20 July 2020

ASX Announcement

ADALTA RECEIVES US FDA REGULATORY ADVICE GUIDING AD-214 DEVELOPMENT

Highlights

- Supportive US Food and Drug Administration (FDA) advice received in relation to AdAlta's lead therapeutic candidate, AD-214
- Pre-clinical program and Phase I trial design for AD-214 deemed sufficient to support an Investigational New Drug (IND) application
- FDA guidance on specific details readily incorporated into current Phase I trial protocol and ongoing development plans
- Participant screening has commenced for the healthy volunteer component of AdAlta's AD-214 Phase I clinical trial in Australia
- Top line safety results from Part 1 of the Phase I trial remain on track to be reported during early CY2021.

MELBOURNE Australia, 20 July 2020: AdAlta Limited (ASX:1AD), the clinical stage biotechnology company developing novel therapeutic products from its i-body platform is pleased to announce that it has received advice from the United States (US) Food and Drug Administration (FDA) indicating that:

- the panel of preclinical studies conducted to date on its lead product AD-214 would be sufficient to support an Investigational New Drug application in the US; and
- AdAlta's Phase I trial design is reasonable.

Specific FDA guidance has been incorporated into the protocol for the current Phase I trial.

The FDA guidance was provided in response to AdAlta's request for a Pre-Investigational New Drug Application (Pre-IND) meeting. IND applications are made when seeking to commence clinical development of therapeutic products in the US. Pre-IND meetings can be requested prior to IND submission to discuss the proposed product and clinical development program and receive guidance from the FDA to ensure completeness of the IND application and maximise probability of IND approval.

AdAlta does not require FDA approval of an IND application in order to conduct its current Phase I program in Australia, however seeking advice now ensures that FDA specific requirements can be incorporated into current clinical and ongoing pre-clinical development.

CEO and Managing Director Dr Tim Oldham said, "This is the second independent review of the AD-214 preclinical data. It provides AdAlta and our potential partners increased confidence that AD-214's development plan can obtain support from the FDA for future US clinical trials and is of international regulatory standard. It has been a straightforward process to incorporate the guidance received into our pre-clinical and Australian Phase I trial program."

AdAlta received written responses to specific questions encompassing AD-214 pre-clinical and manufacturing studies and Phase I clinical trial design. Based on the data provided in

respect of these questions, the FDA has agreed that the panel of preclinical and manufacturing studies conducted on AD-214 is generally sufficient to support an IND application. A small number of supplementary studies suggested by FDA are already completed, underway or planned.

The FDA also agreed that AdAlta's Phase I clinical trial design, encompassing both healthy volunteers and Interstitial Lung Disease (ILD)/Idiopathic Pulmonary Fibrosis (IPF) patients, is "reasonable".

FDA review of the preclinical data concluded that AD-214 may show biological activity at doses lower than AdAlta's originally proposed starting dose of 1 mg/kg. To ensure that a complete clinical profile of AD-214 biological activity is available for future FDA review, AdAlta has amended Part A of its Australian Phase I protocol in healthy volunteers. The amendment incorporates two new sentinel cohorts, each comprising two participants receiving either AD-214 or placebo, at two lower doses. The amendment does not materially affect the expected duration or cost of Part A.

The Human Research Ethics Committee (HREC) overseeing the Phase I trial has approved the amendment, and the first sentinel cohort remains on track to be treated imminently. Part A of the Phase I trial remains on track for completion by the end of 2020 with top line safety data due at the beginning of 2021. Part A of the Phase I clinical study remains fully funded. FDA comments regarding Parts B and C of the Phase I trial in ILD/IPF patients will be incorporated, if warranted, during the planned review of Part A results with the HREC.

AdAlta plans to include the results of the Phase I trial alongside the full pre-clinical data set in an IND application to the FDA which will be required if trials are to be completed in the US by AdAlta or a potential partner.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
July 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 44 healthy volunteers will be divided into seven cohorts. The first two cohorts of two participants will receive a single dose of AD-214 or placebo (1:1 ratio) at dose levels of 0.01 mg/kg and 0.1 mg/kg. The following five cohorts of eight study participants will receive a single dose of AD-214 or placebo (3:1 ratio) at dose levels increasing from 1 to a possible maximum of 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). 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, in cohorts of increasing doses from 0.1 mg/kg to the maximum tolerated dose from Part A of the trial. Subject to successful development and additional HREC approval, it is currently 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:

Investors

Tim Oldham, CEO & Managing Director
Tel: +61 403 446 665
E: t.oldham@adalta.com.au

Media

IR Department
Tel: +61 411 364 382
E: gabriella.hold@irdepartment.com.au