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Antisense Therapeutics ties up with China CRO for trial

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Singapore: Antisense Therapeutics, an Australian publicly listed biopharmaceutical drug discovery and development company, will conduct a chronic toxicology study to support a potential future phase IIb study of ATL1102 in multiple sclerosis (MS) patients. The company is developing its drug ATL1102 in collaboration with Tianjin International Joint Academy of Biotechnology and Medicine (TJAB).

It has agreed to execute an agreement with Pharmaron, an internationally recognized contract research organization in China, to conduct the chronic toxicology study. Antisense Therapeutics has been successful in significantly lowering the costs associated with the conduct of such a study by the choice of this contractor and the agreement of the study design whilst also avoiding the need to manufacture new ATL1102 drug product for the study by qualifying existing clinical supplies of ATL1102.

Antisense Therapeutics estimates that the costs for completing the study will be less than $311,640 (A$300,000). The company anticipates that the toxicology study will be completed by the end of this calendar year. It will own all the data and associated intellectual property rights generated from this study.

In parallel with the toxicology study being conducted, TJAB will undertake a stem cell mobilization study at their cost (up to an agreed cap) at their facility in Tianjin, China. This study will investigate the potential of ATL1102 to release stem cells into the blood when dosed over a short one week period, which will be beneficial for the planning of future human studies in which the drug will also be dosed acutely.

Whilst this study is underway, TJAB and Antisense Therapeutics will prepare and submit a clinical trial application for a follow on human stem cell mobilization study based on data previously generated. This study will use ATL1102 to optimize release of stem cells for their collection from the blood to characterize their potential use in cancer patients to restore immune cells depleted by chemotherapy.

To enable the above development activities to proceed without delay, Antisense Therapeutics and TJAB have agreed on a time extension to the establishment of the joint venture proposed under the strategic alliance and license agreement. The parties have subsequently executed a side-letter to the agreement that formally extends the period to September 30, 2013,

by which the conditions precedent for establishing the JV are to be met, including the requisite capitalization of the venture by TJAB.

No benefits in ATL1102 will accrue to TJAB unless and until all of the conditions precedent to the agreement are fulfilled. Antisense Therapeutics Limited CEO and Managing Director, Mark Diamond said: "We are pleased that we have agreed on a way forward with TJAB on the development of ATL1102 that allows us to undertake two key valuing adding activities while working towards the establishment of a JV. The company is very excited by the prospect of having toxicology study results by the end of this year that could see ATL1102 positioned to move into phase IIb studies in MS patients in 2014."

The MS therapeutics market has grown significantly and is now valued at $12 billion. The company believes that ATL1102, with the recent granting of a US patent significantly extending its patent life, has great commercial potential, particularly if the toxicology study clears the way for the conduct of phase IIb studies. "Similarly, we are very keen to see ATL1102's potential as a stem cell mobilization agent re-enforced by the studies to be conducted by TJAB. We look forward to all these development activities getting underway, which we are confident can add substantial value to this asset," he said.