



ASX RELEASE

Positive results of phase IIa AK trial

EMERYVILLE, California and BRISBANE, Australia 12 December 2007: Peplin, Inc. (ASX:PLI) today announced positive preliminary results of PEP005-007, its Australian and New Zealand based phase IIa actinic (solar) keratosis (AK) clinical trial. This trial is the first in which PEP005 Topical for AK, Peplin's patient-applied topical gel, has been tested as a field-directed investigational therapy on the face or face and scalp treatment areas. AKs are common pre-cancerous skin lesions, caused by sun exposure, a portion of which develop into skin cancer.

PEP005-007 is an open-label, multi-center clinical trial designed to determine the optimal tolerated treatment regime and evaluate the safety and efficacy of PEP005 Topical for AK when applied to a 25 square centimeter area of skin on either the face or the face and scalp for the treatment of AK.

The clinical trial evaluated formulation strengths from 0.0025% to 0.025% (respectively, 1/10th of and equal to the lowest formulation strength studied in PEP005-006, Peplin's clinical trial that evaluated the treatment of AK on non-facial sites) at two and three consecutive day dosing regimes.

The trial established the maximum tolerated dose (MTD) at 0.025% PEP005 Topical for AK applied daily for two consecutive days as a field directed therapy to the face or face and scalp sites.

The drug suggested a favorable safety profile and for all doses studied at and below the MTD was well tolerated. Side effects were consistent with Peplin's earlier clinical trials and comprised primarily transient local skin responses at the treatment site. There were no drug related serious adverse events reported.

In addition, a two or three day course of PEP005 Topical for AK demonstrated complete and partial clearance of AK lesions in some patients tested at each formulation strength, with the exception of the lowest formulation strength which demonstrated partial clearance in some patients and no patients with complete clearance.

Based upon an evaluation of the local toleration profiles and complete and partial clearance rates demonstrated in this clinical trial, Peplin believes it has identified a range of doses, likely to be between 0.005% and 0.025% PEP005 Topical for AK applied daily

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for two consecutive days, for further development in treatment of AK on the face or face and scalp.

Finally, patient assessments in one of the treatment groups (those patients who were scheduled to receive three days of dosing) of convenience and ease of use, healing time, cosmetic outcome, satisfaction compared to prior AK treatment and overall patient satisfaction with PEP005 Topical for AK were, on average, positive to very positive.

Peplin CEO Michael Aldridge said this trial delivered valuable information about the activity of Peplin's drug on AK sites on the face and face and scalp.

"In particular we are pleased to have identified a range of doses which when applied to the face and face and scalp for two days are well tolerated and, which we believe may have the potential to provide clinically relevant complete AK clearance rates. We believe this information will be useful as we prepare to meet FDA to discuss plans for our clinical program through to NDA."

Sydney dermatologist Dr Robert Rosen, who served as the trial's lead investigator said the study supported the further development of the drug for treating AK on the face.

"AK is a skin condition associated with sun exposure and sun damage. Accordingly, the face is an important treatment site in the goal of reducing the potential for the development of skin cancer. These results, in conjunction with Peplin's earlier clinical trial on non-facial sites, point to a product which may, with further development, provide an attractive, patient friendly and convenient treatment alternative for treating AKs on both the body or face."

Peplin intends to discuss the results of this trial with the FDA, together with results of its previously completed PEP005-006 non-facial AK clinical trial, pre-clinical, manufacturing and other data. Peplin also intends to present plans for a clinical program and other studies required to support a new drug application (NDA) for PEP005 Topical for AK. Peplin anticipates initiating the first clinical study in this program in the first quarter of 2008.

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Details of the PEP005-007 clinical trial are provided below

The clinical trial (PEP005-007) is a multi-center, open label, cohort study designed to determine the optimal tolerated regime and safety of PEP005 Topical for AK when applied to a 25 cm² contiguous AK treatment area on the face or face and scalp.

Treatment with PEP005 Topical for AK was evaluated at formulation strengths from a concentration of 0.0025% to 0.025% administered daily for two or three consecutive days. Medication was applied to a 25 cm² contiguous area of skin containing 4 to 8 AK lesions on the face or face and scalp.

