



ANTISENSE THERAPEUTICS

4 October 2005



Securities and Exchange Commission
Judiciary Plaza
450 Fifth Street
Washington DC 20549
UNITED STATES OF AMERICA

SUPPL

Dear Sir/Madam

Re: Antisense Therapeutics Limited

Please find attached copy of an announcement lodged with the Australian Stock Exchange (ASX):

Date of Announcement/Lodgement	To:	Title	No of pages
4 October 2005	ASX	Results of ATL1101 Proof of Concept Study in psoriasis patients	2

Yours sincerely

Kathryn Andrews
Chief Financial Officer

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ANTISENSE THERAPEUTICS

4 October 2005

Results of ATL1101 “Proof of Concept” study in psoriasis patients

Antisense Therapeutics Limited announced today results from its “proof of concept” study of ATL1101 in patients with psoriasis.

Although typically a drug’s activity is not established until completion of Phase II clinical trials, this “proof of concept” study approach was undertaken to allow the company to make an early assessment of activity in patients with psoriasis in a timely and cost effective manner before having to commit to more expensive Phase I and II trials.

The primary endpoint of this “proof of concept” clinical trial (also known as a micro-plaque assay) was a clinical assessment of the treated skin areas using a severity index score – Local Plaque Severity Index (LPSI).

- In this study ATL1101 demonstrated activity in the psoriasis patients and was well tolerated. Both strengths of the ATL1101 cream which were trialled (1% and 10%) showed improvement in the LPSI score compared to placebo, reaching statistical significance for the 1% cream. The ATL1101 1% cream formulation improved the LPSI score by 13% above placebo ($p=0.03$, statistically significant). The 10% cream formulation of ATL1101 showed an 11% improvement over placebo, though did not reach statistical significance in this study ($p=0.09$, positive trend).
- Laboratory investigations of the skin samples were consistent with ATL1101 having an effect on epidermal hyperproliferation (over growth of the top layer of the skin), which is a feature of psoriasis and other common skin disorders such as ichthyosis, keratosis, and dermatitis.

As another primary endpoint of the study, ATL1101 was also compared to two currently marketed prescription medications for the treatment of psoriasis (calcipotriol and betamethasone). As would be expected from drugs currently on the market, both improved the LPSI score versus placebo, and were more effective than the ATL1101 cream in the study (calcipotriol and betamethasone; 36% and 44% above placebo respectively; $p<0.001$. In comparison, ATL1101 1% cream formulation was 13% above placebo; $p=0.03$).

Next steps

While ATL1101, in its current formulation, has shown an effect in this initial investigation into the drug’s efficacy in patients with psoriasis, it was less effective than the reference products in this study. It is important to note that ATL1101 is at an early stage of development, and therefore has not been as fully elucidated or optimised as the reference products. Both reference compounds have been marketed for many years for the treatment of psoriasis, however both have short-comings as treatments based on their tolerance and general side-effect profiles.

The company plans to assess, with the assistance of appropriate experts, if ATL1101 is likely to show improved efficacy in a larger, longer term clinical trial, or if the compound’s activity may be improved through possible formulation enhancement. It is plausible that combining the product with another agent may increase the usefulness or utility of ATL1101, not only in psoriasis, but other skin disorders.

The Company will assess these options, and if appropriate, will explore development opportunities for ATL1101 with relevant pharmaceutical companies.

About the Proof of Concept Study

ATL1101 is a second generation antisense drug to the IGF-I receptor, under development as a cream for the topical treatment of mild to moderate cases of psoriasis.

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

The trial was a double-blinded, placebo-controlled, within patient randomised study. Two concentrations of ATL1101 cream were evaluated in 11 psoriasis patients with mild to moderate severity of the disease. Comparisons were made against a placebo cream (cream without the active agent ATL1101), and also against reference cream products that are currently marketed as prescription medications for treatment of psoriasis.

The study was conducted under two settings: occluded (treatment covered by a dressing or bandage) and non-occluded (no dressing). The results reported above relate to the conventional micro-plaque assay design which is performed under occlusion. In the non-occluded setting no treatment, including the reference formulation, reached statistical significance.

Final evaluations included clinical assessments, as well as assessments of laboratory indices of psoriasis in psoriasis skin samples (punch biopsies).

The trial took place in Adelaide under the management of CMAX, a Division of the Institute of Drug Technology Australia Limited. The Psoriasis project is supported by a Commonwealth Government R&D Start grant of \$1.1 million.

***About ATL1101:** ATL1101 is a second generation antisense drug designed to silence, or suppress, the gene for the insulin-like growth factor-I receptor (IGF-IR). IGF-IR is understood to play a pivotal role in cell division (growth, proliferation), prompting its investigation as a therapeutic target in diseases of excessive cell division (hyperproliferative disorders). Our research partner, Murdoch Childrens Research Institute, demonstrated the potential of antisense targeting of IGF-IR in laboratory and animal models of the skin disease psoriasis. ATL1101 is under clinical investigation at ANP as a topical cream treatment for mild to moderate cases of psoriasis.*

***About Psoriasis:** 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, both of which are in clinical development, target Multiple Sclerosis (ATL1102) and Psoriasis (ATL1101).*

ANP plans to commercialise its pipeline via licensing/collaboration agreements with major biotechnology and pharmaceutical companies.

ANP's major shareholders include Circadian Technologies Limited and Isis Pharmaceuticals Inc

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