10 June 2020

ASX Announcement

ADALTA RECEIVES APPROVAL TO COMMENCE PHASE I CLINICAL TRIAL OF AD-214

Highlights

- Human Research Ethics Committee approves Phase I human clinical trial of AD-214
- No further regulatory review required
- First healthy volunteer subject expected to receive AD-214 in late July
- Top-line safety results from healthy volunteer component of trial expected at beginning of CY2021
- Ethics approval process represents first independent review of complete AD-214 pre-clinical safety and efficacy data
- Development of PET tracer version of AD-214 has restarted at collaborator laboratory

MELBOURNE Australia, 10 June 2020: AdAlta Limited (ASX:1AD), the biotechnology company developing novel therapeutic products from its i-body platform is pleased to announce that it has received Human Research Ethics Committee (HREC) approval to commence a Phase I clinical trial of its lead product candidate, AD-214.

The ethics approval is confirmation that AdAlta has completed all the necessary pre-clinical safety and efficacy testing of AD-214 required to commence human clinical trials. The Phase I trial is being conducted under Australia's Clinical Trials Notification (CTN) Scheme meaning that no further regulatory review is required and AdAlta can now notify the Therapeutic Goods Administration (TGA) of HREC approval and complete site initiation activities.

Healthy volunteer screening for Part A of the trial is expected to commence in late June with the first subject expected to receive AD-214 in the second half of July. Top line safety results from the healthy volunteers are expected to be available at the beginning of CY2021. Subject to satisfactory completion of Part A of the trial, initiation of Parts B and C of the trial in patients with Interstitial Lung Disease (ILD), including patients with Idiopathic Pulmonary Fibrosis (IPF), is expected early in 2021.

The primary end point of the trial is safety and tolerability of AD-214. AdAlta will also investigate pharmacokinetic (concentration of AD-214 in the blood over time) and pharmacodynamic (biological effects of AD-214 over time) parameters as secondary end points. The trial is not designed to show evidence of efficacy against ILD or IPF, though respiratory effects of AD-214 will be monitored for information. Additional details about the trial design can be found below and at ClinicalTrials.gov, a database of privately and publicly funded clinical studies conducted around the world: https://clinicaltrials.gov/ct2/show/NCT04415671?term=AdAlta&draw=2&rank=1.

AdAlta Chief Scientific Officer, Prof Michael Foley commented, "This approval is a milestone that AdAlta has been working towards for many years. It is based on the first independent review of our complete pre-clinical development package and confirms that

AdAlta has completed all the necessary safety and efficacy testing to support progressing the development of AD-214 into human clinical studies. We are incredibly grateful to the healthy volunteers, patients and physicians who will participate in this study to help improve outcomes for those suffering the debilitating effects of ILD and IPF."

CEO and Managing Director Dr Tim Oldham added, "We are enormously proud to be able to say that AdAlta is now a clinical stage company. This milestone is significant not only for AD-214 and all the patients for whom we are working to improve outcomes, but also because it demonstrates that AdAlta can use our i-body platform to develop therapeutic candidates against complex biological receptors from discovery through the complete pre-clinical development phase."

AdAlta also advises that the development of a radio-labelled version of AD-214 for PET imaging has recommenced following staged return to work at a collaborator laboratory. The radio-labelled version remains on track for introduction into the patient cohorts of the Phase I program in the first quarter of 2021 where it will add significant clinical and partnering value to the Phase I program.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
June 2020

Notes to Editors
About AdAlta

AdAlta Limited is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body technology platform to solve challenging drug targeting problems and generate a promising new class of single domain antibody protein therapeutics with the potential to treat some of today's most challenging medical conditions. The i-body technology mimics 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. The result is a range of unique proteins capable of interacting with high selectivity, specificity and affinity with previously difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases.

AdAlta is conducting Phase 1 clinical studies for its lead i-body candidate, AD-214. AD-214 is being developed 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 is also entering collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

AdAlta's strategy is to maximise the products developed using its next generation i-body platform by internally discovering and developing selected i-body enabled product candidates against GPCRs implicated in fibrosis, inflammation and cancer and

partnering with other biopharmaceutical companies to develop product candidates against other classes of receptor, in other indications, and in other product formats.

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

About the Phase I trial of AD-214

The Phase I trial of AD-214 will comprise three parts. In Part A of the trial, up to 40 healthy volunteers will be divided into five cohorts, each cohort receiving a single dose of AD-214 or placebo (3:1 ratio) at dose levels increasing from 1 to 20 mg/kg. Part A will be conducted at CMAX Clinical Research (CMAX) in Adelaide with support from AdAlta's Contract Research Organisation (CRO), Clinical Network Services (CNS). Screening of healthy volunteers is expected to commence in late June with the first subject receiving AD-214 in the second half of July. Top-line safety results from Part A of the trial are anticipated by the beginning of CY2021.

Parts B and C of the trial will be conducted in 27-54 Interstitial Lung Disease (ILD) patients, including Idiopathic Pulmonary Fibrosis (IPF) patients. These patients will receive single and multiple doses of AD-214 respectively, again in cohorts of increasing doses from 0.1 to 20 mg/kg. Subject to successful development and additional HREC approval, it is planned that some patients in the study will also receive a radio-labelled PET tracer version of AD-214 to enable imaging of AD-214 in the lungs.

The primary end point of each part of the trial is safety and tolerability of AD-214. AdAlta will also investigate pharmacokinetic (concentration of AD-214 in the blood over time) and pharmacodynamic (biological effects of AD-214 over time) parameters. Exploratory endpoints will explore the respiratory effects of AD-214 in patients with ILD, however, the trial is not designed to show efficacy against ILD or IPF.

For more information, please contact:

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