23 July 2020

ASX Announcement

FIRST PARTICIPANTS TREATED IN AD-214 PHASE I CLINICAL TRIAL

MELBOURNE Australia, 23 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 the first healthy participants in the blinded Phase I clinical trial of AD-214 have been treated. One participant received AD-214 and one received placebo. Both participants have passed the 72-hour observation window without a dose limiting adverse event (DLAE).

CEO and Managing Director Dr Tim Oldham said, "We are pleased to have achieved this next important milestone in the initial clinical evaluation of AD-214. We also wish to express our gratitude to the volunteers who have agreed to participate in this trial and help advance a potential new therapy for patients battling interstitial lung disease, beginning with idiopathic pulmonary fibrosis."

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
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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:

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