19 April 2021

ASX Announcement

MUTIPLE DOSE PART OF AD-214 PHASE I TRIAL COMMENCED

MELBOURNE Australia, 19 April 2021: AdAlta Limited (ASX:1AD), the clinical stage biotechnology company developing novel medicines using its i-body platform is pleased to announce that the first cohort of healthy volunteers have received the first of three doses in Part B of the Phase I clinical trial of AD-214. Eight participants have received 5 mg/kg AD-214 or placebo with no reported dose limiting adverse events.

VP Clinical Product Development Dr Claudia Gregorio-King said:

"*We are pleased to have progressed into the multiple dose part of our initial clinical evaluation of AD-214. The excellent safety profile and high receptor occupancy observed in the single dose Part A of our study facilitated rapid ethics approval of Part B of the Phase I program. We also remain on track to begin our multi-dose study in interstitial lung disease patients in the third quarter of 2021. We continue to express our gratitude to the volunteers who have agreed to participate in our study and help advance a potential new therapy for patients battling idiopathic pulmonary fibrosis and other interstitial lung diseases*."

Completion of Part B of the Phase I study is expected by the end of 2021 and is anticipated to provide the data necessary to support Phase II clinical trial applications in 2022.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
April 2021

Notes to Editors
About AdAlta

AdAlta Limited (ASX:1AD) is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body technology platform to generate a promising new class of medicines with the potential to treat some of today's most challenging diseases.

The Company's lead asset, called AD-214, is a first-in-class product being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF), other human fibrotic diseases and potentially cancers, for which current therapies are sub-optimal and there is a high unmet medical need. AD-214 is well progressed in Phase I clinical trials.

AdAlta is also entering collaborative partnerships to co-develop i-body enabled therapeutics. The Company has a revenue generating partnership agreement with GE Healthcare which is designed to discover a diagnostic imaging agent for use in immuno-oncology.

AdAlta's growth strategy is to add value to its existing assets and build a pipeline of wholly owned and co-developed therapeutic products enabled by i-bodies.

About i-bodies

Traditional monoclonal antibodies transformed the pharmaceutical industry's ability to address drug targets selectively and specifically. There remain many targets and applications they have been unable to address. i-bodies are designed to solve these challenging drug targeting problems.

i-bodies are single domain antibodies that mimic the shape and stability of a unique and versatile antigen-binding domain that was discovered initially in sharks and then developed as a human protein. These unique proteins are capable of interacting with high selectivity, specificity and affinity with difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases. i-bodies are the first fully human single domain antibody scaffold.

About AD-214

AD-214 is being developed for the treatment of IPF and other human fibrotic diseases and potentially cancers, for which current therapies are sub-optimal and there is a high unmet medical need. AD-214 targets a GPCR called CXCR4 and has been specifically engineered to include features making it suitable for chronic use in fibrosis. It is the only agent against CXCR4 being developed for fibrotic diseases, giving it first-in-class status.

AD-214 has demonstrated efficacy in animal models of IPF and kidney fibrosis and studies in eye fibrosis and metastatic cancer are underway.

In Phase I clinical trials, AD-214 is well tolerated in single doses in healthy volunteers and demonstrates high and sustained duration of CXCR4 receptor occupancy. Repeat dose studies in healthy volunteers have commenced. Safety and biodistribution (PET imaging) studies in IPF and ILD patients are in advanced planning.

AD-214 has Orphan Drug Designation (ODD) from the US Food and Drug Administration.

Further information can be found at: https://adalta.com.au

For more information, please contact:

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