

Company Announcement
Sunburn injury drug study
First subjects successfully complete trial

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Melbourne, Australia

EpiTan Limited ("EpiTan") (ASX:EPT) today announced that the first group of subjects in its Phase IIb human "sunburn" trial have now completed the three month study. The trial's key objective is the measurement of the effectiveness of EpiTan's natural tanning drug Melanotan® on increasing skin melanin density and reducing the sunburn injury which results in DNA and skin damage. The trial is being performed at Sydney's Royal Prince Alfred Hospital and the Royal Adelaide Hospital where more than half the projected 80 volunteers have now been recruited. Trial completion is expected in August this year.

The volunteers, of varying skin types, receive controlled levels of UVA and UVB radiation onto a small area of skin resulting in a level of burning similar to spending 30 – 120 minutes in strong sun without sunscreen. A skin biopsy is taken to measure the level of resulting sunburn injury. The volunteers then receive a regime of Melanotan, the same UV radiation exposure, and another skin biopsy.

Professor Ross Barnetson, Head of Dermatology at the Royal Prince Alfred Hospital and principal investigator in this clinical trial, said, "It has been relatively easy to recruit the volunteers so far as quite a lot of people do want to tan. The great advantage of obtaining a tan with Melanotan is that people don't get the sun damage in getting it."

Dr Stuart Humphrey, Clinical Development Manager of EpiTan, said, "We have been extremely encouraged by progress reports and fully expect results to show that sunburn skin damage is markedly reduced following Melanotan treatment."

Dr Wayne Millen, EpiTan's Managing Director, said, "We are excited by this further confirmation of our confidence in Melanotan. We expect to satisfactorily conclude the Phase IIb study in August and are extremely well positioned to be able to move into Phase III clinical trials in 2004. We plan to conduct those trials in Australia and a number of other countries including the USA, Great Britain and in Europe, using a recently developed single dose slow-release implant."

Dr Millen added, "EpiTan is now in a very select group of biotechnology companies with an advanced drug candidate on the road to commercialisation."

ABOUT THE COMPANY: EpiTan Limited (ASX ticker: "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 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.

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Media Release

First Tanning Drug Trial Volunteer Reports “Excellent Results” on Sunburn Protection

Monday 5 May, 2003

A Sydney-based surf lifesaver who has completed his participation in the Phase II human trial into the sunburn-prevention aspects of the natural tanning drug Melanotan® at Sydney's Royal Prince Alfred Hospital has reported “excellent results”.

Adrian (whose surname cannot be divulged due to the strict trial protocol), a competitive surf lifesaver, says he believes the drug has given him a tan and that he has ceased to burn when going out in the sun.

“Since taking Melanotan I have developed a very good tan and am not burning at all when I go out in the sun,” he said. “I used to have quite pale skin, especially on my face and my upper chest but now have developed a healthy tan. It's been excellent.”

Melanotan, like sunlight, stimulates the production of melanin in the skin resulting in a normal tan. Importantly, it allows a tan to develop without exposure to harmful levels of ultraviolet radiation typically received from exposure in the sun or in a solarium. The drug is being developed by Melbourne-based biotechnology company EpiTan Limited and will probably be administered by implant when available commercially.

The trial, being held at Sydney's Royal Prince Alfred Hospital and the Royal Adelaide Hospital, is to measure the effectiveness of Melanotan in reducing sunburn among a group of 80 healthy volunteers. The trial is now at the halfway stage and is scheduled for completion in August.

The volunteers, of varying skin types, receive controlled levels of UVA and UVB radiation onto a small area of skin resulting in a level of burning similar to spending 30 – 120 minutes in strong sun without sunscreen. A skin biopsy is taken to measure the level of resulting sunburn injury. The volunteers then receive a regime of Melanotan, the same UV radiation exposure, and another skin biopsy.

Head of the trial, Professor Ross Barnetson from Royal Prince Alfred Hospital, says he is happy with the progress of the trial. “A number of the volunteers have developed a tan as expected,” he said.

Professor Barnetson says he believes Melanotan could contribute to the reduction of skin cancer in Australia. “Australia has the highest incidence of skin cancer in the world and it is a very expensive problem. I think Melanotan will cut down the incidence of skin cancer in the long term,” he says. “People will always want a tan and the benefit of Melanotan is that they don't get the sun damage before they tan. Melanotan stimulates the melanocytes to produce melanin, so it's a natural function that is being accelerated by this process,

that's the great advantage of this. The only way to get a tan at present is to get the damage first. The market for this drug will certainly stretch beyond Australia to places like the United States and Europe."

Professor Alan Cooper, Head of the Department of Dermatology at Sydney's Royal North Shore Hospital, says: "If people have natural protection that reduces their likelihood of burning, then they will significantly reduce their likelihood of getting skin cancer. This is a tan that is good. Where you can get a tan without UV radiation, then that tan is a safe tan, and it can have protective benefits."

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