ASX Announcement

AdAlta completes confirmation run for AD-214

MELBOURNE Australia, 2nd May 2019, AdAlta Limited (ASX: 1AD), the biotechnology company advancing its lead i-body candidate toward clinical development, is pleased to announce that it remains well on track with development of its lead program, AD-214 for Idiopathic Pulmonary Fibrosis, following the successful completion of a confirmation run for manufacturing of AD-214.

The confirmation run has seen for the first time AD-214 cell-line expression at a 50L scale (upstream) and purification (downstream) combined into a single manufacturing process. This confirmation run has enabled AdAlta to demonstrate that the process for production of AD-214 materials has been developed and AD-214 can be made at a larger scale.

“Importantly, we remain on track with the development of the manufacturing process for AD-214 and look forward to completing the demonstration run over the next few months which will deliver the materials for our four-week non-human primate toxicology study,” said AdAlta’s Chief Operating Officer Dallas Hartman.

With the AD-214 materials available at the end of June, AdAlta will commence its four-week non-human primate Good Laboratory Practice (GLP) toxicology study in July 2019, which is expected to be completed later this year. The Company also remains on track to deliver Good Manufacturing Practice (GMP) material for its Phase 1 human study which is expected to commence in January 2020.

The completion of the confirmation run follows the announcement in January this year of improved cell line expression results for AD-214 of 3 grams per litre (3g/L) – up from the 1g/L reported in October 2018.

“Confirming that the processes can be pulled together and AD-214 can be made on a larger scale is important as we continue to progress our lead candidate AD-214 towards the clinic. We expect to complete the four-week non-human primate toxicology study for AD-214 in the second half of 2019, which will then lead us into the clinic in early 2020,” said AdAlta’s Chief Executive Officer, Sam Cobb.

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Notes to Editors

About AdAlta

AdAlta Limited is an Australian based drug development company headquartered in Melbourne. The Company is focused on using its proprietary technology platform to generate i-bodies, a new class of protein therapeutics, with applications as therapeutic drugs to treat disease.

I-bodies are a promising, novel class of drugs that offer a new and more effective approach to treating a wide range of human diseases. They are identified and developed using our proprietary technology platform.

We have pioneered a technology that mimics the shape and stability of a crucial antigen-binding domain, that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, now known as i-bodies, for use in treating serious diseases.

AdAlta is developing its lead i-body candidate, AD-214, for the treatment of idiopathic pulmonary fibrosis (IPF) and other human fibrotic diseases, for which current therapies are sub-optimal and there is a high-unmet medical need.

AD-214 is an Fc-fusion protein that contains two i-body molecules that bind with high affinity to the human target CXCR4. At the back end of AD-214 is the Fc fragment, or tail region, of a traditional monoclonal antibody that will extend the drug's half-life. As AD-214 is made using Fc-fusion technology, it requires an alternate manufacturing process to the original drug, AD-114.

The Company also plans to continue further drug discovery and development directed towards other drug targets and diseases with its i-body technology platform.

Further information can be found at: www.adalta.com.au.

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