

## ATL1102 for Multiple Sclerosis – Phase IIb Investigational New Drug (IND) Application Submitted to the FDA

Antisense Therapeutics ("ANP" or the "Company") wishes to advise that the ATL1102 for Multiple Sclerosis (MS) Phase IIb IND application has been submitted to the US Food and Drug Administration (FDA) for its 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. IND clearance is required for receipt of such grant funding.

The ATL1102 Phase IIb IND application was composed of over 24,000 pages of ATL1102 information and data that required specific formatting and critical review by the Company's US Regulatory Agents to ensure compliance with the FDA requirements for electronic IND submission.

Mark Diamond, CEO of Antisense Therapeutics said; "We are pleased to have reached this significant milestone in the development of ATL1102 for MS and look forward to the prospect of positive outcomes following the FDA's review".

Details on the IND process are available on the FDA website:

https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/ approvalapplications/investigationalnewdrugindapplication/default.htm

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**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. The products in ANP's development pipeline are in-licensed from Ionis Pharmaceuticals Inc., world leaders in antisense drug development and commercialisation. ATL1102 (injection) 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 successfully reduced blood IGF-I levels in Phase II clinical trials in patients with the growth disorder acromegaly.

**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 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)