company announcement

Tuesday 14 June 2005

Phase IIb "Endpoint" trial of MELANOTAN™ begins in Sydney

Melbourne, Australia

EpiTan Limited (ASX: EPT, ADR: EPTNY, XETRA: UR9) today announced that the first volunteers have been recruited into the Phase IIb study to evaluate the photoprotective effect of a sustained release dose of MELANOTAN™ in Sydney (see Appendix 1). Ethics approval for this trial was announced on 7 March 2005.

The trial is designed to validate two primary endpoints for MELANOTAN™ for fair-skinned Caucasians who are the expected target patients for this therapy. The trial aims to establish a "protection" rating for MELANOTAN™ similar to that used in sunscreens. The second primary endpoint is to determine the change in skin pigmentation from baseline to week 4, 8 and 12 across 6 anatomic sites as determined by melanin density. The melanin density is measured by a "spectrophotometer". Further endpoints are designed to determine the reduction in UV induced skin damage.

The Principal Investigator for the trial is Professor Ross Barnetson, Head of Dermatology at the Royal Prince Alfred Hospital, Sydney. Professor Barnetson was the Principal Investigator for the company's Phase II sunburn trial in 2003 using daily liquid injections.

This trial is scheduled to take six months to complete. These endpoints are expected to be used in the company's final Phase III trial for which EpiTan is investigating suitable trial sites in Australia and Europe.

MELANOTAN™ stimulates the body to make eumelanin, the dark pigment in the skin ("a tan"). EpiTan has completed clinical trials which have demonstrated that the drug reduced UV induced skin damage by 50% in fair-skinned volunteers. Sunburn is widely recognised as a precursor to skin cancer. Australia has the highest skin cancer rate in the world, it is

estimated that two out of every three Australians will develop skin cancer at some stage during their lives.

Appendix 1:

Name of Trial:	A Double-Blind, Randomised, Placebo-Controlled Study to Evaluate the Photoprotective Effect of a Sustained–Release Dose of MELANOTAN™ in Fair-Skinned Healthy Caucasians
Primary endpoint:	1. To determine the change in skin pigmentation from baseline to week 4, 8 and 12 across 6 anatomic sites as determined by melanin density. 2. To determine the change in slope of the erythema ("reddening of the skin") index at week 4, 8 and 12 compared to baseline. The erythema dose-response is defined as the mean increase in erythema intensity plotted against the logarithm of the ultraviolet (UV) radiation dose. The erythema response is represented by the slope of the linear regression line. This endpoint defines the increased protection of the skin to UV radiation attributed to the increased pigmentation – a type of "sun protection factor".
Secondary endpoints:	1. To determine the change in the number of thymine dimers present in the basal layer in the epidermis resulting from a 3 x MED (Minimal Erythema Dose) exposure after 8 weeks of active or placebo treatment 2. To identify the MC1-R genotype (subjects with one or more variant alleles versus none) and compare the degree of increase in skin pigmentation in MELANOTAN™-treated and placebo-treated individuals at 6 anatomic sites for each of the sub groups.
Blinding status:	Double-Blind
Treatment method:	A single subcutaneous injection of a solid dose implant (MELANOTAN™ or placebo)

Number of trial subjects:	48 (includes 24 placebo)
Patient recruitment:	Approximately 16 per month
Subject selection criteria:	Healthy male and female fair-skinned Caucasians aged between 18 and 65
Trial location:	Royal Prince Alfred Hospital, Sydney
Partners involved:	N/A
Expected duration of trial:	6 months

About EpiTan

EpiTan Limited is a Melbourne-based specialty pharmaceutical company with a strategy focused on growing a business centred on dermatology products.

The company's leading drug candidate, for which EpiTan holds exclusive worldwide rights, is MELANOTAN™ which is in clinical development. MELANOTAN™ is EpiTan's brand name for [Nle^{4},D-Phe^{7}]-alpha-MSH, a synthetic analogue of the naturally occurring hormone alpha-MSH, which stimulates eumelanin production. EpiTan holds the rights to four other products for Australia and New Zealand; Linotar®, Exorex®, Zindaclin® and OraDisc™ A. Linotar and Exorex are in market. Zindaclin and OraDisc A are scheduled to be launched in late 2005 and 2006 respectively.

EpiTan is currently evaluating the in-licensing of other dermatology products to add to its portfolio.

About MELANOTAN™

MELANOTAN™ stimulates the body to make eumelanin; the dark pigment in the skin ("a tan") which is known to protect the body from UV induced skin damage as a result of exposure to UV radiation. UV radiation damage can cause sunburn which is widely

recognised as a precursor to skin cancer. MELANOTAN™ stimulates eumelanin production without the need to expose the skin to UV radiation.

MELANOTAN™ has completed a Phase II clinical trial (daily liquid injections) in Australia which demonstrated that the drug reduced UV induced skin damage by up to 50% in fair-skinned volunteers. This represents a significant breakthrough for people most at risk of sunburn and skin cancer. EpiTan has expanded its clinical studies of MELANOTAN™ into Europe. These trials have two aims: to assess MELANOTAN™'s potential both as a preventative to reduce the effects of UV damage to skin and as a therapy for UV-associated skin disorders such as polymorphous light eruption (PMLE).

MELANOTAN™ has a number of delivery formulations in development. The most advanced is a sustained release injectable implant which is being used in current clinical trial programs.

An independent report commissioned by the company identified that there are two potentially lucrative markets for MELANOTAN™. Firstly, the prophylactic market which includes those fair-skinned populations that seek additional protection from UV damage because their levels of eumelanin do not normally increase when they are exposed to UV radiation. There may also be a number of people who normally visit solariums (artificial tanning sunbeds) who may choose to take this drug instead. Secondly, the therapeutic market consisting of patients with UV-associated skin diseases or disorders for which MELANOTAN™ may provide a therapeutic benefit.

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