23 October 2023
ASX Announcement

AD-214 PHASE I EXTENSION: FAVOURABLE TOLERABILITY AFTER THIRD DOSE

Key points

- **Eight healthy volunteers have now received three doses of AD-214 in Phase I extension study**
- **Study investigators continue to report no safety concerns, confirming favourable tolerability profile from lower doses**
- **Headline pharmacokinetic and receptor engagement data still anticipated November 2023 for ongoing, advancing partnering discussions**

MELBOURNE Australia, 23 October 2023: AdAlta Limited (ASX:1AD), the clinical stage company developing novel protein and cell therapeutic products from its i-body® platform, is pleased to report that all healthy volunteers in its AD-214 Phase I extension study have now successfully received three doses, enabling pharmacokinetic and receptor engagement analysis to be completed on schedule and confirming the favourable tolerability profile observed at lower doses.

AD-214 is AdAlta's lead drug candidate, which is being developed as a first-in-class therapy to treat debilitating and fatal fibrotic (scarring) diseases including Idiopathic Pulmonary Fibrosis (IPF). The Phase I extension study[1] is designed to assess the safety and availability of multiple 10 mg/kg intravenous doses of AD-214, which is the highest dose anticipated to be used in forthcoming Phase II clinical studies.

All eight participants have now successfully received three doses of AD-214 or placebo.

Dr Tim Oldham, CEO and Managing Director, commented:
"We continue to be grateful to the volunteers participating in this Phase I extension study. The favourable safety profile of AD-214 continues to be demonstrated at the anticipated Phase II clinical study doses.

"This study also supports our partnering program for AD-214 and we are pleased to have materially progressed several partnering and project financing discussions over the past month to help progress AD-214 into Phase II studies."

Study investigators have reported no dose limiting toxicity, no need to interrupt doses and no requirement to administer medication to manage infusion reactions. The frequency of mild infusion related reactions appears lower than that observed at lower doses in the original Phase I study.[2]

Full pharmacokinetic and receptor engagement analysis and then updated dose finding simulations can now commence and remain on schedule for discussion with partners in November 2023. The study participants will receive a final dose in twelve weeks with the aim of confirming that there is no immune response to AD-214 that might affect efficacy and safety. Full safety and tolerability results are due in the March Quarter of 2024.

Authorised for lodgement by:
Tim Oldham
CEO and Managing Director
October 2023

[1] ASX releases 29 June 2023 and 4 August 2023
[2] ASX release 19 July 2021

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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 enabled protein and cell 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 preclinical 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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