



ASX AND MEDIA RELEASE

Peplin Initiates its Final Phase 3 Clinical Trial for PEP005 Gel in AK

EMERYVILLE, California and BRISBANE, Queensland, 23 July 2009: Peplin, Inc. (ASX:PLI) today announced the initiation of its second non-head Phase 3 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.

This second pivotal Phase 3 trial for non-head locations, known as REGION-Ib, is designed to replicate the recently completed REGION-I trial and confirm the results of PEP005 gel, which showed a total clearance rate across all anatomical non-head locations of 27.4% ($p < 0.0001$), a median lesion reduction of 66.7% ($p < 0.0001$) and statistical significance when compared to vehicle for clearance of AK's on the chest and the especially difficult-to-treat locations, the arm and back of hand.

Chief Executive Officer Tom Wiggins said: "Achieving this additional milestone immediately following the rapid enrolment in our Phase 3 head trials, demonstrates our commitment to progressing PEP005 gel through the final phase of our clinical development process. Based on the data we generated in the REGION-I trial, we believe PEP005 gel with its short course of therapy represents a significant advance in the treatment of a common skin condition, which if left untreated can progress to squamous cell carcinoma."

REGION-Ib is a randomised, double-blind, vehicle-controlled clinical trial that will be conducted at multiple sites in the US. Peplin expects to enrol approximately 200 patients who will self-apply the study medication (0.05%) or vehicle gel for two consecutive days to a 25 cm² treatment area containing four to eight AK lesions. As with prior trials, the primary efficacy endpoint for the REGION-Ib 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 also measure the overall median reduction of AK lesions.

In addition to the REGION-Ib trial on non-head locations, Peplin recently completed enrolment in its REGION-IIa and REGION-IIb trials for head locations, which include the face and scalp, and announced the results from its REGION-I trial, the first Phase 3 for non-head locations, earlier this year. Peplin will complete their Phase 3 clinical trials for AK by the end of this year and plans to file a New Drug Application in mid-2010.

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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 ingenol mebutate, or PEP005, which is a novel compound 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 3 clinical trials, having just completed their first Phase 3, known as REGION-1a.

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.