

ASX AND MEDIA RELEASE

Peplin starts phase II clinical trials

BRISBANE, Australia, 16 March 2005: Peplin Limited (ASX:PEP) announced today that it had commenced its program of three phase IIa clinical trials of its proprietary topical product PEP005 Topical for the treatment of actinic keratosis or sun spots (AK) and non-melanoma skin cancer (NMSC).

These phase IIa clinical trials will comprise three separate studies, which are designed to evaluate the ability of PEP005 Topical to treat three diseases — AK and superficial and nodular forms of basal cell carcinoma, the most common form of NMSC.

Peplin's Managing Director and CEO Michael Aldridge said the trials were a world first, with leading dermatologists in major metropolitan centres around Australia using an Australian discovered and developed non-surgical, topical treatment for skin cancer.

"It is very exciting to have started these clinical trials for Peplin's skin cancer product in Australia," he said.

"Given the high profile and prevalence of the disease in this country — where it affects more people per capita than anywhere else in the world — we are expecting relatively rapid recruitment and enrolment of patients and a high level of interest in the trials.

"We plan to announce the results of the first of the three trials early in the fourth quarter of 2005."

Mr Aldridge said Peplin expected the phase IIa trials to build on the positive results of last year's phase I AK clinical trial.

"The phase I trial demonstrated the safety of the drug, with all local skin responses mild and as expected. In that trial patients received a single, low dose of the drug, but even with such a low dose the results showed unexpectedly positive indications of rapid lesion clearance. The current trials are now testing various concentrations of the drug and repeat dosing," he said.

“The trials are a key component of Peplin’s PEP005 Topical global product development program. While these studies are being conducted in Australia, future trials would include dermatologists practising in the US and Europe.

“Our committed and talented group of Australian dermatologists are excited by the potential of this rapidly acting non-surgical approach to the treatment of actinic keratosis and non-melanoma skin cancer.”

Peplin’s Director, Drug Development Dr Peter Welburn said the three phase IIa clinical trials would enrol 180 patients and evaluate three different concentrations of the drug and two treatment regimens of two days. Patients would undergo follow-up for three months.

“Based on our extensive studies of PEP005 in animal models, the pilot clinical trial we conducted at the Mater Hospital in Brisbane some years ago, and the results of last year’s phase I trial; we are confident that the phase IIa development program will confirm PEP005 Topical is a new and highly attractive topical therapy for actinic keratosis and non-melanoma skin cancer,” Dr Welburn said.

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ABOUT PEPLIN

Peplin is focused on the development and commercialisation of prescription human therapeutic products for the treatment of cancer.

Peplin’s lead product is PEP005 Topical which is presently in phase II clinical trials. Peplin is developing PEP005 Topical for the treatment of actinic keratosis and non-melanoma skin cancer. Peplin’s lead product is supported by the Australian Federal Government under its R&D Start program.

Peplin’s earlier stage pipeline is targeted at bladder cancer using PEP005 in an intra-cavitary or intravesical formulation (PEP005 IC) and leukaemia (a blood borne cancer) using an intravenous formulation (PEP005 IV). Peplin holds global proprietary rights for PEP005 Topical and all rights worldwide to other oncology applications of PEP005. Its research portfolio of EPUFA compounds opens additional potential opportunities in cancer and adds candidates for cardiovascular disease, pain, inflammation and diabetic complications.

Market opportunity

Actinic keratosis is the most common pre-cancerous skin lesion; actinic keratosis lesions typically occur on sun damaged skin of older Caucasians. Non-melanoma skin cancer is the most common form of cancer worldwide. Peplin is developing PEP005 Topical to address the highly attractive and significant market opportunity for a non-surgical approach to the treatment of actinic keratosis and non-melanoma skin cancer.

APPENDIX

In accordance with ASX and AusBiotech's Draft Code of Best Practice on Reporting for Biotechnology, Medical Device and other Life Sciences Companies Peplin provides the following information.

Background

PEP005 is Peplin's lead compound and chemically is described as an angeloyl substituted ingenane. PEP005 is a well characterised, single molecular entity isolated and purified from a rapidly growing and common non-indigenous plant. It is not a botanical for regulatory purposes and represents the first of a new class of drug in clinical development. PEP005 Topical is a topical formulation of PEP005 which Peplin is developing under investigational new drug applications (INDs) filed with the US Food and Drug Administration (FDA) for the treatment of actinic keratosis (AK) and the most common form of non-melanoma skin cancer (NMSC), basal cell carcinoma (BCC).

Peplin's proprietary rights to PEP005 and other related compounds for the treatment of skin cancer (and other forms of cancer) are by virtue of patents granted in Australia, Singapore and the US and filed and under prosecution in other countries and regions. Peplin owns worldwide rights to PEP005's therapeutic applications protected by these patents.

In June 2004 INDs were filed with the FDA and in August 2004 a phase I clinical study was initiated to evaluate the topical treatment of AK using PEP005 Topical. This trial completed successfully and the final results have been reported and are available at www.peplin.com.

Phase IIa clinical trials

The three PEP005 Topical phase IIa clinical trials are each multi-centre, randomised, double-blind, parallel-group, vehicle-controlled studies to determine the safety of PEP005 0.0025%, 0.01% and 0.05% gel in two alternative treatment regimens: day 1 and day 2 or day 1 and day 8 applications to either:

1. actinic keratosis
2. superficial basal cell carcinoma; or
3. nodular basal cell carcinoma

The primary objective in each study is to determine the safety of PEP005 0.0025%, 0.01% and 0.05% gel administered according to the two treatment schedules.

The secondary objectives of each study comprise:

- to evaluate the efficacy of PEP005 0.0025%, 0.01% and 0.05% gel administered according to two treatment regimens, day 1 and day 2 or day 1 and day 8 applications;
- to determine a recommended treatment regimen; and
- to evaluate patients for cosmetic outcome

Study subjects will all be male or female patients at least 18 years of age with:

1. in the actinic keratosis trial: at least 5 AK lesions on the arm, shoulder, chest, face or scalp with one AK lesion confirmed by small punch biopsy;
2. in the superficial basal cell carcinoma trial: a histologically confirmed sBCC tumour on the arm, shoulder, chest, face or scalp suitable for surgical excision; or
3. in the nodular basal cell carcinoma trial: histologically confirmed nBCC tumour on the arm, shoulder, chest, face or scalp suitable for surgical excision.

The studies will all exclude women of child bearing age.

Each study will enrol 60 patients. Subjects will be randomised on a 1 to 1 ratio to arm A or arm B. Arm A of each study will enrol 30 subjects who will receive treatment on day 1 and day 2. Arm B of each study will enrol 30 subjects who will receive treatment on day 1 and day 8. Subjects will be randomised to receive one of the three active treatments or vehicle gel, with patients receiving active or vehicle in the ratio of 4 to 1.

The studies will be conducted by consulting dermatologists located in Brisbane, Gold Coast, Sydney, Melbourne and Perth. The duration of the trials will depend on the rate of recruitment. Peplin expects the actinic keratosis trial to report early in Q4 2005 and the superficial and nodular basal cell carcinoma trials to report in Q1 2006.