

24 April 2017

## **ATL1102 for Multiple Sclerosis – Phase IIb Investigational New Drug (IND) Submission**

Antisense Therapeutics (“ANP” or the “Company”) has initiated the process for submission of the ATL1102 for Multiple Sclerosis (MS) Phase IIb IND application with documentation being provided to its Regulatory Agent in the US who, on the Company’s behalf, will submit the IND application to the US Food and Drug Administration (FDA). This submission process is expected to be completed in May. Following the IND submission, the Company must wait 30 calendar days for the FDA review.

The Company’s IND application is for a Phase IIb trial in 195 R-MS (both RR and SPMS) patients. As previously advised, ANP is seeking to secure non-dilutive funding for the conduct of the Phase IIb trial from a US Federal Agency (Agency). ANP has submitted its clinical study synopsis for the Phase IIb study and is awaiting the Agency’s approval to lodge its full award grant application. IND clearance is required for such grant funding.

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### **About Antisense Therapeutics Limited**

Antisense Therapeutics Limited 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. Antisense Therapeutics has 4 products in its development pipeline that it has in-licensed from Ionis Pharmaceuticals Inc. (formerly Isis Pharmaceuticals Inc.), a world leader 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 targeting the growth hormone receptor which in a Phase II clinical trial, successfully reduced blood IGF-1 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.

### **About Multiple Sclerosis (MS)**

MS is a life-long, chronic disease that progressively destroys the central nervous system (CNS). It affects approximately 400,000 people in North America and more than 2 million worldwide. It is a disease that affects more women than men, with onset typically occurring between 20 and 40 years of age. Symptoms of MS may include vision problems, loss of balance, numbness, difficulty walking and paralysis. In Australia MS affects over 20,000 people. **Relapsing-Remitting MS (RR-MS):** People with this type of MS experience clearly defined attacks of worsening neurologic function. These attacks—which are called relapse or exacerbations—are followed by partial or complete recovery periods (remissions), during which no disease progression occurs. Approximately 85% of people are initially diagnosed with relapsing-remitting MS. **Secondary-Progressive MS (SP-MS)** occurs when after an initial period of relapsing-remitting MS, many people develop a secondary-progressive disease course in which the disease worsens more steadily, with or without occasional flare-ups, minor recoveries (remissions), or plateaus. Before the disease-modifying medications became available, approximately 50% of people with relapsing-remitting MS developed this form of the disease within 10 years. The market for drugs treating RR-MS has been valued at more than USD\$20 billion. There are limited treatment options for SP-MS patients. The market potential for SP-MS treatments has been estimated at US\$7billion.

### **About ATL1102**

ATL1102 is an antisense inhibitor of CD49d, a subunit of VLA-4 (Very Late Antigen-4). Antisense inhibition of VLA-4 expression has demonstrated activity in a number of animal models of inflammatory disease including asthma and MS with the MS animal data having been published in a peer reviewed scientific journal. ATL1102 was shown to be highly effective in reducing MS lesions in a Phase IIa clinical trial in RR-MS patients. The ATL1102 Phase IIa clinical data has been published in the medical Journal *Neurology* (Limmroth, V. et al *Neurology*, 2014; 83(20): 1780-1788)