22 January 2014

ATL1102 for Stem Cell Mobilisation Trial Approval

Antisense Therapeutics (ASX:ANP) is pleased to advise that it has now received approval to conduct a Phase I Stem Cell Mobilisation Human Proof of Concept trial of ATL1102. Nucleus Network, one of Australia's leading Clinical Research Organisations, is to conduct the trial at its clinical trial unit located at the Alfred Hospital, Melbourne, Victoria.

The mobilisation of stem cells from the bone marrow into the blood is an important medical procedure used to improve outcomes for patients undergoing chemotherapy to treat certain cancers.

The ATL1102 Stem Cell Mobilisation (SCM) Proof of Concept trial will be a randomized, open label study to assess safety, tolerability, pharmacokinetics and pharmacodynamics, including effects on the release of hematopoietic stem cells, of ATL1102 dosed over 5 days (given on day 1, 3 and 5) alone or in combination with Granulocyte Colony-Stimulating Factor (G-CSF) in 10 healthy volunteers.

The study is to commence in Q'1 2014 and be completed in time for the results to be reported by the middle of 2014. The development of ATL1102 for the SCM application will be a relatively inexpensive and quick clinical program given it is to be an acute treatment of 1 week drug administration. Furthermore, given the study is to be conducted in Australia, ANP expects to benefit from the R&D tax credit where 45% of the costs of the study are potentially redeemable.

Mark Diamond, CEO and Managing Director of Antisense Therapeutics said, "We are very pleased to have received approval for this Proof of Concept study designed to confirm the potential of ATL1102 in the SCM application and we look forward to the trial commencement and reporting the results mid-year. This adds another key project value inflection point, along with those for ATL1103 for acromegaly and ATL1102 for Multiple Sclerosis, anticipated by the Company within the next 6 months."

About Stem Cell Mobilisation in Cancer treatment: stem cell mobilization and transplantation is a medical procedure used to improve clinical outcomes for patients undergoing chemotherapy to treat cancer. Some chemotherapy has toxic effects on bone marrow, so hematopoietic stem cells are collected from the blood of the patient – or from a donor's blood – before the patient receives chemotherapy. These collected stem cells are then stored and given back later to replace those lost during chemotherapy. There are normally only a small number of stem cells in the blood, so stem cell mobilization agents are used to increase this number before stem cell collection from a donor or more typically a patient. Granulocyte colony-stimulating factor (G-CSF) is the main agent used for hematopoietic stem cell mobilization. While G-CSF is successful in mobilizing hematopoietic stem cells, and there are additional complimentary mobilizing therapies, there is an opportunity to improve on the level of stem cell release achieved with current therapies.

ATL1102 is a second generation antisense inhibitor of CD49d, a subunit of VLA-4 (Very Late Antigen-4). In inflammation, white blood cells (leukocytes) move out of the bloodstream into the inflamed tissue, for example, the Central Nervous System (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 slowing progression of the disease. VLA-4 is a clinically validated target in the treatment of MS. Antisense inhibition of VLA-4 has demonstrated positive effects in a number of animal models of inflammatory disease including MS with the MS animal data having been published in a peer reviewed scientific journal. ATL1102 was previously shown by Antisense Therapeutics to be highly effective in reducing MS lesions in a Phase IIa clinical trial in MS patients. The company has also lodged an International patent application on ATL1102 based on preliminary data in mice and humans supporting its' potential application as a stem cell mobilization agent for use in combination with G-CSF to improve the level of stem cell release achieved with G-CSF alone.

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 multiple sclerosis (MS) and has entered clinical development as a 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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