The study's primary objective was to determine the optimal tolerated regime of PEP005 Topical for AK, when administered as either two day or three day application schedules (Day 1 and Day 2 or Day 1, Day 2 and Day 3), to a 25 cm² contiguous AK treatment area on the face or face and scalp.

The study's secondary objective was to evaluate efficacy as

- complete clearance rate (CCR) of AK lesions at Day 57
- partial clearance rate (PCR) of AK lesions at Day 57
- baseline clearance rate (100%CR) of AK lesions at Day 57

Complete AK lesion clearance rate (CCR) defined as the proportion of patients who, on the 57th day post treatment, manifested no clinically visible AK lesions in the treatment area, whether they existed at the baseline measurement or emerged during the study period.

Partial clearance rate (PCR) is defined as the proportion of patients who, on the 57th day post-treatment, manifested 75% or greater reduction in the number of AK lesions identified at baseline in the treatment area. Lesions that are not present at the baseline measurement but that emerge during the course of treatment do not affect this measurement.

Baseline AK lesion clearance rate (100% CR) defined as the proportion of patients who, on the 57th day post treatment, manifested 100% reduction in the number of AK lesions identified at baseline in the treatment area. Lesions that are not present at the baseline measurement but that emerge during the course of treatment do not affect this measurement.

Description of trial subjects

A total of 94 patients were screened into the study, with 88 patients meeting the eligibility criteria and subsequently scheduled for treatment with PEP005 Topical for AK. 86 patients completed the study.

All patients enrolled in this study were Caucasian. The age of patients ranged from 42 years to 89 years. The majority of patients (73%) were male and most had Fitzpatrick-Pathak skin types 1 or 2 (burn easily and tan rarely or minimally).

The mean number of lesions in the treatment area was 5.9 (range 4-8). 78% of lesions were on the face and 22% on the face and scalp.

Treatment method

Study drug from single use mini-tubes was applied by the patient to the defined 25 cm² treatment area once daily for up to three consecutive days.

The PEP005-007 clinical trial evolved through an initial design and two subsequent amendments during the course of the study. The clinical trial was initially structured as a dose escalation study with the first dose at 0.025% PEP005 Topical for AK for 3 consecutive days. Based on a Dose Escalation Steering Committee (DESC) review of local skin responses seen in the initial cohorts, the DESC set this first formulation strength dosed for three days as the Dose Limiting Toxicity (DLT) and established the Maximum Tolerated Dose (MTD) as this same formulation strength when dosed for two days. To explore a range of activity below the MTD, an additional two lower formulation strengths (in both 2 and 3 day consecutive day dosing) were added in a first amendment together with an expansion cohort to confirm the MTD. Subsequent to this and to further explore toleration, a second amendment, dosing at three further lower formulation strengths down to 0.0025% PEP005 Topical for AK for up to 3 days, was incorporated.

Preliminary results

Maximum tolerated dose: The trial established the maximum tolerated dose (MTD) at 0.025% PEP005 Topical for AK applied daily for two consecutive days as a field directed therapy to the face or face and scalp. Based on an assessment of local skin responses, the dose limiting toxicity (DLT) was established at 0.025% PEP005 Topical for AK applied daily for three consecutive days.

Safety: The drug suggested a favourable safety profile and all dosages at and below the MTD were well tolerated by patients. There were no reports of serious adverse events (SAEs) related to study medication. The most common side effects were localised skin responses including

erythema (redness), flaking or scaling, crusting, vesicles and swelling in the treatment area. Prior to treatment and at each of the assessment dates, investigators evaluated each of the LSRs on a scale designed to measure the intensity of the LSR. The scores for each LSR were added to create a composite LSR score for each patient. The average composite LSR score increased significantly on days 2 and 3 from the pre-treatment score, but had generally declined to approximately the pre-treatment score by day 29. There was no requirement for any medical intervention to manage local skin responses. On a global severity rating scale of none, mild, moderate and severe the majority of scores were graded as either mild or moderate in all treatment groups.

Efficacy: Given the small number of patients in each treatment group, the trial was not designed to generate meaningful efficacy data and a clear dose response was not apparent from any of the three efficacy measures. Complete clearance rates ranged from 38% to 100% in the various dosage groups (excluding the lowest which had 0%) and partial clearance rates ranged from 63% to 100% in the various dosage groups (excluding the lowest which had 25%).

