



company announcement

Monday 14 November 2005

Ethics approval for pharmacokinetic trial (EP006)

Melbourne, Australia

Epitan Limited today announced that it had obtained ethics approval for a Phase I/II study to confirm the drug release characteristics in humans of the commercial formulation of the sustained-release solid dose implant of EPT1647.

The Principal Investigator will be Associate Professor Robert Milne from the University of South Australia, School of Pharmacy and Medical Services in Adelaide. The trial is due to begin in January 2006 and is expected to take four months with a final report expected by September 2006.

This will be the first clinical use of a formulation derived from the results of the dose escalation clinical study EP004. The sustained-release implant is expected to be the final product formulation that will be used in the remaining Phase II and III trials of EPT1647 and the first generation formulation to be commercialised. The implant has been developed in conjunction with Brookwood Pharmaceuticals, which was formed as a spin-off company from the drug delivery group of Southern Research Institute (Birmingham, Alabama).

During the development of the implant, there was a significant formulation discovery which resulted in a full international patent filing. Epitan's intellectual property counsel confirmed that if this patent application is granted, Epitan is likely to have up to 20 years' commercial exclusivity for EPT1647, administered in a sustained release manner.



About Epitan

Epitan Limited (ASX: EPT, ADR: EPTNY, XETRA: UR9) is a Melbourne-based pharmaceutical company with a focus on prescription dermatology products.

Epitan has two primary activities: (1) to complete the remaining clinical development of its leading drug candidate EPT1647, for which Epitan holds exclusive worldwide rights in the field of use for melanogenesis and (2) marketing and selling prescription dermatology products in Australia and New Zealand.

As at November 2005, Epitan has five drugs in its portfolio of dermatology products. Epitan continues to evaluate the in-licensing of additional similar products although its main focus is to complete the development and commercialisation of EPT1647 for the world markets.

About EPT1647

EPT1647 is the new non-proprietary name for Epitan's MELANOTAN™. MELANOTAN™ is Epitan's brand name for [Nle⁴, D-Phe⁷]-α-MSH. From June 2005, Epitan is using EPT1647 rather than its brand name to avoid any confusion between MELANOTAN™ (or MT-I) and other chemicals such as Melanotan-II (or MT-II) and melatonin.

EPT1647 stimulates the body to make eumelanin, the dark pigment of the skin which is known to have protective effects on the skin from exposure to both UV-A and UV-B radiation. Simply, EPT1647 is a photoprotective agent that acts by increasing the levels of eumelanin in the skin without the need to expose the skin to UV radiation. Therefore, it has the potential to be used as a photoprotective agent for those persons seeking additional protection from UV damage, because their levels of eumelanin do not normally increase when they are exposed to UV radiation or persons who suffer from the clinical symptoms of UV associated skin diseases and disorders, such as Polymorphous Light Eruption (PMLE).

About EpiPharm

During the past 12 months, we have been establishing a business to market and distribute dermatology products in preparation for the launch of EPT1647. There are many international pharmaceutical companies with excellent dermatology products that are not launched onto the Australian and New Zealand markets. EpiPharm is actively exploiting this opportunity. We have built a portfolio of five products and we continue to source other



prescription dermatology products for which there is an unmet medical need in Australia and New Zealand.

The products in the EpiPharm portfolio are Exorex[®] (currently on market for psoriasis, PBS-listed from December 2005), Zindaclin[®] (registered, for acne), ZORAC[®] (registered, for acne and psoriasis), Linotar[®] (currently on market for eczema), and OraDisc[™] A (for mouth ulcers, launch expected 2007).

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