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Company Announcement

EpiTan announces human implant trials to begin

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Melbourne, Australia

EpiTan Limited (ASX:EPT) today announced that it had obtained approval from the Queensland Institute of Medical Research (QIMR) to begin its first human implant trial for its leading drug candidate Melanotan®. This trial is scheduled to take six months to complete.

In this trial up to twenty four healthy volunteers will receive only one injection of Melanotan contained in a long acting implant. This formulation is a much more commercially viable delivery mechanism and is a major advancement on the daily injections currently being used in the company's Phase IIb clinical trial shortly to be completed in September 2003. Similar implants, such as Zoladex® (AstraZeneca) for the treatment of prostate cancer, have already been approved for use in Australian and worldwide markets.

Dr Wayne Millen, EpiTan's Managing Director, said, "We are delighted to receive this approval from QIMR's Human Research Ethics Committee to begin these important human trials. The fact that this type of sustained-release formulation has already been proven to work with Melanotan in our preclinical studies is of great assistance. The implant will now be used in the remaining clinical program and Melanotan is likely to be commercialised first in this formulation."

"EpiTan plans to meet with the US Food & Drug Administration later this year in order to obtain an IND approval for the Melanotan implant."

The company also announced that it had engaged Southern Research Institute, USA, (Southern Research) to manufacture the implants, which are expected to be available in November 2003.

Mr Michael Kleinig, EpiTan's Pharmaceutical Development Manager, said, "The implant, which was developed in collaboration with Southern Research, is designed to be placed under the skin, enabling a uniform delivery of Melanotan."

"The implant is made from the same material as is used in self-dissolving stitches and is therefore known to be safe and reliable. The implant is totally biodegradable and therefore does not have to be removed at the end of the treatment."

EpiTan has already announced that it is also working on a topical delivery form to provide consumers with a choice of how they can take Melanotan – as an implant or topical formulation.

ABOUT THE COMPANY: EpiTan Limited (ASX: EPT) is an emerging biotechnology company with a pre-eminent position on the prevention of DNA & 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®. The company has the exclusive worldwide rights to develop Melanotan, which, like sunlight, stimulates the production of melanin in the skin resulting in a natural tan. It allows a tan to develop without exposure to harmful levels of UV light.

Melanotan is currently in Phase IIb clinical trials at two sites – the Royal Prince Alfred Hospital in Sydney and the Royal Adelaide Hospital. These trials are designed to demonstrate that Melanotan can reduce the incidence of skin damage resulting from harmful exposure to ultra-violet light.

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 other indications such as vitiligo, albinism, psoriasis and various recognised sun allergies such as polymorphous light eruptions (PMLE or sun poisoning) and solar urticaria.

Potential markets worldwide for Melanotan for dermatology purposes are estimated at US$1.5 billion. An even greater market (more than US$5 billion) exists for Melanotan as a new safe (sunless) tanning drug.

ABOUT SOUTHERN RESEARCH: Southern Research Institute, an affiliate of the University of Alabama, at Birmingham, USA, was established in 1941 and has a long reputation for leadership and excellence in drug discovery and development of delivery formulations. Their drug-delivery programs range from feasibility studies, pre-formulation studies, pre-clinical development, scale up and clinical trial material production.

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