ANTISENSE THERAPEUTICS

31 August 2005

Antisense Therapeutics to submit application to restart ATL1102 Phase IIa trial in MS patients

- Medical Advisory Board determines that "ATL1102 appears to have significant potential as a therapeutic agent in treating MS" and recommends that development should continue
- Board of Directors accept recommendation of Medical Advisory Board to continue development of ATL1102 in MS and restart the Phase IIa trial currently on hold in Germany
- Trial program has been amended to incorporate all modifications recommended by the Medical Advisory Board
- Application to restart Phase IIa trial to be submitted to Institutional Review Board and Ethics Committee of primary trial centre
- Study to commence once approval received from trial regulators

The Directors of Antisense Therapeutics have accepted and agree with the recommendation of the Medical Advisory Board (MAB) to continue the development of ATL1102 as a treatment for patients with relapsing remitting Multiple Sclerosis. Following its formal review, the advisory board recommends that the Phase IIa trial currently on hold in Germany, be restarted with additional safety monitoring of patients.

While the current market for MS drugs is large (in excess of US$4 Billion per annum) there continues to be a high demand for improved MS therapies. The Directors believe ATL1102 could have significant commercial potential should clinical investigations show the compound to be suitably safe and effective.

Background

Antisense Therapeutics established and convened the MAB after it voluntarily halted its Phase IIa trial of ATL1102 in MS patients in light of the safety issues associated with Biogen Idec and Elan Corporation's multiple sclerosis drug Tysabri®.

In the MS clinical trials of Tysabri® two patients were reported to have developed a specific type of viral infection (JC virus) leading to the rare but frequently fatal disease of the central nervous system, progressive multifocal leukoencephalopathy (PML).

While ATL1102, an antisense inhibitor, is a different drug from Tysabri®, a monoclonal antibody, and thereby works by a different mechanism, the relevance of the Tysabri® issue to Antisense Therapeutics is that ATL1102 is designed to target the same immune system protein (VLA-4) as Tysabri®.

The objective of the Medical Advisory Board, comprising relevant independent experts, was to consider the potential development paths for ATL1102 in MS, including the possible restart of the Phase IIa program.

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Medical Advisory Board – Key Recommendations

The recommendations provided by the MAB to the Board of Antisense Therapeutics Ltd are summarised below. Specific details are outlined in the attached formal recommendation document from the Advisory Board

- ATL1102 appears to have significant potential as a therapeutic agent in relapsing-remitting MS, and therefore its development should continue in earnest.
- The risk of PML developing in patients in the proposed 8-week dosing trial is considered minimal. However, to further minimize any risk potential, and to obtain a fuller understanding of the drug's safety profile with respect to its potential to cause PML, all patients enrolled into the trial should undergo regular monitoring for possible activation of the JC virus, for the entire duration of the trial. To assist in this regular monitoring process Antisense Therapeutics should establish an independent Drug Safety Monitoring Board that will assess all safety results arising from the study, including virus monitoring data.
- Patient enrollment criteria should be strictly followed for those who may have previously received immune-modulating drugs. This is to eliminate any risk of a synergistic adverse effect of drug combinations, as it would appear that the two patients who developed PML in the Tysabri® MS trial received a combination of two immune-modulating drugs.

The recommendations of the Advisory Board to address the potential safety issues related to JC viral activation and the appearance of PML reported in the Tysabri® trials have been incorporated by the Company into the clinical trial program for ATL1102 and provide the Company with increased confidence that appropriate safety measures are in place to safeguard patients in the trial.

Apart from these changes, the trial design and clinical assessment objectives remain the same for the Phase IIa trial as reported by the Company when this trial was first initiated in December 2004.

Application to be submitted to restart Phase IIa trial

An application to restart the Phase IIa trial is to be submitted to the Institutional Review Board (IRB) and Ethics Committee (EC) of the University of Essen, the primary site for the Phase IIa trial. Should the IRB and EC approve the restart of the trial, the Company will then lodge the same application with the IRB and EC's of the other 7 trial centres. The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte: BfArM) in Germany will also be notified, who will have the authority to raise questions or issues prior to the restart of the trial.

Upon receipt of all relevant approvals from the trial regulators, the Company will be in a position to initiate the trial with the commencement of patient enrolment. The Company will need to formulate additional ATL1102 compound to complete the trial. Manufacture will commence once requisite regulatory approvals are in place.

The Company is hopeful that, subject to receiving these approvals, the trial may recommence before the end of the year. The Company will be in a position to provide guidance on forecast completion dates for the trial following the necessary regulatory approvals.

About ATL1102 for MS

ATL1102 is a second generation antisense inhibitor of CD49d, a subunit of VLA-4 (Very Late Antigen-4), and is currently in development as a treatment for MS. In inflammation, white blood cells (leukocytes) move out of the bloodstream into the inflamed tissue, for example, the CNS in MS, and the lung airways in asthma. The inhibition of VLA-4 may prevent white blood cells from entering sites of inflammation, thereby halting progression of the disease. Antisense inhibition of VLA-4 has demonstrated positive effects in a number of animal models of inflammatory disease including MS. .

About Antisense Therapeutics Limited

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, which are both 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, Isis Pharmaceuticals Inc and Queensland Investment Corporation.

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