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ATL1102 for MS further development plans – US FDA Pre-IND response timing confirmed; European Patent Allowance

Antisense Therapeutics Limited ("ANP" or "the Company") is pleased to advise that it has received the US Food and Drug Administration's (FDA) response to the Company's formal request for a Pre-Investigational New Drug (Pre-IND) assessment of ANP's plans for further clinical development of ATL1102 to treat multiple sclerosis (MS).

The Company is also seeking FDA guidance and agreement on the intended content of the planned IND submission, including the proposed Phase IIb clinical study design and supporting non-clinical toxicology studies.

The FDA has confirmed that its goal date for providing written responses to the Company's previously submitted questions is October 17, 2014.

Antisense Therapeutics' CEO and Managing Director Mark Diamond said:

"The receipt of the FDA guidance will be a pivotal step in the continued development of ATL1102. A positive outcome would underpin our partnering and commercialisation plans for this drug and allow us to capitalise on the substantial development and investment made to date in this project asset."

European Patent Allowance

The Company is also pleased to announce that the European Patent Office has allowed European patent application 09798248.2, entitled "Methods for Treating Multiple Sclerosis using Antisense Oligonucleotides" which extends coverage of the ATL1102 compound for the treatment of relapsing-remitting multiple sclerosis (RRMS) patients until 2029 with potential for up to 5 year extension to 2034. With this allowance the granting of the European patent is a formality and will take place in the coming months.

The Company is delighted to extend the patent protection on ATL1102 for this major commercial market in MS. The global annual sales for drugs treating RRMS in 2013 were approximately US$14 billion.

The new European patent forms part of the Company's extensive portfolio of intellectual property protecting ATL1102 and its uses in MS. This includes an equivalent granted United States patent US 8,759,314, US patent 8,415,314, Australian Patent 2009271678 and corresponding applications in Japan and Canada, covering the use of ATL1102 in the treatment of the most common form of the disease, RRMS.

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 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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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 a second-generation antisense 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.