23 July 2014

ATL1102 for Stem Cell Mobilisation Trial Results

Antisense Therapeutics (ASX:ANP) today announced the results from its Phase I Stem Cell Mobilisation (SCM) Human Proof of Concept trial of ATL1102.

The randomised, open label study in 10 healthy volunteers was designed to assess the effect of ATL1102 on the release of hematopoietic stem cells (CD34+) into the blood when dosed alone (monotherapy) and in combination with an existing mobilisation therapy (Granulocyte Colony Stimulating Factor (G-CSF)) with there being an acknowledged clinical need for increasing mobilisation levels in combination with G-CSF beyond those achieved by G-CSF alone.

The results of the trial showed that use of ATL1102 in combination with G-CSF did not appear to increase the release of CD34+ stem cells beyond that achieved with G-CSF alone. ATL1102 when dosed as a monotherapy, however, was observed to increase the number of CD34+ stem cells in the blood, though the level of CD34+ cell release was not regarded as sufficient to be therapeutically relevant for a commercially desirable product opportunity.

This Human Proof of Concept study of ATL1102 in SCM was a relatively low cost trial (and eligible for the 45% R&D tax incentive refund) designed to assess the drug's effect in this specific application. It was the first occasion in humans that the effects of ATL1102 on CD34+ stem cell release had been assessed over a short (5 day) dosing period, with the ATL1102 dosing schedule designed to fit in with current G-CSF dosing practice. It is possible that ATL1102 could have achieved greater CD34+ cell release if it were dosed for a longer duration. While the Company is assessing with clinical experts the potential feasibility (including from a safety/tolerability perspective) and commercial viability of longer dosing regimens of ATL1102, it is not planning to move forward with the clinical development of ATL1102 in the SCM indication as originally envisaged i.e. for short (5 day) use in combination with G-CSF.

The decision not to proceed with further clinical development of ATL1102 in this application has no bearing on ANP's development plans in relation to ATL1102 for Multiple Sclerosis (MS) where the drug has already been shown to significantly reduce brain lesions in MS patients. With respect to the use of ATL1102 in the MS indication, the Company remains on track with its plans to meet with the FDA, anticipated by the end of Q3'2014, having now submitted its formal request for a pre-IND meeting for the FDA's assessment of ANP's design for a Phase IIb clinical trial. This follows the now completed review of the previously conducted toxicology study with the main findings as per the 1 April 2014 ASX announcement.

Antisense Therapeutics Limited CEO and Managing Director Mark Diamond said "The stem cell mobilisation trial was designed with a clear therapeutic goal to provide clinical proof of concept to support the ongoing development of the drug in this specific application. While this goal was not met in this trial, we were able to reach this decision point quickly and at relatively low expense. In the short-term, with respect to ATL1102, we remain focussed on the ongoing development in the MS indication where we have already demonstrated potent clinical activity."

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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 multiple sclerosis (MS), ATL1103 a second-generation antisense drug designed to block GHr production and thereby lower blood IGF-I levels and is in clinical development as a potential treatment for growth and other GH-IGF-I disorders, 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.

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