



ASX AND MEDIA RELEASE

Positive Results for Peplin's First Phase III AK Trial

- Met primary and secondary efficacy endpoints with statistically significant clearance of AK lesions vs. vehicle
- First topical treatment to demonstrate statistically significant benefit over vehicle across non-head anatomical locations, including back of hand
- Median reduction in overall lesion count of 66.7%

EMERYVILLE, California and BRISBANE, Australia, 17 May 2009 Peplin, Inc. (ASX:PLI) today announced positive results for PEP005 (ingenol mebutate) Gel in REGION-I, its Australian and US based Phase III actinic (solar) keratosis (AK) clinical trial for the treatment of lesions on non-head locations, which include the trunk and extremities. AK is a common pre-cancerous skin condition caused by sun exposure, which can develop into skin cancers if left untreated.

Peplin's Chief Executive Officer, Tom Wiggins, is pleased with the positive results and said: "Once again, our team has done an excellent job of obtaining great clinical results while completing our first Phase III trial within the expected timeframe."

He continues "These strong results achieve an important step towards commercialisation. In addition, they confirm efficacy signals with prior trials and market need, since no currently marketed product has proven efficacy for this range of locations for non-head lesions, especially with a 2-day course of therapy. PEP005 Gel continues to provide patients the potential for a compelling alternative".

REGION-I tested a 0.05% concentration of PEP005 Gel applied once a day for only two consecutive days. This resulted in a median reduction in the number of AK lesions of 66.7% (p-value<0.0001), a total clearance rate across all anatomical non-head sites, including the extremely difficult-to-treat back of hand and arm locations, equal to 27.4% (p-value<0.0001) and a partial clearance rate of 44.4% (p-value <0.0001). In addition, statistical significance was established in back of hand, arm and chest locations. These highly statistically significant results, as evidenced in the favourable p-values, suggest that the drug has significant benefit over vehicle.

As anticipated, the inclusion of treatment sites for all non-head AK lesions contributed to the lower clearance rates when compared to previous trials, but the total clearance rates ranged from 16% to 89% by anatomical location with chest, back of hand and arms achieving statistical significance. The other areas did not show statistical significance due to the low number of patients that enrolled with these types of AK lesions.

Dr. Robert Rosen, a Sydney dermatologist and scientific advisor to Peplin, who has also been involved in the PEP005 clinical trial program, said that current treatment

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options for solar keratosis have a number of shortfalls, including pain, persisting skin irritation and redness during prolonged treatment periods.

“As a result, patients are often unwilling to use their medications,” he said. “A topical agent like PEP005 Gel, which can effectively and conveniently treat lesions in two days, will be of significant benefit to doctors and their patients.”

Brian Berman, M.D., Ph.D., Professor of Dermatology and Internal Medicine at the University of Miami, Miller School of Medicine, states: “Practicing dermatologists recognise that the successful treatment of AK lesions found on the arms or back of hands is a challenge generally unmet by topical treatments currently on the market. PEP005 Gel’s strong results across these difficult treatment areas provide the opportunity to satisfy our AK patients’ unmet need.”

As seen in previous non-head trials, the local skin responses (LSRs) peaked at Day 8 and returned to baseline by Day 29. The most frequent LSRs included erythema, flaking and scaling with no significant adverse effects reported.

Peplin will conduct its End-of-Phase II meeting with the FDA on June 3, 2009. Peplin was notified by the FDA of their need to postpone the meeting by two weeks from the originally scheduled date due to internal scheduling conflicts at the FDA. Peplin will initiate the Phase III program for patients with AK lesions on the head, an estimated 70% of the AK market, in the second quarter of 2009.

REGION-I Trial Details

Design and treatment method: REGION-I was a 250-patient, Australian and US multi-centre, randomised, parallel group, double-blind, vehicle-controlled clinical trial to evaluate the safety and efficacy of a 0.05% concentration applied for 2 consecutive days for Peplin’s patented product, PEP005 Gel in patients with AK lesions on non-head sites, including arm, back, back of hand, chest, leg and shoulder.

The study was conducted at 19 study centers within the United States and Australia. All eligible patients were centrally randomised to either active (PEP005 Gel, 0.05%) or vehicle gel in a 1:1 ratio. Randomisation was stratified by study site and anatomical location. This field-directed therapy was applied to a 25 cm² contiguous AK treatment area containing four to eight clinically typical AK lesions. Study medication was patient-applied, at home, to the selected treatment area. Patients returned to the clinic for study follow-up visits on Days 3, 8, 15, 29 and 57 (study exit) following study medication application.

