2 March 2020

ASX Announcement

AD-214 pre-clinical pharmacokinetics and pharmacodynamics support Phase I target of weekly dosing

Highlights:

- **AD-214 achieves high levels of durable CXCR4 receptor binding**
- **Results indicate that the therapeutic window for AD-214 in humans may include 10 mg/kg weekly or every two weeks**
- **Planned Phase I clinical trial dose range includes this potential therapeutic window**

MELBOURNE Australia, 2 March 2020: AdAlta Limited (ASX: 1AD), the next generation antibody company using its i-body technology to develop drug candidates against hard to reach drug targets, reports pre-clinical and pharmacokinetic and pharmacodynamic data confirming that the dose range planned in Phase I trials of its lead product candidate, AD-214, includes doses that are potentially therapeutically effective. Final preparation for Phase I trial ethics submission are underway, with targeted first patient dosing mid-year.

AdAlta conducted a Good Laboratory Practice (GLP) toxicology study of AD-214 in non-human primates (NHPs) in the second half of 2019. Top-line safety results of that study were reported on 29 October 2019. This study also investigated pharmacokinetic (blood plasma concentration over time) and pharmacodynamic (biological effects over time) aspects of AD-214.

As expected, AD-214 exhibited a pharmacokinetic profile typical of antibody-like drugs. A key feature is the drug's clearance or elimination half-life (the time taken for blood plasma concentration to halve). This is a measure of how long AD-214 is circulating in the bloodstream and therefore available to reach its biological target, the CXCR4 receptor. A longer half-life indicates that less frequent dosing is needed to maintain a therapeutically effective concentration of AD-214. The elimination half-life of AD-214 in NHPs was 22-29 hours. Modelling suggests this could translate into a half-life in humans of up to 71 hours, thereby supporting weekly dosing.

This study also measured CXCR4 receptor occupancy (the proportion of CXCR4 receptors on circulating white blood cells bound by AD-214). The longer that AD-214 occupies a large proportion of CXCR4 receptors, the greater the likelihood of therapeutic effects such as preventing fibroblast migration and other fibrotic mechanisms. Figure 1 shows that AD-214 doses greater than 30 mg/kg achieved high levels of receptor occupancy for at least three days in NHPs.

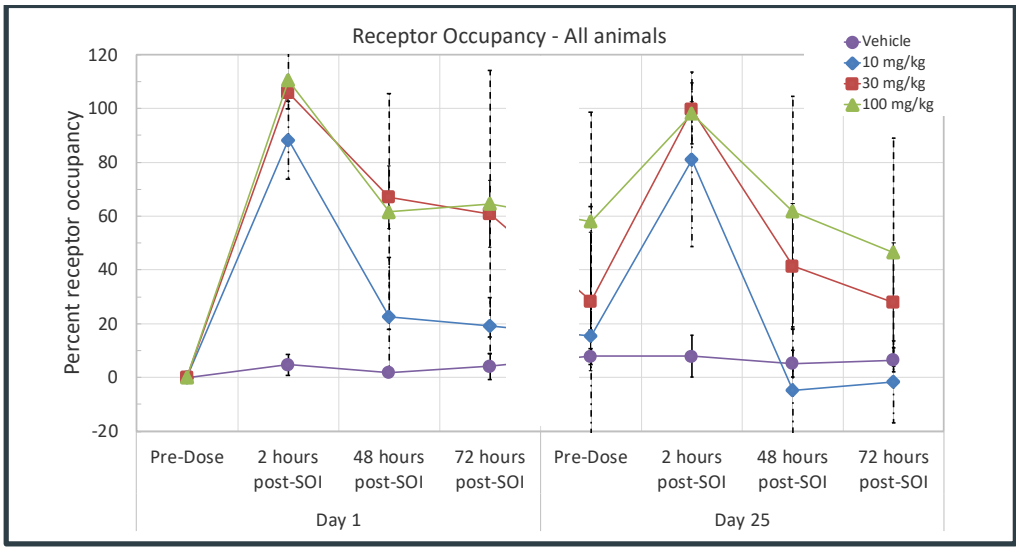

Figure 1: Proportion of CXCR4 receptors on peripheral blood cells occupied by AD-214 in NHP at varying AD-214. The human equivalent dose is approximately one third of the NHP dose. Error bars represent standard deviation of each group.

AdAlta CSO Prof Michael Foley commented, "In this study we see that CXCR4 receptor occupancy declines much more slowly than the plasma elimination half-life. This suggests that AD-214 could exert a pharmacologic effect over a longer duration than its circulating plasma half-life, supporting less frequent dosing. Longer acting drugs that require less frequent dosing are more cost effective to produce and more convenient for patients. These results are supportive of potential therapeutic efficacy in humans at AD-214 doses of 10mg/kg administered at least weekly and possibly once every two weeks."

CEO Dr Oldham added, "In December we announced our plan to develop a radio-labelled version of AD-214 to use as a PET tracer for imaging our product in the lungs; the data from the receptor occupancy study reinforces the value of this plan, since receptor occupancy in lung tissue cannot be measured by the same method used for white blood cells. We can now move forward with confidence that our planned Phase I human clinical trial includes clinically acceptable dose ranges that span the likely minimum therapeutic window for AD-214 and with a good safety margin."

AdAlta is on track to commence Phase I human clinical studies of AD-214 in mid-2020, with a highest planned dose of 20mg/kg.

Authorised for lodgement by:

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Notes to Editors
About AdAlta

AdAlta Limited is an Australian-based drug development company headquartered in Melbourne. The Company is using its proprietary technology platform to generate a promising new class of single domain antibody protein therapeutics, known as i-bodies, that have the potential to treat some of today's most challenging medical conditions. The technology mimics the shape and stability of a crucial antigen-binding domain, that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, capable of uniquely interacting with previously difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases.

AdAlta is currently preparing for its Phase 1 clinical studies for its lead i-body candidate, AD-214. The clinical program is expected to commence in mid-2020 following finalisation of clinical trial design. 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 in collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

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 imnplicated 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: www.adalta.com.au

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