

company announcement

Friday 17 December 2004

German PMLE trial to start January 2005

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EpiTan Limited (ASX: EPT, ADR: EPTNY, XETRA: UR9) today announced that the German trial to test Melanotan[®] on sufferers of Polymorphous Light Eruption (PMLE) will commence in early January (for details see Appendix 1).

PMLE or “sunburn poisoning” is a UV induced skin allergy most prevalent in northern latitudes. Statistics reveal that between 10-20% of US and northern European populations suffer from PMLE. PMLE usually appears as small red, burning or itchy eruptions on sun-exposed skin. It is the second most common sun-related skin problem after sunburn as seen by doctors. It is most common during the spring and summer months when the level of exposure to UV radiation increases.

The trial has been scheduled for the European winter when people’s natural melanin levels are at their lowest and is intended to test whether the melanin-inducing drug Melanotan alleviates the clinical symptoms of PMLE.

Dr Wayne Millen, EpiTan’s Executive Chairman and CEO said: “In this trial, we are seeking a therapeutic indication for Melanotan. There is a large unmet medical need as PMLE has approximately 100 million sufferers worldwide. Significantly for EpiTan, this is the first European trial of Melanotan.”

About EpiTan

EpiTan Limited is a Melbourne-based specialty pharmaceutical company with a focus on niche prescription dermatology products. Its leading drug candidate Melanotan[®] stimulates the body to make melanin, the dark pigment of a tan which is known to protect

the body from skin damage as a result of exposure to ultra-violet (UV) radiation. UV radiation damage can cause sunburn which is a known prime cause of skin cancer. Simply, Melanotan induces a protective tan without the need to expose the skin to harmful levels of UV radiation. EpiTan recently acquired three products - Linotar[®] (eczema), Exorex[®] (psoriasis) and Zindaclin[®] (acne) – and is currently evaluating the acquisition or in-licensing of other dermatology-based products to add to its portfolio.

About Melanotan

Melanotan has completed a Phase II clinical trial in Australia that demonstrated the drug increases melanin content by up to 100% and reduces sunburn injury by up to 50% in fair-skinned volunteers. This represents a significant breakthrough for people most at risk of sunburn injury and potentially skin cancer. Melanotan will now undergo clinical studies in Europe and the USA. These trials will assess its potential both as a preventative to reduce the effects of UV damage 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 as regards clinical trial progress is a user-friendly and biodegradable sustained-release implant, administered by a single injection. In addition, testing of a selection of transdermal formulations is in various stages of progress.

An independent report commissioned by the company identified that there are three potentially lucrative markets for Melanotan. Firstly, the prophylactic market which includes those populations that do not tan well and seek additional protection from UV damage. Secondly, the therapeutic market consisting of patients with UV-associated skin diseases or disorders for which Melanotan may provide a clinical benefit and, finally, the cosmetic market comprising those people who want a tan, but not specifically for health reasons.

Appendix 1:

Name of Trial:	A pilot, Phase II, open, controlled study to evaluate the safety, tolerability and efficacy of a subcutaneous implant of Melanotan in patients suffering from recurrent Polymorphous Light Eruption
Primary endpoint:	To determine whether Melanotan implants given as a prophylactic can prevent or reduce the occurrence of symptoms like urticae, vesiculae, papulae, eczema, erythema and itching associated with PMLE
Blinding status:	Open, controlled

Treatment method: Implant

Number of trial subjects: 20

Patient recruitment: 10 per month

Subject selection criteria: Male and Females (18-70 years) diagnosed with PMLE-like syndrome

Trial location: Düsseldorf, Germany

Expected duration of trial: 4 months

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