

Company Announcement

EpiTan Develops Sustained Release Formulation for Melanotan

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Melbourne, Australia

Drug-development company EpiTan Limited (ASX:EPT) today announced the development of its sustained-release formulation for the melanin inducing drug Melanotan. The new formulation is a result of the strategic collaborative agreement with Southern Research Institute of Birmingham, Alabama, USA, initiated in May 2002.

The new formulation is a small implant designed to be placed under the skin. It is made of the same material that has been used for many years in "self-dissolving" stitches and is therefore known to be safe and reliable. As the implant is totally biodegradable it does not have to be removed at the end of the treatment.

The formulation is a major advancement on the daily injections being used in the company's current Phase IIb clinical trial. Melanotan will be released into the body over a period of time so that the subjects participating in the next clinical trial will need only one injection.

Similar implants, such as Zoladex® (AstraZeneca) for the treatment of prostate cancer, have already been approved for use in Australian and worldwide markets.

Southern Research Institute, an affiliate of the University of Alabama, 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.

EpiTan recently announced that the first of the volunteers in its Phase IIb human "sunburn" trial had been administered Melanotan at Sydney's Royal Prince Alfred Hospital and the Royal Adelaide Hospital. The trial is to measure the effectiveness of Melanotan in reducing sunburn among a group of eighty healthy volunteers.

"The successful development of the sustained release implant builds on EpiTan's successes of its completed Phase I/II trial and the recent commencement of the Phase IIb clinical trial," said Dr Wayne Millen, EpiTan's Managing Director. "The fact that this type of sustained-release formulation has already been proven to work with Melanotan in our preclinical studies will accelerate the development of this product towards the completion of our clinical trial program."

"Southern Research Institute's capabilities were extremely well suited to our drug-delivery development program," said Mr Michael Kleinig, EpiTan's Pharmaceutical Development Manager. "The group's expertise and experience has enabled the development of the implant on time and to budget."

ABOUT EPITAN: EpiTan Limited is an emerging biotechnology company with a focus on skin protection, headquartered in Melbourne, Australia. The company has the exclusive worldwide rights to develop its unique leading drug candidate Melanotan.

Melanotan, like sunlight, stimulates the production of melanin in the skin resulting in a tan. It allows a tan to develop without exposure to harmful levels of ultraviolet (UV) light.

Melanin is the body's natural defence mechanism against skin damage resulting from exposure to sunlight and UV radiation, essentially acting like an internal sunscreen. EpiTan believes Melanotan may assist in reducing skin damage from sun exposure and thus the incidence of skin cancer.

Research shows that people with high levels of melanin have a far lower incidence of skin cancer than those with fair skin. For example, skin cancer rates among white Americans are 100 times higher than those among the African-American population.

Melanotan is a synthetic analogue of the body's own tanning hormone α -MSH (alpha-MSH). Melanotan however is 1000 times more active and has a longer duration in the body than the natural hormone.

EpiTan is listed on the Australian Stock Exchange.

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