4 August 2023
ASX Announcement

AD-214 RETURNS TO CLINICAL STUDIES

Key points:

- **First dosing of AD-214 achieved in Phase I extension study**
- **On track to obtain interim results in 2023, full results in Q1 2024**
- **Will generate valuable data to inform and de-risk the Phase II study design**
- **Ongoing discussions confirm value of study for potential partners**

MELBOURNE Australia, 4 August 2023: AdAlta Limited (ASX:1AD), the clinical stage drug discovery company developing novel therapeutic products using its i-body platform provides an update on its lead fibrosis asset, AD-214. The first participants in the Company's Phase I extension study of AD-214 have successfully received their first dose.

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",[1] aims to confirm safety and pharmacokinetic and pharmacodynamic profile of multiple doses of AD-214, using higher doses than in the previous Phase I study. Commencing this study returns AD-214 to the clinic more than a year earlier than forecast in 2022. The new clinical data is crucial as it will better inform the safety profile and target dosing schedule of AD-214 for future Phase II studies and will also strengthen partnering initiatives.

AdAlta CEO and Managing Director, Dr Tim Oldham commented, "*We extend our gratitude to the volunteers who are participating in this extension study. Their involvement is essential in advancing a potential new therapy for sufferers of debilitating and incurable idiopathic pulmonary fibrosis and other fibrotic diseases. The Company's meetings with potential partners continue to indicate that this study will materially enhance the attractiveness of AD--214 to partners.*"

The study is initially enrolling up to 8 healthy volunteers, six participants to receive AD-214 and two participants placebo. The first, or sentinel, group of two participants has now received the first of four 10 mg/kg doses of AD-214 or placebo with no issues reported. AdAlta continues to anticipate interim results before the end of 2023, with final assessment visits to be completed and full results expected to be available in the first quarter of 2024.

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

Authorised for lodgement by:
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[1] ASX Announcement, 28 April 2023, 29 June 2023

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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 is extending 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. Preparation for Phase II clinical studies is also underway. 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

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