



ANTISENSE THERAPEUTICS

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ATL1101 for Psoriasis: Approval for “Proof of Concept” clinical trial

Antisense Therapeutics Limited is pleased to announce that its application to conduct a “proof of concept” study of ATL1101 in patients suffering from psoriasis has been approved by the Institutional Review Board and the Ethics Committee of the Clinical Research Organisation that will conduct the study. Patient recruitment for the study is currently underway.

ATL1101 is a second generation antisense drug designed to block the synthesis of the IGF-1 receptor, a protein involved in the regulation of cell overgrowth in psoriasis. ATL1101 is being developed as a cream for the topical treatment of mild to moderate cases of psoriasis.

The trial will take place in Adelaide under the management of CMAX, a Division of the Institute of Drug Technology Australia Limited.

Proof of Concept – Microplaque Assay

In the “proof of concept” clinical trial (also referred to as Small Plaque Assay or Microplaque Assay), a relatively small quantity (100 μ L) of ATL1101 cream will be applied to areas of psoriatic skin in patients, once every two days, over a one month period.

A comparison will be made against a placebo cream (cream without the active agent ATL1101), and also against some reference cream products that are currently marketed as prescription medications for treatment of psoriasis.

The patients will be monitored over the duration of the trial, and on completion of dosing, for signs of response and improvement in their skin condition. The final evaluations will include clinical assessments, as well as assessments of laboratory indices of psoriasis in psoriasis skin samples (punch biopsies).

The primary end point will be a clinical assessment of the treated skin areas using a severity index score. The trial will be double-blinded, placebo-controlled, randomised, and two concentrations of ATL1101 cream will be evaluated in 14 psoriasis patients with mild to moderate severity of the disease.

Typically a drug’s activity is not established until completion of Phase II clinical trials. However, a “proof of concept” study of ATL1101 can be undertaken relatively inexpensively for a disease such as psoriasis, unlike for many other diseases, which will provide early evidence of activity. While the “proof of concept” study will not replace the requirement to undertake formal (Phase I, II and III) human clinical trials, if early indications of the drug’s effectiveness are shown, the company will have increased confidence in the prospects for successful commercial development of ATL1101 and appropriate data to pursue potential early partnering opportunities.

The clinical trial is expected to be completed in the second quarter of 2005 and results reported in the third quarter of 2005.

The Psoriasis project is supported by a Commonwealth Government R&D Start grant of \$1.1 million.

Psoriasis is a chronic, non-contagious skin disorder, which affects 2% of the population. While the precise cause of psoriasis is unknown, it is thought to be triggered by an immune system defect leading to excessive skin cell division. Severity varies, with around 75% of psoriasis cases classified as "mild to moderate", and the remainder classified as "moderate to severe". Topical therapies are first-line treatments for mild to moderate cases of the disease. The worldwide market for psoriasis treatments was more than US\$500 million in 2000 and there is an acknowledged unmet medical need for more effective and safer treatments. The market is forecast to grow to beyond US\$2 billion with the emergence of new therapies.

***Antisense Therapeutics Limited (ASX: ANP)** is an Australian publicly listed biopharmaceutical drug discovery and development company. ANP's mission is to create, develop and commercialise novel antisense pharmaceuticals for large unmet markets. Its two most advanced projects target Multiple Sclerosis (ATL1102), and Psoriasis (ATL1101).*

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