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ATL1102 for MS – FDA Response to Phase IIb Study Plans

Antisense Therapeutics Limited ("ANP" or "the Company") is pleased to announce that the US Food and Drug Administration (FDA) has responded affirmatively to the Company's plan to submit a U.S. Investigational New Drug (IND) application for initiation of longer term Phase IIb human trials of ATL1102 for the treatment of Multiple Sclerosis (MS). Supportive guidance was obtained from the agency's Pre-IND assessment of the development strategy for ATL1102, including plans for a Phase IIb study in MS patients.

The FDA response is an important and positive step in advancing the ATL1102 MS program. As previously advised, ANP is seeking a pharmaceutical partner for ATL1102's further development.

Antisense Therapeutics' CEO and Managing Director Mark Diamond said:

"The FDA Response is an excellent outcome and important step in moving ATL1102 forward into late stage clinical development and to capitalise on the substantial development and investment made to date on this key project asset. We look forward to providing further updates as we advance development and commercialisation plans for this exciting new therapeutic to treat MS."

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ATL1102 background Information:
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 expression has demonstrated positive effects 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 by the Company to be highly effective in reducing MS lesions in a Phase II clinical trial in RRMS patients and the data has recently been published (Limmroth, V. et al Neurology September 19, 2014). 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, at the same 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.

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 relapsing-remitting multiple sclerosis (RRMS) , ATL1103 drug designed to block GHr production which in a Phase II clinical trial, successfully reduced blood IGF-I 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.