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Dosing Commences in Final Stage of Clinical Trial of ATL1103

- **Single ascending dose stage of Phase I trial of ATL1103 completed**
- **Multiple dose stage of the trial commences with first subjects dosed**
- **Reporting of trial results anticipated by end of this year - ahead of previous expectations**

Antisense Therapeutics Limited (ASX:ANP) is pleased to advise that the dosing of subjects has now commenced in the final stage of the Phase I trial of the Company's growth hormone receptor (GHr) targeting drug ATL1103. The multiple dosing stage follows the completion of the initial single ascending dose stage of the trial in which 24 subjects were administered four dose levels of ATL1103 as a single injection starting at 25mg and escalating to 75, 250 and 400mg or placebo. No serious adverse events were reported in this stage of the trial with general safety observations appearing to be in line with those reported in the clinical testing of other 2nd generation antisense drugs at similar doses.

Based on a review by the Data Monitoring Committee of the safety data from the single ascending dose stage, the 250mg dose level has been selected for the multiple dose component of the study. The Company feels this is an appropriate dosing level from which to start the testing of multiple doses of ATL1103 based on the broader clinical experience with 2nd generation antisense drugs where this level of dosing has shown to be both tolerated and clinically active. Multiple dosing will be undertaken in 12 subjects and will consist of six subcutaneous (under the skin) doses of either ATL1103 or placebo administered on Days 1, 3, 5, 7, 14 and 21. Subjects will be monitored out to Day 35.

The ATL1103 Phase I trial is a randomized, placebo controlled, double blind study of single ascending doses and multiple doses of ATL1103 in healthy adult male subjects aged between 18 and 45 years. The primary objective of the study is to assess the safety, tolerability and pharmacokinetics of ATL1103 administered by subcutaneous injection.

A secondary, but important, objective of this study is to obtain data on the effect of ATL1103 on IGF-I levels in the blood of the trial subjects. Reducing elevated levels of serum IGF-I to normal is the therapeutic endpoint in the treatment of the growth disorder acromegaly, and reducing the effects of IGF-I has a potential role in the treatment of diabetic retinopathy, nephropathy and certain forms of cancer. While the Phase I trial is not primarily designed to assess the efficacy of ATL1103, which will occur in larger and longer term clinical trials in patients, the Company does expect that the monitoring of serum IGF-I in subjects in this multiple dose stage of the study should provide a useful guide or indication of the potential effectiveness of ATL1103 as a treatment for these medical conditions.

The ATL1103 Phase I trial remains 'blinded' - a procedure that prevents study subjects, care givers and outcome assessors from knowing whether drug or placebo has been administered to a subject(s). Accordingly definitive details on the outcomes of the trial will not been known until the study is un-blinded and all the clinical trial data is entered into the trial data base and the database locked for statistical analysis. Results of this analysis will then be reported to the market. The Company currently anticipates that this process will be finalised in time for the results to be reported by the end of this year, which is ahead of previous expectations.

As previously advised, ANP is also undertaking its ATL1103 cancer experimental program in parallel with the conduct of the Phase I clinical trial outlined above. The cancer experimental program has

been established with leading expert Dr Pinchas Cohen MD whose laboratory team will look at ATL1103's effect on exploratory markers of cellular activity relevant to cancer in the serum of the subjects from the multiple dose stage of the Phase I trial of ATL1103. This data will assist in determining the potential of ATL1103 in the new application of preventing certain forms of cancer in high risk individuals.

Background Information

ATL1103 is a second generation antisense drug designed to block growth hormone receptor (GHr) expression thereby reducing levels of the hormone insulin-like growth factor-I (IGF-I) in the blood and is a potential treatment for diseases associated with excessive growth hormone and IGF-I action. These diseases include acromegaly, an abnormal growth disorder of organs, face, hands and feet, diabetic retinopathy, a common disease of the eye and a major cause of blindness, diabetic nephropathy and some forms of cancer. Acromegalic patients are known to have significantly higher blood IGF-I levels than healthy individuals. Reduction of these levels to normal is accepted by clinical authorities as the primary marker of an effective drug treatment for the disease. GHr is a clinically validated target in the treatment of acromegaly. In the case of diabetic retinopathy, published clinical studies have shown that treatments producing a reduction in IGF-I levels retarded the progression of the disease and improve vision in patients. Scientific papers have been published on the suppression of blood IGF-I levels in mice (Tachas et al., 2006, J Endocrinol 189, 147-54) and inhibition of retinopathy in a mouse retinopathy model (Wilkinson-Berka et al., 2007, Molecular Vision 13, 1529- 38;) using an antisense drug to the GHr. ANP have also previously reported that ATL1103 suppressed circulating levels of IGF-I in primates and that toxicology studies had been completed supporting the Company's plans to move ATL1103 into clinical development. ATL1103 commercialisation is covered by patents to at least 2024, with the potential for extensions up to 2029 in some countries and 2030 in the US.

Antisense Therapeutics Limited (ASX: ANP) is an Australian publicly listed biopharmaceutical drug discovery and development company. Its mission is to create, develop and commercialise second generation antisense pharmaceuticals for large unmet markets. ANP has 4 products in its development pipeline. ATL1102 (injection) has successfully completed a Phase II efficacy and safety trial, significantly reducing the number of brain lesions in patients with multiple sclerosis. ATL1103 is a second-generation antisense drug designed to block GHr production and thereby lower blood IGF-I levels and is in clinical development as a potential treatment for growth and vision disorders. ATL1102 (inhaled) is at the pre-clinical research stage as a potential treatment for asthma. ATL1101 is a second-generation antisense drug at the pre-clinical stage being investigated as a potential treatment for prostate cancer.

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