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ATL1102 for Multiple Sclerosis – Development & Grant Funding Progress Update

Antisense Therapeutics (“ANP” or the “Company”) provides the following update on ATL1102 for Multiple Sclerosis (MS).

Phase IIb Investigational New Drug (IND) Submission / Award Grant Application

The Company’s IND application for a Phase IIb trial in 195 MS patients is on track for submission to the US Food and Drug Administration (FDA) by April 2017. Monkey plasma samples from a previously conducted animal toxicology study have been assayed and the pharmacokinetic data will soon be available for inclusion in the IND application. Following the IND submission, the Company must wait 30 calendar days for the FDA to review the submission.

ANP is seeking to secure non-dilutive funding for the conduct of the Phase IIb trial with the assistance of consulting firm FreeMind, and has been interacting with a US Federal Agency (Agency) who has encouraged the Company to make an application for an appropriate award grant. As a key part of the process, ANP has also confirmed the interest of a leading US neurologist (who has experience and success in accessing such grant funding for a Phase IIb MS trial) to be the Principal Investigator of the proposed ATL1102 Phase IIb trial.

ANP will submit its clinical study synopsis for the Phase IIb study this month for the Agency’s formal review, and assuming the program meets the requisite criteria, ANP would look to lodge its full award grant application in Q2’17. IND clearance is required for such grant funding.

Investigative Study / National Multiple Sclerosis Society Grant Funding Application

As previously reported, ANP is proposing to undertake a smaller investigative study of ATL1102 in relapsing Secondary-Progressive MS (SP-MS) patients in Germany with Professor Volker Limmroth (Cologne City Hospital, Department of Neurology, Germany) as Principal Investigator.

In August 2016, an application was submitted to the National Multiple Sclerosis Society in the US for grant funding to conduct this study. After receiving feedback from the clinical expert reviewers, a suitably revised application has subsequently been resubmitted. The Company expects official notification of successful grants in late June 2017, which could allow for a potential study start in early Q4’17.

The proposed study will investigate the efficacy, safety, and mechanism of action of ATL1102 dosed 200mg once weekly for 24 weeks in 16 relapsing SP-MS patients. This study would be expected to generate important and supportive data on the use of ATL1102 in this patient population and allow for the potential Early Access Program (EAP) treatment of patients who do not adequately respond to or tolerate existing therapies.

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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.

Early Access Program

Early Access Programs allow biopharmaceutical companies to provide eligible patients with ethical access to investigational medicines for unmet medical needs within the scope of the existing early access legislation. Access is provided in response to physician requests where other treatments have been unsuccessful and no alternative or appropriate treatment options are available to these patients.

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).