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ATL1103 Acromegaly Phase II Trial Recruitment Completed

- 24 patients now recruited into the trial
- 16 patients have completed dosing
- No treatment related patient withdrawals or serious adverse events
- Results to be reported mid 2014

Antisense Therapeutics Limited ("ANP") is pleased to report that 24 acromegalic patients have been successfully enrolled and randomized to one of the two treatment regimens of dosing in the Phase II trial of ATL1103 for the growth disorder, acromegaly. This satisfies the necessary patient numbers proposed for the trial.

Following from the positive results achieved from the interim analysis of the serum Insulin-like Growth Factor-I (sIGF-I) data from the 8 patients who had completed the full 13 weeks of dosing in the trial, a further 8 (16 in total) have now completed dosing. Notably to date no patients dosed with ATL1103 have withdrawn from the study nor have there been any reports of serious adverse events identified as treatment related.

With patient enrollment now complete, ANP anticipates reporting the results of the statistical analysis of the sIGF-I data from all patients by mid 2014. Reducing sIGF-I levels is the primary marker of ATL1103 activity in this trial as acromegaly patients have elevated sIGF-I levels compared to the normal population, and reduction of sIGF-I to within a normal range in a significant proportion of patients is the goal in Phase III registration trials for acromegaly treatments.

Mark Diamond, Managing Director and CEO of Antisense Therapeutics said "Completion of patient recruitment into a clinical trial is a major milestone and especially in the case of trials involving patients with a rare or orphan status disease such as acromegaly and so we are very pleased to report this significant achievement. We now look forward to completing the dosing in all patients and to the reporting of the results."

ATL1103 Phase II trial is a randomised, open-label, parallel group study of the safety, tolerability, pharmacokinetics and efficacy of two subcutaneous dosing regimens of ATL1103 in 24 adult patients with acromegaly dosed with ATL1103 for 13 weeks (3 months) with two months of follow up. Two ATL1103 dosing regimens are being tested (a) 200 mg 3 times in the first week then once weekly thereafter (200 mg/week) or (b) 200 mg 3 times in the first week then twice weekly thereafter (400 mg/week). The primary endpoints or main purposes of the trial as listed on the trial protocol are (i) to evaluate the safety and tolerability of ATL1103 in patients with acromegaly, and (ii) to evaluate the single dose and multiple dose pharmacokinetic profiles of ATL1103 via the subcutaneous route in patients with acromegaly. A secondary, but important endpoint that is also on the trial protocol is the evaluation of ATL1103's effect on serum insulin like growth factor I (IGF-I) levels in patients. The secondary endpoint is the average percentage reduction in serum IGF-I levels at the end of treatment compared to baseline levels for each of the two dosing regimens used in the Phase II study.

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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, a common disease of the kidney and major cause of kidney failure, 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 reported that ATL1103 suppressed circulating levels of IGF-I in primates. In a Phase I study in normal volunteers, ATL1103 was assessed as being safe and well tolerated, while also demonstrating a preliminary indication of drug activity including suppression of IGF-I and the target GHR (growth hormone binding protein) levels. 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.

Acromegaly is a serious chronic life threatening disease triggered by excess secretion of growth hormone (GH) by benign pituitary tumours. Oversupply of GH over stimulates liver, fat and kidney cells, through their GH receptors, to produce excess levels of (IGF-I) in the blood manifesting in abnormal growth of the face, hands and feet, and enlargement of body organs including liver, kidney and heart. The primary treatments for acromegaly are to surgically remove the pituitary gland and/or drug therapy to normalize GH and serum IGF-I levels. In North America and Europe there are approximately 85,000 acromegaly patients with about half requiring drug therapy. Cost of drug therapy ranges from approximatelyA$30,000/annum to over A$60,000/annum depending on the treatment.

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 5 products in its development pipeline that it has in-licensed from Isis Pharmaceuticals Inc., world leaders in antisense drug development and commercialisation - ATL1102 (injection) which has successfully completed a Phase II efficacy and safety trial, significantly reducing the number of brain lesions in patients with multiple sclerosis and is also in clinical development as a potential stem cell mobilisation agent, ATL1103 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 other GH-IGF-I disorders, ATL1102 (inhaled) which is at the pre-clinical research stage as a potential treatment for asthma and ATL1101 a second-generation antisense drug at the pre-clinical stage being investigated as a potential treatment for cancer.

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