14 December 2020

ASX Announcement

ADALTA TO EXTEND PHASE I HEALTHY VOLUNTEER STUDY FOLLOWING ENCOURAGING DATA IN MOST RECENT COHORT

Highlights

- Safety Management Committee approves progression to the highest dose healthy volunteer cohort in Part A of AD-214 Phase I clinical study
- Higher than expected receptor occupancy 7 days after dosing suggests potential for longer duration of effect and therapeutic dosing interval
- Protocol amendment in development to enable these findings to be explored
- Additional data will better inform Phase I Part B design in patients with lung fibrosis

MELBOURNE Australia, 14 December 2020: AdAlta Limited (ASX:1AD), a clinical stage biopharmaceutical discovery and development company using i-body technology to address challenging drug targets will extend the healthy volunteer Part A of its Phase I clinical study of AD-214 to explore encouraging results from cohorts studied to date.

AdAlta has now treated 34 healthy volunteers with lead product candidate AD-214 or placebo at doses ranging from 0.01 mg.kg to 10 mg/kg. The Safety Management Committee has found no adverse safety events of clinical concern and has now approved dose escalation to 20 mg/kg, the maximum planned dose in Part A of the Phase I clinical study.

A key secondary endpoint of the Phase I study is the extent and duration of receptor occupancy, the percentage of target receptors on certain circulating white blood cells that are occupied by AD-214. High levels of receptor occupancy are generally required for therapeutic effect of any drug and the time over which receptor occupancy remains high is a key indicator of likely therapeutic dosing intervals (with longer intervals generally more convenient and lower cost).

Throughout Part A of the Phase I study, AdAlta has observed a dose dependent increase in both the duration of white blood cell receptor saturation (~100% receptor occupancy) and the time receptor occupancy remains above 50%. Blinded data from the most recent cohorts at 5 and 10 mg/kg shows that receptors remained saturated for three days after infusion of AD-214 and remained at 55% ± 14% and 86% ± 11% at seven days after infusion respectively.

AdAlta Vice-President Clinical Product Development, Dr Claudia Gregorio-King commented “AD-214 has maintained high levels of receptor occupancy for substantially longer than predicted from results of pre-clinical studies in non-human primates and substantially longer than the time taken for AD-214 to be eliminated from free circulation in the blood. If repeated in IPF patients, these results are strongly supportive of longer dosing intervals in future clinical studies than currently planned.”

To further explore these findings and optimise that design of Part B of the Phase I study in patients, AdAlta will submit a protocol amendment to enable receptor occupancy in the final healthy volunteer cohort to be investigated at two and three weeks following

infusion. As a result, dosing of this final cohort will be deferred to January 2021. Design of Part B of the Phase I study in Idiopathic Pulmonary Fibrosis (IPF) and Interstitial Lung Disease (ILD) patients continues to progress and incorporating these new findings into this part of the study is not expected to result in any material changes to previously forecast milestones.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
December 2020

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 is conducting Phase 1 clinical studies for its lead i-body candidate, AD-214. AD-214 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.

The Company is also entering collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare to discover i-bodies as diagnostic imaging agents against Granzyme B, a biomarker of response to immuno-oncology drugs.

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: +61 411 364 382
E: gabriella.hold@irdepartment.com.au