



ASX & MEDIA RELEASE

Peplin announces the commencement of its Phase III clinical trial for PEP005 Gel in AK

EMERYVILLE, California and BRISBANE, Queensland, 9 September 2008: Peplin, Inc. (ASX:PLI) today announced the initiation of its first Phase III clinical trial to confirm the efficacy and safety of PEP005 (ingenol mebutate) Gel for the treatment of actinic (solar) keratoses (AK), a common pre-cancerous skin lesion, when applied to non-head locations, which include the trunk and extremities.

Australian dermatologist and investigator, Dr. Robert Rosen, said that PEP005 Gel for AK has the potential to offer an effective and much more convenient treatment.

"The greater number of AKs a person has, the greater chance they have of developing the form of skin cancer known as squamous cell carcinoma," Dr. Rosen said.

"Having a treatment that can treat a large region of skin, with potentially just two applications, rather than older forms of therapy which can be painful or involve long-term treatment schedules, should be well received by the medical community."

The pivotal Phase III trial, REGION-I (formerly referred to as PEP005-014), will involve sites in Australia and the United States (US) and is designed to replicate PEP005 Gel's efficacy and safety in AK as shown in previous studies. The trial is being conducted under a Special Protocol Assessment (SPA) with the FDA. 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. The FDA's agreement on the SPA is binding, except in limited circumstances, such as if a safety issue is identified after the testing is initiated.

Chief Executive Officer Tom Wiggins said: "We are excited to see PEP005 Gel for AK enter its first Phase III trial under an SPA and achieve this major milestone, entering into the final stage of development for this important product. Based on the data we have generated up to this point, we believe PEP005 Gel represents a significant advance in the treatment of a common skin condition that reaches its highest worldwide prevalence in Australia, where approximately half of adults have at least one AK lesion."

REGION-I is a randomised, double-blind, vehicle-controlled clinical trial that will be conducted at multiple sites in the US and Australia to confirm the efficacy and safety of the proprietary product candidate, PEP005 Gel, when compared to vehicle gel in patients with AK lesions on non-head locations.

Peplin expects to enrol approximately 250 patients who will apply the study medication or vehicle gel to a 25 cm² treatment area containing four to eight AK lesions. The gel will be applied at home once a day for two consecutive days. The primary efficacy endpoint for the REGION-I trial will be the complete clearance rate of AK lesions and the secondary efficacy endpoint will be the partial clearance rate of AK lesions within the treatment area. Peplin will evaluate these endpoints on the 57th day after the start of treatment.

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REGION-I is one of the planned Phase III trials for PEP005 Gel for AK. Pending supporting data from Peplin's recently enrolled PEP005-015, a dose-ranging Phase IIb clinical trial in patients with AK lesions on the head, and assuming a successful End-of-Phase II meeting with the FDA, Peplin plans to initiate a subsequent Phase III clinical trial in patients with AK lesions on the head in 2009.

Peplin believes that its current cash, together with the net cash it expects to acquire on the closing of its recently announced private placement and acquisition of Neosil (each of which remains subject to shareholder approval), will be sufficient to fund Phase III testing of PEP005 Gel for AK on both the head and non-head locations. Peplin currently owns worldwide commercialisation rights for PEP005 for AK.

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ABOUT PEPLIN

Peplin is a development-stage, specialty pharmaceutical company focused on advancing and commercialising innovative medical dermatology products. Peplin has offices in Brisbane, Queensland and Emeryville, California and a manufacturing facility in Southport, Queensland.

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 now in Phase III clinical trials and is referred to as PEP005 (ingenol mebutate) Gel.

ABOUT ACTINIC KERATOSES

Actinic (solar) keratoses (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. 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 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, failure to close the acquisition of Neosil, Inc., 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 obtain the stockholder approval necessary to approve the pending private placement, 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.