ASX Announcement

AdAlta commences key toxicology study with AD-214

MELBOURNE Australia, 16th July 2019, AdAlta Limited (ASX: 1AD), the biotechnology company advancing its lead i-body candidate toward clinical development, has commenced its key toxicology study with AD-214, representing the final step before initiation of the human clinical trial for AD-214, which is being developed to treat Idiopathic Pulmonary Fibrosis.

AdAlta has initiated its four-week non-human primate study to evaluate the safety and toxicology of AD-214, which is being completed under Good Laboratory Practice (GLP) conditions. Data from this toxicology study is expected in the second half of 2019 and will inform the dosing regimen and safety readouts for AdAlta's human clinical trial. The results will also form part of a subsequent IND (investigational new drug) submission to the US FDA and will be of interest to potential partners evaluating AD-214.

The four-week non-human primate study is being undertaken with AD-214 materials from a recently completed demonstration run, highlighting the achievement of another manufacturing milestone. AdAlta now remains focused on delivering material manufactured under Good Manufacturing Practice (GMP) conditions which is necessary for its Phase 1 human study, expected to commence in January 2020.

"We are excited to start this critical non-human primate study which will enable us to commence our human clinical studies. As per our timeline proposed 12 months ago and without delay, we have met all our manufacturing objectives for our lead candidate, AD-214. Manufacturing is a key step in making any product, and is particularly difficult with new biologic drugs. We are delighted to have met this critical milestone as anticipated," said AdAlta's Chief Executive Officer, Sam Cobb.

"We now have the materials to commence our four-week toxicology study, which will evaluate the safety of AD-214. It is the final step before we start our human trials this coming January."

The completion of manufacturing follows the announcement in May that a confirmation run had been completed, demonstrating that AD-214 can be made at sufficient yields to meet our pre-clinical and clinical programs.

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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.

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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