ASX Announcement | 21 November 2023
AdAlta Limited (ASX:1AD)

AD-214 Phase I extension study interim data reinforces safety profile, dose selection

Receptor occupancy and safety results after three 10 mg/kg doses of AD-214 consistent with prior studies and dose simulation model, further enhancing the safety profile and reinforcing potential efficacy of planned Phase II doses

Key highlights

- Interim analysis of Phase I extension study of AD-214 conducted after three 10 mg/kg doses
- Target receptor occupancy of AD-214 consistent across doses and in line with dose simulation model
- Immune response to AD-214 lower at this time point than observed in prior multidose studies
- Results reinforce safety profile and potential efficacy of this dose in planned Phase II studies
- Full results anticipated in the first quarter of 2024

AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company") is pleased to announce interim results of its Phase I extension clinical study of its lead asset AD-214 which reinforces the safety profile and potential efficacy of the 10 mg/kg dose, further de-risking planned Phase II studies in Idiopathic Pulmonary Fibrosis.

Study designed to establish tolerability and dose regimen of AD-214 for Phase II studies

AD-214, AdAlta's lead asset, is a first in class molecule being developed for fibrotic diseases including Idiopathic Pulmonary Fibrosis (IPF). As previously announced (August 2023), AdAlta has commenced a Phase I extension clinical study of AD-214 in healthy volunteers to establish the safety of multiple 10 mg/kg doses of AD-214 and confirm this as the target dosing regimen for Phase II clinical efficacy studies. All participants have now received three doses of AD-214, the same number as previously administered at 5 mg/kg doses, enabling interim comparison with these prior studies and dose simulation models.

Interim results consistent with prior findings at lower doses

As previously announced (October 2023), 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 5 mg/kg in the original Phase I study.

The bioavailability of AD-214 and the blocking of its target receptor, CXCR4 (receptor occupancy) was in line with prior single dose studies, consistent across all three doses and, most significantly, in line with the predictions of previously announced dose simulation models (September 2023).

The immune response to AD-214, as measured by the number of participants in which anti-drug antibodies were detected and the level of these antidrug antibodies, was lower at this time point than observed in prior multi-dose studies.

Interim results reinforce safety profile and potential efficacy of this dose, de-risking Phase II studies and enhancing partnering discussions

AdAlta CEO and Managing Director, Tim Oldham said: "*These interim results are very much in-line with our expectations. We have therefore materially reduced Phase II clinical trial risk by reinforcing the favourable safety profile for AD-214 at planned Phase II doses, and matching the predictions of our dose simulation model that led us to believe this 10 mg/kg dose every two weeks could be effective. We are sharing these results with potential partners and anticipate that they will further enhance our existing out-licensing and project financing discussions*."

The study participants will receive a fourth and final dose twelve weeks after their third dose 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.

This ASX announcement has been authorised for release by the Board of AdAlta Limited (ASX:1AD).

For further information, please contact:

AdAlta Limited (ASX:1AD)
Tim Oldham
CEO & Managing Director
P: +61 3 9479 5159
E: t.oldham@adalta.com.au

Media & Investor Enquiries
The Capital Network
Julia Maguire
P: +61 2 8999 3699
E: julia@thecapitalnetwork.com.au

About AdAlta Limited

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.

The Company is also entering collaborative partnerships to advance the development of its i-body® platform. It has a collaboration with Carina Biotech to codevelop 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.

For more information

To learn more about AdAlta please click here: www.adalta.com.au