



NEWS & ASX RELEASE

UK Leukaemia Research Reports High Potency of PEP005 Against AML

Brisbane, Australia & Birmingham UK, 12 September 2003.

Peplin Biotech Ltd (ASX: PEP) today announced the first exciting results from independent research into the potential of its lead drug PEP005 for the treatment of leukaemia.

In laboratory experiments conducted in Professor Janet Lord's laboratory at the Medical Research Council Centre for Immune Regulation at Birmingham University, PEP005 was shown to be highly effective against a number of established leukaemic cell lines at very low (nanogram per millilitre) concentrations of drug.

The reported effects include induction of growth arrest, differentiation (reversion to normal shape and behaviour) and apoptosis (programmed cell death) of the cancer cells.

In addition, primary blast cells extracted from two patients with relapsed acute myelogenous leukaemia (AML) showed significant responses to PEP005 within 24 hours at similar low drug concentrations.

AML is one of a group of blood-borne cancers, which, according to the World Health Organisation, strikes around 380,000 new cases each year. The American Cancer Society estimates the number of Americans presently suffering one of these diseases at more than 670,000. AML affects people of all ages, 25% of cases occurring in people under the age of 25, although the majority of cases occur in later life.

Dr Lord said, "The outlook for the majority of AML patients is very bleak and new drugs are urgently required".

PEP005, which late last year became the first Australian anti-cancer drug to be licensed to the US market, is under independent study against a range of cancer targets in a number of prestigious research institutes in Australia, the UK and the USA. These latest leukaemia results from the Birmingham group support the data reported earlier from studies conducted by the US National Cancer Institute.

POTENCY & UNIQUE MECHANISM

The Birmingham group's findings are particularly exciting not only because of the potency of PEP005 against the disease, but also because the drug appears to be working by a novel mechanism of action.

Dr Peter Welburn, Peplin's Director of Clinical and Regulatory Affairs, believes that PEP005 could be in clinical study against leukemia in the first half of 2004.

"We are making great progress in finalising pre-clinical studies in toxicology in preparation for our first IND filing with the FDA for skin cancer. Much of that work will be directly relevant in supporting an early evaluation of a systemic formulation of PEP005 in patients with refractory leukaemia" said Dr Welburn, who is currently located in the UK, coordinating the development of PEP005.

“Apart from skin cancer, leukaemia and the other blood cancers are the most accessible for study. Samples are easy to obtain, and the results of treatment options can be obtained quickly. This makes an early clinical study of this disease particularly valuable to our goal of rapid progress with PEP005,” said Dr Welburn.

“The hunt for new ways to fight cancer that are more effective and have fewer side-effects is both crucial for patients and important for commercial success” said Peplin Biotech’s CEO, Garry Redlich. “We are particularly delighted to be confirming the value of progressing our work with PEP005 against diseases other than skin cancer, where most of our early work and our first licence is focussed. Work with prostate cancer is progressing, and we are preparing to initiate a colorectal cancer research programme soon.”

POWERFUL COMBINATION WITH ESTABLISHED AML DRUGS

This data from the Birmingham group indicates that PEP005 synergises with *all-trans* retinoic acid (ATRA) in inducing both apoptosis and cell differentiation in AML cells from both patients and cell lines that are used as laboratory models of the disease. ATRA has had a major clinical impact upon the treatment and survival of around 10% of AML patients suffering a form of the disease known as acute promyelocytic leukaemia (APL). However, this treatment has had little, if any, benefit in other forms of the disease. The synergy observed by the Birmingham team could indicate that PEP005 will make this kind of therapy possible in non-APL AML patients.

Dr Chris Bunce, Senior Lecturer with the Leukaemia Research Fund in Birmingham, said of these latest results with PEP005, “We have many years of experience in testing potential new therapeutics in AML. In the context of this experience the early findings with PEP005 are very exciting”.

ABOUT PEPLIN BIOTECH

Peplin Biotech Ltd is a biotechnology company based in Brisbane, Australia, discovering and developing drugs for the treatment of cancer and other diseases. Its strategy is to leverage its pipeline of novel proprietary products through collaborative development arrangements with international pharmaceutical companies. In November 2002, Peplin signed an Americas-focused research collaboration and license agreement involving its lead drug for skin and eye disease with Allergan, Inc. that may result in milestone and other payments to Peplin of up to US\$23m. Peplin’s product pipeline comprises small molecule drug candidates addressing major cancer targets including breast, colorectal, pancreatic and prostate cancer, leukemia and melanoma, using topical, intralesional and systemic routes of administration.

Further information:

Garry Redlich,
Managing Director & CEO
Peplin Biotech Ltd
Tel: 0417-728-583
garry.redlich@peplin.com