

11 November 2003

Company Announcement

US Food & Drug Administration gives EpiTan go ahead to file application for Investigational New Drug

For more information contact:

Dr Wayne Millen, Managing Director, EpiTan Limited, Tel: 03 9662 4688

Mr Iain Kirkwood, Chief Administrative Officer, EpiTan Limited, Tel: 03 9662 4688

Mr Richard Allen, Monsoon Communications, Tel: 03 9620 3333

mail@epitan.com.au

www.epitan.com.au

Melbourne, Australia

EpiTan Limited (ASX:EPT) today announced that, following a successful meeting with the United States Food & Drug Administration last month, the company expects to lodge an Investigational New Drug (IND) application in mid-2004 and begin clinical trials shortly thereafter.

Importantly, from EpiTan's discussions with the FDA an acceptable indication for Melanotan is expected to be for the prevention or reduction of UV-induced skin damage (sunburn indication) in subjects at high risk (genetic or occupational). The IND application will be for Melanotan® in a sustained-release implant formulation.

Dr Stuart Humphrey, EpiTan's Manager, Clinical Development said, "Agreeing the proposed clinical development pathway with the FDA is a major step forward. This should allow EpiTan to develop an ethical product for the US market essentially in the form of a prescription sunscreen using EpiTan's newly developed long-acting implant.

"Melanotan is one of a new breed of pharmacogenomic drugs which is expected to be of significant benefit to those people with fair skin types who are most at risk of sunburn injury and of developing skin cancers."

Dr Wayne Millen, EpiTan's CEO said, "We are delighted with the outcome of this meeting with the FDA. This opens the way for EpiTan to start clinical trials next year in the world's biggest pharmaceutical market. Melanotan is a new photo-protective tool that can be used safely in the fight against the harmful effects of UV radiation.. We are working flat out to bring Melanotan to commercialisation as soon as possible."

EpiTan's recently completed a Phase IIb "sunburn injury" clinical trial in both Sydney and Adelaide.

This month, clinical trials for the sustained-release implant formulation will begin at Q-Pharm in Queensland. This trial is expected to conclude in May 2004, following which clinical trials are expected to begin in the US once the FDA has approved the company's IND application.

ABOUT THE COMPANY: EpiTan Limited (ASX: EPT) is an emerging biotechnology company with a pre-eminent position on the prevention of DNA and skin damage from ultra-violet (UV) radiation exposure. Based in Melbourne, Australia, EpiTan holds a unique technology platform centred on its leading drug candidate Melanotan®, one of a new breed of pharmacogenomic drugs.

The company has the exclusive worldwide rights to develop Melanotan which, like sunlight, stimulates the production of melanin in the skin or “melanogenesis” – a unique biochemical process. However, and most importantly, the body’s melanin levels are increased before exposure to harmful UV radiation. This will become a new photo-protective tool which will be of significant benefit to people with fair skin types who are most at risk of sunburn injury and therefore of developing skin cancers.

Melanotan has concluded its Phase IIb clinical trials at two sites – the Royal Prince Alfred Hospital in Sydney and the Royal Adelaide Hospital. These trials demonstrated that Melanotan significantly increased skin melanin density and reduced sunburn injury.

EpiTan has now successfully developed a more user-friendly drug delivery formulation of Melanotan in the form of a slow release implant. This will be used in the remaining clinical programme and the commercialised product.

EpiTan is also investigating Melanotan as a therapeutic agent for UV-induced skin allergies such as polymorphous light eruption (“PMLE”) and solar urticaria. PMLE is a significant UV-induced skin allergy in northern latitudes and the company expects to begin trials in Europe in early 2004 to examine the ability of Melanotan to alleviate or cure this disorder.

Potential markets worldwide for Melanotan for dermatology purposes are estimated at US\$2.5 billion. An even greater market (more than US\$5 billion) exists for Melanotan as a new safe (prescription) sunscreen drug.

-End-