

7 April 2014

ATL1102 for MS – US Patent Allowance Extends Strong IP Position

- **Strengthened IP position, development to date and recent toxicology results support partnering and commercialisation plans**

Antisense Therapeutics Limited (“ANP” or “the Company”) is pleased to announce that the US Patent Office has allowed US Patent 61/132973 entitled “Methods for treating multiple sclerosis (MS) using antisense oligonucleotides”. This covers the use of the ATL1102 compound to reduce brain lesions in relapsing-remitting multiple sclerosis (RRMS), and progressive forms of MS including secondary progressive MS (SPMS) and primary progressive MS (PPMS) and at the desired doses, until 23 June 2029, with potential for an extension of up to five years.

The new US patent forms part of the Company’s extensive portfolio of intellectual property protecting ATL1102 and its uses in MS. This includes a granted United States patent US 8,415,314, Australian Patent 2009271678 and corresponding applications in Europe, Japan and Canada, covering the use of ATL1102 in the treatment of the most common form of the disease, RRMS. The annual sales for drugs treating RRMS in 2013 were approximately US\$14 billion.

This new US patent adds important commercial value to ATL1102 and further supports the Company’s partnering plans with a recent publication showing that reduction in brain lesions with Tysabri® a monoclonal antibody drug to the VLA-4 receptor (same target as ATL1102), can benefit patients with progressive forms of MS¹. There is only one approved compound in the US, Novantrone®, for use in secondary (chronic) progressive MS which can only be used for two to three years because of safety limitations.

The patent also claims all desired doses of ATL1102 for use in these treatments including those described in the pharmacometric modeling² for dosing in the next clinical trial being a six month Phase IIb study. The modelling recommended doses that on a cumulative basis are equivalent to those tested in the recent toxicology study. ANP announced to the ASX on 1st April 2014, major findings from an ATL1102 chronic monkey study and plans to meet with the FDA in Q3’2014 at a proposed pre-Investigational New Drug meeting regarding the study design for a Phase IIb MS trial. The Company expects these interactions with the FDA to run in parallel to those with potential pharmaceutical partners.

Antisense Therapeutics CEO and Managing Director Mark Diamond said;

“We estimate that over \$30 million has been spent on the development work undertaken to date by the Company and its previous commercialisation partner in progressing ATL1102 in the MS indication towards moving the compound into a Phase IIb trial. We are delighted that the recent findings from the toxicology study provide the opportunity for us to capitalise on this investment and this together with our US patents will underpin our partnering and commercialisation plans.”

1. Christensen RJ et. al. Neurology. 2014 March 28 [Epub ahead of print] “ Natalizumab in progressive MS: Results of an open-label, phase 2A, proof-of-concept trial”.

2. Guzy S and Bauer R. “Pharmacometrics in Drug Development: Concepts and Applications” In: F. W. Faltin, R. S. Kenett and F. Ruggeri editors, Statistical Methods in Healthcare John Wiley & Sons, Ltd, Chichester, UK. 2012; Chapter 3:56-77.

Glossary: Pharmacometrics - is an emerging science defined as the science that quantifies drug, disease and trial information to aid efficient drug development and/or regulatory decisions.

Background Information

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 relapsing-remitting multiple sclerosis (RRMS) 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.

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 the Company to be highly effective in reducing MS lesions in a Phase II clinical trial in RRMS patients. The efficacy outcomes from this study were viewed to be as good as, if not superior to, those achieved with Tysabri® (natalizumab) the monoclonal antibody drug to the VLA-4 receptor (same target as ATL1102), at the 3 month time point in its clinical development. Tysabri® is linked to JC virus activation causing a potential lethal viral brain infection known as progressive multi focal leukoencephalopathy (PML) The company anticipates that ATL1102 could be as potent as Tysabri® (2013 sales - US\$1.67 billion) but potentially safer (possibly not causing PML), cheaper to manufacturer, and more conveniently (self administered).

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