24 February 2017

ATL1103 Patent Update

- Key patent allowances in Europe and Japan expanding IP portfolio
- ATL1103 compound patent protection in major pharmaceutical markets
- Strengthened IP protection includes extended market exclusivity via granted orphan drug designation in the United States and Europe

Antisense Therapeutics Limited (ASX:ANP or "the Company") today reports on important advancements made in expanding it's intellectual property (IP) portfolio protecting ATL1103, an antisense drug targeting the Growth Hormone receptor (GHr), in clinical development for acromegaly. These advancements include the allowance of the claims of the European patent application 04715642.7 and Japanese patent application 2014-138603, both entitled "Modulation of Growth Hormone Receptor Expression and insulin like growth factor expression".

The European patent application claims covers ATL1103 and many other active oligonucleotides 20 nucleobases in length that target GHr. The patent may be extended up to 5 years once the drug is registered. ANP plans to register this patent in Germany, France, Italy, United Kingdom, Spain, Netherlands, Switzerland Sweden, Finland, and Denmark. The Japanese Patent covers ATL1103 and many other potent oligonucleotides to GHr for use in the reduction of sIGF-I. The Japanese patent will provide protection to February 2024, and may also be extended up to 2029.

The Company now has all of its patents that cover the compound ATL1103 registered or allowed in the major pharmaceutical markets including the US, Canada, Europe, Japan, and Australia.

The Company is also both expanding, and extending the life of, its IP protection by filing patents applications on the use of ATL1103 in combination with the marketed acromegaly treatments Somavert and the somatostatin analogues. This includes patent applications under examination in the US, Europe, Japan, Canada, and Australia, which if granted would provide protection to 2033/2034 and potentially extendible up to a further 5 years. The NZ patent, the first granted patent relating to patent family applications PCT/AU2013/000095 that cover the use of ATL1103 in combination with Somavert for potential enhanced efficacy in patients who do not have their sIGF-I normalized with monotherapies, is registered in NZ to 2033.

The Company anticipates potential new patent applications on ATL1103 as data is generated in other disease indications such as cancer.

ATL1103 for acromegaly has also been granted orphan drug designation by both the US Food and Drug Administration and European Commission (based on the recommendation of a positive opinion from the European Medicines Agency Committee for Orphan Medicinal Products) which provides 7 years of market exclusivity in the United States and 10 years of exclusivity in all countries of the European Union.

Contact Information: Website: www.antisense.com.au
Managing Director: Mark Diamond +61 (0)3 9827 8999

About ATL1103

ATL1103 is a second-generation antisense drug designed to block growth hormone receptor (GHr) expression thereby reducing levels of the hormone insulin-like growth factor-1 (IGF-1) in the blood and is a potential treatment for diseases associated with excessive growth hormone and IGF-1 action. These diseases include acromegaly, an abnormal growth disorder of organs, face, hands and feet, diabetic retinopathy, a common disease of the eye and a major cause of blindness, diabetic nephropathy, a common disease of the kidney and major cause of kidney failure, and some forms of cancer. Acromegalic patients have significantly higher blood IGF-1 levels than healthy individuals. Reduction of these levels to normal is accepted by clinical authorities as the primary marker of an effective drug treatment for the disease. GHr is a clinically validated target in the treatment of acromegaly. In the case of diabetic retinopathy, published clinical studies have shown that treatments producing a reduction in IGF-1 levels retarded the progression of the disease and improve vision in patients. Scientific papers have been published on the suppression of blood IGF-1 levels in mice (Tachas et al., 2006, J Endocrinol 189, 147-54) and inhibition of retinopathy in a mouse retinopathy model (Wilkinson-Berka et al., 2007, Molecular Vision 13, 1529- 38) using an antisense drug to inhibit the production of GHr. In a Phase I study in healthy subjects, ATL1103 demonstrated a preliminary indication of drug activity, including suppression of IGF-1 and the target GHr (via circulating growth hormone binding protein) levels. In a Phase II trial in acromegalic patients, ATL1103 met its primary efficacy endpoint by showing a statistically significant average reduction in sIGF-1 levels from baseline ($P<0.0001$) at week 14 (one week past the last dose) at the twice weekly 200 mg dose tested. Antisense has also recently completed a higher dose study in acromegaly patients.

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 Ionis 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.