Evaluation criteria: This Phase III trial aimed to evaluate the safety and efficacy of Peplin’s proprietary product, PEP005 (ingenol mebutate) Gel, in patients with AK lesions on non-head locations. The primary efficacy objective was *complete clearance* of AK lesions. *Complete clearance* was defined as the proportion of patients at the Day 57 visit with no clinically visible AK lesions in the selected treatment area.

The secondary objectives were *partial clearance* and *percent median reduction* of AK lesions. *Partial clearance* was defined as the proportion of patients at the Day 57 visit with a 75% or greater reduction in the number of AK lesions identified at Baseline in the selected treatment area. *Percent median reduction* was defined as the median number of AK lesions within the selected treatment area no longer clinically visible for any given patient at the Day 57 visit.

The primary safety evaluation included:

- Incidence of adverse events (AEs) and serious adverse events (SAEs) recorded throughout the study
- Incidence and grade of local skin responses (LSRs), and changes in pigmentation and scarring following study medication

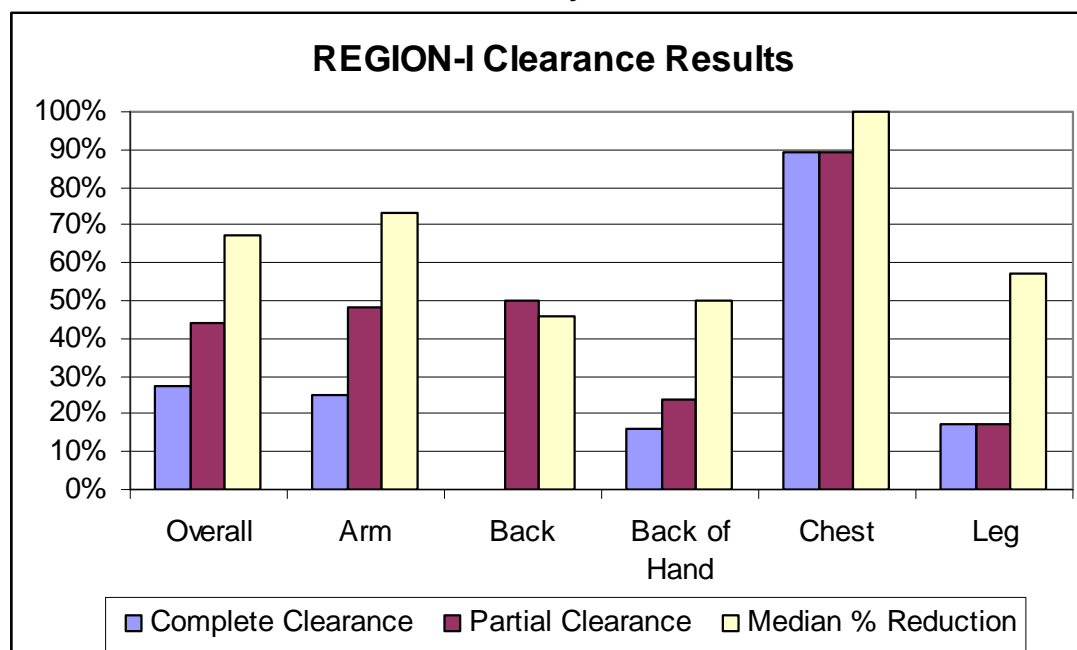
Patients: A total of 255 patients were randomised into the study and included in the intent to treat (ITT) population. 254 patients received at least one application of study medication and were included in the safety population. Twenty patients were excluded from per protocol efficacy analyses due to protocol deviations, leaving 235 patients to be included in the per protocol population.

The mean age of patients was 67.1 years (range 36 – 88 years), 62.4% of patients were male and 37.6% female. Patients were randomised across the six anatomical locations as follows: 166 (65.1%) arm, 54 (21.2%) back of hand, 17 (6.7%) chest, 2 (0.8%) shoulder, 5 (2.0%) back and 11 (4.3%) leg

REGION-I Results

Efficacy: A 0.05% concentration of PEP005 (ingenol mebutate) Gel applied once daily for two consecutive days resulted in a total clearance rate in the intent to treat population equal to 27.4% (p-value<0.0001), a partial clearance rate of 44.4% (p-value<0.0001) and a median reduction in overall lesion count of 66.7% (p-value<0.0001).