Subjective assessments: The study collected a subjective impression of treatment as reported by patients (although only for patients in Analysis Group 2 who were scheduled to receive three days dosing). Questions were answered using a 7-point scale where a score of 1 is very negative and a score of 7 is very positive. On this scale 4 is a neutral impression. The questions related to overall level of satisfaction, healing time, cosmetic outcome, ease of use and comparison with prior treatment. The mean and median overall level of satisfaction reported is presented below.

Patient assessments of PEP005 Topical for AK (Analysis Group 2)						
Concentration of active	0.0025%	0.0050%	0.0075%	0.0100%	0.0125%	0.0175%
	N=8	N=8	N=8	N=11	N=10	N=6
Overall level of satisfaction						
Mean	6.4	6.5	6.8	6.9	6.6	6.5
Median	7.0	7.0	7.0	7.0	7.0	7.0

All questions were answered using a 7-point scale where 1=very negative, 4=neither negative nor positive and 7=very positive

Implications

Peplin believes the PEP005-007 study has identified a range of doses which are well tolerated and demonstrate lesion clearance. Based upon an evaluation of the local toleration profiles and complete and partial clearance rates Peplin believes it has identified a range of doses, likely to be between 0.005% and 0.025% PEP005 Topical for AK applied daily for two consecutive days for further development in the treatment of AK on the face or face and scalp.

Peplin intends to discuss the results of this study with the FDA, together with results of its PEP005-006 non-facial AK clinical trial, pre-clinical, manufacturing and other data. Peplin also intends to present plans for a clinical program and other studies required to support a new drug application (NDA) of PEP005 Topical for AK. Peplin anticipates initiating the first clinical study of this program in the first quarter of 2008.

ABOUT ACTINIC KERATOSIS

AK is generally considered the most common pre-cancerous skin condition. AK usually appears as small, rough, scaly areas on the face, lips, ears, back of hands, forearms, scalp or neck. If left untreated, AK lesions may progress to a form of skin cancer called squamous cell carcinoma, or SCC. The Lewin Group, Inc., estimates that the total direct costs for AK in the United States was \$1.2 billion in 2004, and in 2002 there were approximately 8.2 million office visits for the treatment of AK with a cost to the U.S. healthcare system of approximately \$1.2 billion. The Lewin Group also estimated that there were 58 million people in the United States living with AK in 2004. According to a May 2006 issue of *The Journal of Family Practice*, in northern hemisphere populations, 11% to 25% of adults have at least one AK lesion, compared with 40% to 60% of adults in Australia, which has the highest prevalence of AK worldwide.

ABOUT PEPLIN

Peplin is a development stage specialty pharmaceutical company focused on advancing and commercializing innovative medical dermatology products. Peplin is currently developing PEP005, which is the first in a new class of compounds and which is derived from the sap of *Euphorbia peplus*, or *E. peplus*, a rapidly growing, readily-available plant commonly referred to as petty spurge or radium weed. *E. peplus* has a long history of traditional use for a variety of conditions, including the topical self-treatment of various skin disorders, including skin cancer and pre-cancerous skin lesions. Peplin's lead product candidate is a patient-applied topical gel containing PEP005, a compound the use of which Peplin has patented for the treatment of actinic keratosis, or AK. This product candidate is currently in Phase II clinical trials and is referred to as PEP005 Topical for AK.

FORWARD LOOKING STATEMENTS

This press release contains "forward-looking statements" as defined under U.S. federal securities laws, including, but not limited to, the expected timing for Peplin's future clinical development program and other clinical trials. These forward-looking statements can be identified through the use of words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "may," "will," and variations of these words or similar expressions. Forward-looking statements are based on management's current, preliminary expectations and actual results could differ materially as a result of various risks and uncertainties, including, but not limited to, delays in the completion of clinical trials resulting from ambiguous or negative interim results, unforeseen safety issues, failure to conduct the clinical trials in accordance with regulatory requirements or clinical protocols, suspension or termination of a clinical trial by the FDA or other regulatory authorities, lack of adequate funding to continue a clinical trial and other important factors disclosed from time to time in Peplin's disclosures to the ASX. Forward-looking statements speak only as of the date they were made. No undue reliance should be placed on any forward-looking statements. Such information is subject to change, and we undertake no obligation to update such statements.