



## ASX RELEASE

### Peplin to start Phase III under SPA agreement with FDA

**EMERYVILLE, California and BRISBANE, Australia, 10 June 2008: Peplin, Inc.** (ASX:PLI) today announced that it will initiate a Phase III clinical trial, PEP005-014, in the third quarter of 2008, based on its recent receipt of a Special Protocol Assessment (SPA) from the FDA. PEP005-014 is a Phase III clinical trial designed to test the safety and efficacy of PEP005 (ingenol mebutate) Gel, (0.05%) in the treatment of actinic (solar) keratosis (AK) in non-head treatment sites.

The SPA represents the FDA's agreement that the design, clinical endpoints and planned statistical analyses of Peplin's Phase III trial protocol are adequate to form a basis for approval of a new drug application (NDA). An SPA is binding upon the FDA, unless a safety issue is identified after the testing is initiated.

PEP005 (ingenol mebutate) Gel is Peplin's proprietary product being developed for the treatment of AK. Prior to filing an NDA with the FDA, Peplin intends to complete a series of clinical trials in two general anatomical areas: head, which comprises areas on the face or scalp, and non-head, which primarily comprises areas on the back of the hand, arm, shoulder and back. PEP005-014 is the first Phase III clinical trial in this program.

Peplin plans to conduct supportive safety and other studies in parallel with these clinical trials and expects to file a single NDA for applications on both head and non-head treatment locations with the FDA in mid 2010, assuming a successful End-of-Phase II meeting with the FDA and the successful completion of a Phase III clinical program.

#### Non-head Phase III clinical trial

PEP005-014 is a US and Australian Phase III multi-center, randomized, double blind, vehicle controlled clinical trial designed to evaluate the safety and efficacy of PEP005 (ingenol mebutate) Gel, (0.05%) compared to vehicle gel in patients with AK lesions on non-head locations. Peplin expects to enroll approximately 250 patients who would apply the study medication or vehicle gel to a 25 cm<sup>2</sup> treatment area containing four to eight AK lesions. The medication would be applied at home once a day for two consecutive days.

The primary efficacy endpoint for the PEP005-014 clinical trial will be the complete clearance rate of AK lesions and the secondary efficacy endpoint will be the partial clearance rate of AK lesions. Peplin will evaluate efficacy on the 57<sup>th</sup> day after treatment.

#### Head Phase IIb and Phase III clinical trials.

As previously announced, Peplin expects to initiate PEP005-015, a dose ranging Phase IIb clinical trial in patients with AK lesions on head locations, in June 2008.

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This trial is a US and Australian multi-center, randomized, double blind, vehicle controlled clinical trial to evaluate the safety and efficacy of each of three concentrations (0.005%, 0.010% or 0.015%) of PEP005 (ingenol mebutate) Gel.

Patients participating in this trial will be randomized into two treatment arms, either a two day or three day treatment regimen. Patients in each treatment arm will apply either one of the active concentrations of PEP005 (ingenol mebutate) Gel or the vehicle gel to AK lesions on head locations. Peplin expects to enroll approximately 240 patients who would apply the study medication or vehicle gel to a 25 cm<sup>2</sup> treatment area containing four to eight AK lesions. The medication would be applied at home once a day for either two or three consecutive days.

The primary efficacy endpoint for this clinical trial will be the complete clearance rate of AK lesions and the secondary efficacy endpoint will be the partial clearance rate of AK lesions. Peplin will evaluate efficacy on the 57th day after treatment.

This Phase IIb clinical trial is intended to support the design of a subsequent Phase III clinical trial in patients with AK lesions on head locations, which Peplin plans to initiate in 2009, assuming a successful End-of-Phase II meeting with the FDA.

Peplin believes that its current cash, together with the net cash it expects to acquire on the closing of its recently announced acquisition of Neosil should be sufficient to fund the PEP005-014 Phase III and PEP005-015 Phase IIb clinical trials.

#### Investor conference call

Peplin will host an investor conference call to discuss this announcement at 9:00 am Australian Eastern Standard Time, Wednesday, 11 June 2008. The dial-in numbers are 1800 157 000 (Australia) and 888 830 9551 (US) with code 802 246 63.

#### **Further information:**

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#### **ABOUT PEPLIN**

Peplin is a development stage specialty pharmaceutical company focused on advancing and commercializing 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 keratosis, or AK. This product candidate is currently in Phase II clinical trials and is referred to as PEP005 (ingenol mebutate) Gel.

#### **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 clinical development plan 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 the completion of 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, failure to close the acquisition of Neosil, Inc. lack of adequate funding to commence or continue planned clinical trials 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.