



ASX AND MEDIA RELEASE

Peplin Announces Filing of IND

BRISBANE, Australia, 23 March, 2004: Peplin Biotech Ltd (ASX: PEP) today announced the filing of three separate Investigational New Drug (IND) applications with the US Food and Drug Administration (FDA) for a topical formulation of its lead compound PEP005. The individual INDs are for the treatment of the pre-cancerous condition actinic keratosis (AK) and the two most common forms of non-melanoma skin cancer (NMSC), basal cell carcinoma (BCC) and squamous cell carcinoma (SCC).

Peplin's Managing Director and CEO, Michael Aldridge said that the filings were the most significant event in the company's history.

"These filings were made under our collaboration with Allergan, Inc. for the development of a topical treatment for non-melanoma skin cancer and actinic keratosis. This has been a very positive and successful relationship and this milestone points to the quality and expertise of the team we have put together " said Mr Aldridge.

"Importantly Peplin has been fundamentally responsible for the enormous quantum of pre-clinical studies and data which have been assembled for the INDs. This represents a hugely valuable base which Peplin can rapidly leverage into other applications for PEP005 in other forms of cancer, including those treated by systemic and intra-lesional forms of therapy," he said.

These filings were made by Allergan and represent a milestone event under the joint development and license agreement between Peplin and Allergan triggering the payment of US\$1 million to Peplin.

"According to our partner Allergan, AK affects approximately 50% of Caucasians who are older than 40 years of age, with 78% of cases having multiple lesions," said Mr Aldridge

"Up to 15% of lesions that have been removed will recur and if left untreated, approximately 10% of AKs develop into squamous cell carcinoma.

"BCC and SCC affect an estimated 1.85 million patients in the USA. NMSC is the most common of all forms of cancer and is the fastest growing with incidence increasing at 6-7% per annum," Mr Aldridge said.

ABOUT PEPLIN BIOTECH

Peplin Biotech Ltd is focused on the discovery, development and commercialisation of prescription human therapeutic products for the treatment of cancer and other diseases which have limited therapeutic options. Peplin's strategy is to leverage its pipeline of novel proprietary products through collaborative development arrangements with international pharmaceutical companies. Peplin's lead product is a potential topical therapy for actinic keratosis and non-melanoma skin cancer. It is the subject of a joint development agreement with Allergan, Inc. of Irvine, California for commercialisation in North and South America.

Peplin's earlier stage pipeline is targeted at other forms of cancer using intralesional and systemic routes of administration. Its new portfolio of EPUFA compounds opens additional potential opportunities in cancer and adds candidates for cardiovascular disease, pain, inflammation and diabetic complications.

Further information on Peplin:

Michael Aldridge,
Tel: 07-3854-0980
michael.aldridge@peplin.com

Media enquiries:

Anita Westerberg-Jaensch
PhillipsGroup
Tel: 07-3230 5000
awesterberg-jaensch@phillipsgroup.com.au

Peplin Biotech Ltd ABN 55 090 819 275

Ground Floor, South Tower, Terrace Office Park, 527 Gregory Terrace, Bowen Hills, Queensland 4006, Australia.

Tel: 61-7-3854 0980

Fax: 61-7-3854 0989

www.peplin.com

NOTES FOR EDITORS

The development process:- from IND to market

An IND filing is the culmination of an extensive pre-clinical (or pre-human) development program. Its filing typically follows a pre-IND meeting with the FDA at which the proposed content of the IND is discussed and broad parameters agreed.

There are three main sections to the IND comprising:

- The chemistry, manufacturing and controls (CMC) section in which the chemistry of the therapeutic agent and a validated manufacturing process and quality control system are documented
- The pharmacology and toxicology section which documents the pre-clinical efficacy and safety profile of the drug using a number of well validated models and studies
- A clinical section which contains the clinical investigators' brochure (CIB) and the clinical trial protocol for the proposed trial which is to be conducted under the IND.

Following approval of the IND by the FDA (typically within a 30-60 day period) the sponsor is then free to initiate clinical (or human) development of the drug. In this case, Allergan will commence three parallel phase I/II clinical trials in patients with confirmed AK, BCC and SCC at various clinical sites in North America.

The clinical stage of a drug's development program is typically conducted in three phases. These comprise phase I (safety), phase II (safety, efficacy and dose ranging) and phase III or pivotal (efficacy and safety). This clinical phase of the development program typically takes a number of years. The completion of this phase is then followed by the filing of a New Drug Application (NDA) with the FDA. The FDA may take a year or more to review and potentially approve the NDA, based on its assessment of the drug's demonstrated safety and efficacy. Following approval of the NDA filing by the FDA the sponsor of the NDA can market the drug for the uses or indications approved by the FDA.

About PEP005

PEP005 is Peplin's lead compound. PEP005 is a well characterised, single molecular entity isolated and purified from a rapidly growing and common non-indigenous plant and represents the first of a new class of drug in clinical development. Peplin's proprietary rights to PEP005 and other related compounds for the treatment of skin cancer are by virtue of patents granted in Australia, Singapore and the US and filed and under prosecution in other countries and regions.

Peplin initiated a proof of concept pilot clinical study using a topical application of PEP001 (the raw sap from which PEP005 is purified) on patients suffering from NMSC and AK at the Mater Misericordiae Hospital in Brisbane, Australia in May 1999. This trial has completed, further details are available at Peplin's web site at www.peplin.com.

Peplin's collaboration with Allergan

Peplin and Allergan entered into a collaborative development and license agreement in November 2002. Under the agreement, Peplin licensed the rights for Allergan to develop and (subject to relevant regulatory approval) market PEP005 in a topical (gel, cream or ointment) and intralesional (injection into the lesion) format to treat NMSC and AK in North and South America.

Up to US\$23 million in pre-commercialisation payments are payable by Allergan to Peplin. In addition, Peplin will receive royalties based on net sales of the licensed drug. Pre-commercialisation payments include a US\$1 million sign-on fee (received in November 2002), US\$1 million milestone fee on filing of an IND (now due from Allergan), a 2004 development payment of US\$2 million payable in equal quarterly instalments during the course of 2004 (first quarterly payment received in December 2003) and further milestone and development payments. Future milestones include initiation of phase III trials, filing of an NDA and approval of an NDA.

Peplin retains all rights to PEP005 for the topical or intralesional treatment of skin cancer in markets outside of North and South America and all rights for PEP005 in other formulations (such as intravenous and intralesional) for the treatment of other forms of cancer.

NMSC in Australia

According to the Australian Cancer Council, NMSC (BCC and SCC) is the most common cancer diagnosed in Australia. The most common forms of skin cancer have increased by more than one third since 1995 and doubled over the past two decades. 374,000 Australians over the age of 14 were treated for NMSC in 2002. Of all cancers, skin cancer is the biggest burden on the health system costing approximately \$300 million per year to treat. Treatment of NMSC can leave disfiguring scars and NMSC kills 360 people per year. Around a quarter of all Australians treated for NMSC in 2002 had more than one skin cancer. Further information on skin cancer in Australia is available at www.ncci.org.au (National Cancer Control Initiative) and www.cancer.org.au.

About Allergan

Allergan, Inc., with headquarters in Irvine, California, is a global specialty pharmaceutical company that develops and commercializes innovative products for the eye care, neuromodulator, skin care and other specialty markets. In addition to its discovery-to-development research programs, Allergan has global marketing and sales capabilities in over 100 countries that deliver value to its customers, satisfy unmet medical needs and improve people's lives.

Allergan is listed on the New York Stock Exchange under the ticker symbol AGN. Further information is available at www.allergan.com.