29 June 2023

ASX Announcement

IMPORTANT PHASE I EXTENSION CLINICAL STUDY OF AD-214 APPROVED

Key highlights:

- **Human Research Ethics Committee (HREC) has approved Phase I extension clinical study of AD-214**
- **Clinical study is important to extend prior Phase I findings, support partnering and reduce Phase II time and cost**
- **First healthy volunteer expected to receive AD-214 in August 2023 with top-line healthy volunteer results expected January 2024**
- **HREC approval includes a patient cohort which could confirm the safety of AD-214 when administered in combination with standard of care**
- **Study design will reduce duration and cost of Phase II; was well received by potential partners at recent BIO Partnering Conference (June 2023)**

MELBOURNE Australia, 29 June 2023: AdAlta Limited (ASX:1AD), the clinical stage drug discovery 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 extension clinical study of its lead product candidate, AD-214. This approval covers both a healthy volunteer cohort (Part A), and a subsequent patient cohort (Part B).

The Phase I extension study, titled "Safety, Tolerability, PK and PD Study of AD-214 Administered to Healthy Volunteers and Patients With Interstitial Lung Disease or Chronic Kidney Disease", is being conducted under Australia's Clinical Trials Notification (CTN) Scheme, meaning that no further regulatory review is required.

The study will recruit up to 8 healthy volunteers in the previously announced[1] Part A who will receive four 10 mg/kg doses of AD-214. The approval also allows a further 8 fibrotic disease patients suffering interstitial lung disease (including IPF) or chronic kidney disease to be recruited in Part B. Part A will be conducted at C-MAX in Adelaide, with first participant dosing anticipated in August 2023.

AdAlta Director Clinical and Regulatory Operations, Darryn Bampton, commented, "*The AD-214 Phase I extension study aims to confirm safety and pharmacokinetic and pharmacodynamic trends of multiple doses of AD-214 using higher doses than in the previous study. This data is important to establish the safety and to better inform the target dosing schedule of AD-214 at the doses planned for Phase II studies*."

AdAlta CEO and Managing Director, Dr Tim Oldham added, "*Our meetings with potential partners at BIO23 in Boston in June confirmed that this extension study will materially enhance our ongoing partnering discussions as well as shortening eventual Phase II study time and cost. We thank all those shareholders who participated in the recent Rights Offer,*[2] *that contributed towards the funds for Part A of this critical Phase I extension.*

[1] ASX Announcement, 28 April 2023
[2] ASX Announcement: 25 May 2023

AdAlta Limited
15/2 Park Drive
Bundoora VIC 3083 Australia
T +61 3 9479 5159
E enquiries@adalta.com.au
ABN 92 120 332 925
adalta.com.au

We also thank in advance those volunteers who will participate in this extension study, to help progress a potential new therapy for sufferers of idiopathic pulmonary fibrosis and other fibrotic diseases."

Details of the study can be found at: www.clinicaltrials.gov/study/NCT05914909

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
June 2023

Shareholders: please update your communication preferences

We encourage shareholders to update their share registry preferences to receive all communications electronically. Doing so helps us communicate with you in a time-efficient manner on important matters, while minimising our mail costs and environmental impact.

Simply click here or scan the QR code and follow the instructions.

Not a shareholder, but want to keep across our progress? Click here to subscribe to our updates using the Stay in Touch form.

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. i-bodies are the first fully human single domain antibody scaffold and the first based on the shark motif to reach clinical trials.

AdAlta has completed Phase I clinical studies for its lead i-body candidate, AD-214, that 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. AdAlta has a second target in discovery research, also in the field of fibrosis and inflammation.

The Company is also entering collaborative partnerships to advance the development of its i-body platform. It has a collaboration with Carina Biotech to co-develop precision engineered, i-body enabled CAR-T cell therapies (i-CAR-T) to bring new hope to patients with cancer. It has an agreement with GE Healthcare to co-develop i-bodies as diagnostic imaging agents

(i-PET imaging) against Granzyme B, a biomarker of response to immuno-oncology drugs, a program now in pre-clinical development.

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: https://adalta.com.au

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: +61 411 117 774
E: jane.lowe@irdepartment.com.au