FIGURE 1: REGION-I Clearance Summary



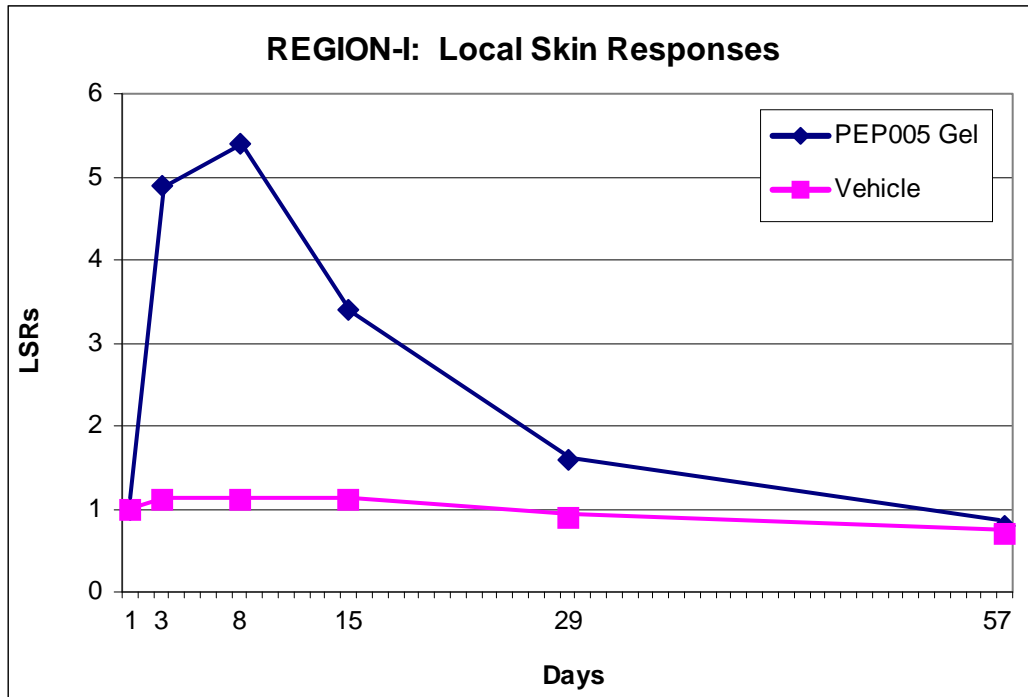
Safety: The drug suggested a favourable profile. There were no treatment-related SAEs, and AEs were generally mild to moderate in severity and resolved by Day 57. The most common treatment-related AEs, occurring within the treatment area, appeared to be application site irritation and pruritus. One patient experienced pain in the treatment area that led to discontinuation from dosing after one application.

The local skin responses (LSRs) assessed in this study were as follows:

- erythema
- flaking/scaling
- crusting
- swelling
- vesiculation/pustulation
- erosion/ulceration

Each response was evaluated on a scale of 0 - 4 and then the mean composite score across responses is calculated.

FIGURE 2: Composite Local Skin Response



Pigmentation and Scarring: A total of 7 patients in the active group had pigmentation changes with 4 reporting improvements and 3 patients in active group reported a worsening of pigmentation. No patients experienced a worsening of scarring during the study.

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ABOUT PEPLIN

Peplin is a development stage specialty pharmaceutical company focused on advancing and commercialising innovative medical dermatology products. Peplin is currently developing PEP005 (ingenol mebutate), 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 ingenol mebutate, a compound the use of which Peplin has patented for the treatment of actinic (solar) keratosis, or AK. This product candidate referred to as PEP005 (ingenol mebutate) Gel is currently in Phase III clinical trials, having just completed their first Phase III, known as REGION-I.

ABOUT AK

Actinic keratoses (AK), also known as solar keratosis or sun spots, 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. 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.

FORWARD LOOKING STATEMENTS

This press release contains "forward-looking statements" as defined under U.S. federal securities laws, including, but not limited to, Peplin's clinical development plan and timing of clinical trials referred to herein. 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 clinical trials resulting from, among other things, 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 and in its Form 10 Registration Statement and most recent quarterly report on Form 10-Q filed with the US Securities and Exchange Commission. 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.