company announcement

Thursday 8 September 2005

Ethics approval obtained for PMLE trial in Melbourne

Melbourne, Australia

Epitan Limited [ASX: EPT] announced today that it has obtained ethics approval from the Human Research Ethics Committee of St Vincent's Hospital, Melbourne, for a Phase II trial of its melanin-producing drug EPT1647 as a treatment for Polymorphous Light Eruption (PMLE), the Western World's second-most common sun-related skin problem.

The Principal Investigator in the trial will be Dr Chris Baker, Director of Clinical Services, Department of Dermatology at St Vincent's. The trial is scheduled to commence later this month.

Dr Baker said: "Polymorphous Light Eruption is a common sun-induced skin disorder. The rash is intensely itchy and consists of obvious red patches and bumps. It occurs on areas of exposed skin after sun exposure and lasts for several days or longer."

This will be the second trial of EPT1647 for PMLE, following a Proof of Concept study conducted in Germany, Finland and Denmark, completed in June this year.

In July Epitan reported that the patients studied in the European trial had experienced a therapeutic benefit from the drug. At one hospital it was noted that two patients who would normally have had severe PMLE reactions on exposure to UV radiation on their faces did not experience any such reaction following EPT1647 treatment.

Epitan has worked closely with leading dermatologists at St Vincent's Hospital and ORION Clinical Services to develop the protocol and reporting procedures. This trial is designed to measure possible changes in the symptoms of PMLE experienced by patients during their normal daily life following treatment with EPT1647. (See Appendix 1 for further trial details and Appendix 2 for PMLE background).

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Iain Kirkwood, CEO and Managing Director of Epitan, said: "This approval is another important step forward in the clinical development programme required to get EPT1647 to market. EPT1647 as a treatment for PMLE holds many advantages for Epitan, including lower development costs, lower regulatory risk for the drug, and therefore a quicker route to market. Success in this trial will allow us to move into a final Phase III trial later next year. The market potential for PMLE is significant, with a reported 15% of the UK and European, 10% of the US and 3-5% of the Australian populations suffering from PMLE."

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 September 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 [Nle^4, D-Phe^7]-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).

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Appendix 1

Name of Trial:	A double-blind, randomized, placebo-controlled Phase II study to evaluate the safety and efficacy of a subcutaneous implant of EPT1647 in patients suffering from recurrent Polymorphous Light Eruption.
Primary endpoint:	To determine whether EPT1647 implants given prophylactically can prevent or reduce the occurrence of symptoms like urticaria, vesiculation, papules, eczema, erythema, burning and itching associated with Polymorphous Light Eruption during a six month (spring and summer) period.
Blinding status:	Double-blind
Treatment method:	Single injection of a sustained release implant
Number of trial subjects:	30 (15 placebo)
Subject selection criteria:	Male and Females (18-70 years) previously diagnosed with PMLE-like syndrome
Trial location:	St Vincent's Hospital, Melbourne
Expected duration of trial:	9 months

Appendix 2 – About PMLE

Polymorphous Light Eruption (PMLE) is a skin disorder which is characterized by recurrent, abnormal delayed reactions to sunlight. It is the most common of the idiopathic photodermatoses. With no cure, this represents a significant unmet medical need with many sources estimating that there are 100 million sufferers worldwide. Sometimes known as "sun poisoning", the cause is unknown but PMLE is a common reaction to sunlight (ultraviolet light) that occurs in "light-sensitive" individuals. It is the second most common sun-related skin problem after sunburn as seen by doctors.

Symptoms and Causes

Common symptoms of PMLE include non-scarring, itchy, red papules, vesicles or plaques on light exposed skin. These symptoms usually occur within two hours following sun exposure. Symptoms may resolve within hours or remain for up to two weeks after sun exposure.

The cause of the disorder is unknown, however is likely to involve or be dependent upon UV radiation and other factors. Lesions most often occur on seasonally covered areas as they begin to be exposed to sunlight, usually during spring. During summer as the skin becomes more exposed to the sun, frequently exposed areas may become hardened to the effects of sunlight, resulting in a decrease of lesions in these areas.

Prevalence

PMLE is most common in temperate climates where there are distinct changes between seasons. It is reported to affect 15% of the UK population, and 21% of people in Sweden[1,2,3] approximately 10% of the US population and 3-5% of the Australian population also suffer from PMLE.[2,3]

Treatment Options

While there are many treatments available for PMLE, there is no cure. Prophylactic therapy such as avoiding sunlight, wearing protective clothing, and using broad spectrum sunscreens remains a key factor in the care of patients with PMLE. Other preventative treatment options include exposure to UV light (phototherapy) at the beginning of spring for several weeks to prevent flare-ups throughout the summer and oral corticosteroids in conjunction with phototherapy to avoid eruption during therapy. Topical corticosteroids, antihistamines, "antimalarial" medication and beta-carotene are often used once preventative measures have failed.[3]

Current treatment options available for PMLE sufferers are not without risks or side effects, however patients are willing to accept these risks in order to prevent or lessen the severity of an outbreak of PMLE.

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[1] *Tutrone WD, Thornton Spann C, Scheinfeld N, Deleo VA, Polymorphic Light Eruption, Dermatologic Therapy, Vol16 (2003), pg 28-29.*
[2] *Pao C, Norris PG, Corbett M, Hawk JLM, Polymorphic light eruption: prevalence in Australia and England, British Journal of Dermatology, 130 (1994), pg 62-64*
[3] *Shirin S, Polymorphis Light Eruption, eMedicine (2005), Department of Dermatology, University of California, Irvine Medical Centre, (www.emedicine.com/derm/topic342.htm)*

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