22 December 2014

Ethics Committee Approves Higher Dose ATL1103 Study in Acromegaly Patients

Antisense Therapeutics (ASX:ANP or "the Company") is pleased to advise that it has received Ethics Committee approval to conduct a clinical trial of ATL1103 at a dose higher than the recently completed Phase II acromegaly study. It is anticipated that the study will commence recruitment in early 2015 once trial arrangements are finalised including the acknowledgement of Clinical Trial Notification from the Therapeutic Goods Administration (TGA). More definitive timing for the conduct and completion of the study together with details relating to the study design will be provided in due course.

As reported previously (9 December 2014), the planned study is a small, higher dose (600mg/week) study in four acromegaly patients using existing drug supplies to support the use of a higher dose in Phase III trials for dose escalation in patients with more active disease. The clinical data generated to date indicate that a larger dose of ATL1103 administered for longer in Phase III trials should be sufficiently well tolerated and result in normalisation of IGF-I in a significant number of patients with acromegaly. This relatively low cost study is eligible for the 45% R&D tax incentive.

As previously advised, ANP plans to commence this additional trial in parallel with the Company's partnering process as this study will add further value to ATL1103 ahead of the Phase III registration trials which would be conducted with a pharmaceutical partner.

Contact Information:

Website: www.antisense.com.au
Managing Director: Mark Diamond +61 (0)3 9827 8999
Australian Investor/Media: Annabel Murphy+61 (0)2 9237 2800; amurphy@buchanwe.com.au

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 4 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 relapsing-remitting multiple sclerosis (RRMS) , ATL1103 drug designed to block GHr production which in a Phase II clinical trial, successfully reduced blood IGF-I levels in patients with the growth disorder acromegaly, 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.