20 September 2023
ASX Announcement

AD-214 PHASE I EXTENSION STUDY COMPLETES HEALTHY VOLUNTEER ENROLMENT

Key points

- **Healthy volunteer enrolment is complete in AD-214 Phase I extension study**
- **Eight participants have now received between one and three doses of AD-214**
- **No safety concerns have been reported by study investigators**
- **Study is helping to advance partnering and project financing discussions designed to progress AD-214 into Phase II studies**
- **Headline pharmacokinetic and receptor engagement data anticipated November 2023**

MELBOURNE Australia, 20 September 2023: AdAlta Limited (ASX:1AD), the clinical stage drug discovery company developing novel protein and cell therapeutic products from its i-body platform, is pleased to report that enrolment of healthy volunteers in its AD-214 Phase I extension study is complete. All participants have now successfully received at least their first dose.

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.

Dr Tim Oldham, CEO and Managing Director, commented:
"We are grateful to all the volunteers that have participated in this Phase I extension study. The data being generated continues to show that AD-214 is well tolerated and is also helping to inform dosing regimens and the broader protocol for our coming Phase II study for AD-214. It is additive to our recent laboratory studies which indicated that commercially suitable dosing frequencies could be clinically effective.

"In parallel with these workstreams, we have been progressing partnering and project financing discussions to help secure the funds to progress AD-214 into Phase II studies. Potential partners continue to respond positively to the current study and recent results".

Eight participants have now successfully received at least one dose of AD-214 or placebo and four have received three doses. No safety concerns have been reported by study investigators. The Company anticipates having pharmacokinetic and receptor engagement results from the first three doses available for discussion with partners in November 2023, with full safety and tolerability results due in the March Quarter of 2024.

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

[1] ASX releases 29 June 2023 and 4 August 2023

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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 (iPET 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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