified at baseline in the treatment area

The study will be run at approximately 20 clinical centres and enrol approximately 200 patients.

Further information:

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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 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 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.

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.