

## ASX AND MEDIA RELEASE

### **Positive anti-leukemia effects of PEP005 IV**

**BRISBANE, Australia, 13 October 2005: Peplin Limited (ASX:PEP)** announced today positive results of an initial efficacy study of its drug candidate PEP005 IV in a mouse model of acute myeloid leukemia.

In this pilot two arm study conducted at a leading European centre either PEP005 IV (active arm) or vehicle (control arm) was delivered intravenously daily for five days to five mice in each arm. These mice had engrafted into their blood system a human form of acute myeloid leukemia.

The study evaluated two endpoints, the first: PEP005 IV's impact on survival. There was a positive impact on survival of mice in the PEP005 IV treated group; in the small number of mice, the difference was not statistically significant. The second endpoint evaluated was PEP005 IV's impact on tumour burden in various organs. There was a dramatic reduction in tumour burden in the abdominal lymph nodes of the leukemic mice in the PEP005 IV treated group compared with the vehicle group and this difference was highly statistically significant ( $p=0.0007$ ). In addition there was a positive impact on tumour burden in bone marrow and blood.

Peplin Managing Director and CEO Michael Aldridge said that these results in this very relevant xenograft model of disease are very promising for PEP005 IV.

"For the first time we have demonstrated in an animal model of human acute myeloid leukemia PEP005 IV's ability as a single agent to have an impact on this devastating disease, the most serious form of leukemia. Strong data in pre-clinical efficacy studies will accelerate and facilitate our clinical trials planned for early next year. We are vigorously pursuing the opportunity to bring this important new medication to market for the benefit of patients suffering from leukemia," Mr Aldridge said.

As previously announced Peplin expects to complete pre-clinical studies of PEP005 IV and file an investigational new drug (IND) application with the US Food and Drug Administration (FDA) in the first quarter of 2006.

Peplin intends to support further studies in this animal model using a larger treatment group to more completely evaluate the observed positive impact on survival and tumour burden. The investigators intend to publish the complete results of these studies in an international peer reviewed journal.

## **ABOUT LEUKEMIA**

Leukemia is a cancer of the blood and blood forming organs. According to the Leukemia & Lymphoma Foundation there will be an estimated 34,810 new cases of leukemia in the US in 2005. According to the Leukaemia Foundation in Australia there are 2,370 people diagnosed with leukemia each year.

The most common type of leukemia is acute myeloid leukemia or AML which is estimated to strike 11,960 people this year in the US. AML is both the most common and the most devastating form of leukemia with a 5 year survival rate of less than 20%.

## **ENDS**

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## **ABOUT PEPLIN**

Peplin is focused on the development and commercialisation of prescription human therapeutic products for the treatment of cancer. Its lead compound is PEP005, the first in a new class of investigational agents. Peplin's lead product is PEP005 Topical, which is being studied in phase IIa clinical trials for the treatment of actinic keratosis (AK) (a pre-cancerous lesion) and non-melanoma skin cancer (NMSC). PEP005 Topical works by a powerful mode of action, directly killing most cancer cells and then recruiting and activating the local immune system to clean-up these dead cancer cells and kill any remaining cancer cells. PEP005 Topical is potentially a rapidly acting and cosmetically attractive non-surgical treatment for AK and NMSC. Peplin's product development activities are supported by the Australian Federal Government under its Pharmaceuticals Partnerships Program.

Peplin's earlier stage pipeline is targeted at leukemia (a blood borne cancer) using its lead compound PEP005 in an intravenous formulation (PEP005 IV) and bladder cancer using an intracavitary or intravesical formulation (PEP005 IC). PEP005 has demonstrated selective and potent anti-leukemia activity in pre-clinical disease models. PEP005 induces apoptosis in leukemia cells via the activation of PKC delta. Peplin holds global proprietary rights for PEP005 Topical and other oncology applications of PEP005. Its research portfolio of EPUFA compounds opens additional potential opportunities in cancer and pain.