2 March 2020

ASX Announcement

AD-214 effective in gold standard pre-clinical animal model of IPF

Highlights:

- **AD-214 reduces fibrosis in gold standard mouse bleomycin model of IPF**
- **These data enable progression of AD-214 into human clinical trials**

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, has demonstrated that its lead product candidate, AD-214, is effective in slowing progression of fibrosis in a mouse model of Idiopathic Pulmonary Fibrosis (IPF), enabling progression into Phase I human clinical trials. Final preparations for ethics submission are underway, with targeted first patient dosing mid-year.

The lead indication for AD-214 is IPF and the gold standard animal model for IPF is the mouse bleomycin model. In this model, bleomycin (an anticancer agent known to cause lung fibrosis), is administered to the lungs of mice leading to the development of fibrosis. Drug candidates are administered therapeutically, typically from day eight after bleomycin infusion when disease has developed, and their ability to reduce fibrosis is evaluated using a range of parameters including a measure called the Ashcroft Score. A change in the day 21 Ashcroft Score of mice treated with the drug candidate compared with untreated mice (receiving bleomycin only) provides an indication of the impact of the drug candidate on fibrosis.

AdAlta conducted a study of AD-214 administered intravenously at various doses and dose intervals in the bleomycin mouse model. Treatment with AD-214 at 1-30mg/kg every second day and 10-30mg/kg every fourth day resulted in a statistically significant reduction in the Ashcroft Score of bleomycin-treated mice compared with mice receiving bleomycin alone (Figure 1). In contrast, treatment with two drugs currently approved for IPF – pirfenidone and nintedanib – did not result in a statistically significant reduction in Ashcroft score under test conditions.

The study evaluated a range of other fibrosis parameters and concluded that a number of different AD-214 dosing regimens can be used and that 10mg/kg intravenously every second day shows effectiveness as judged by most of these parameters.

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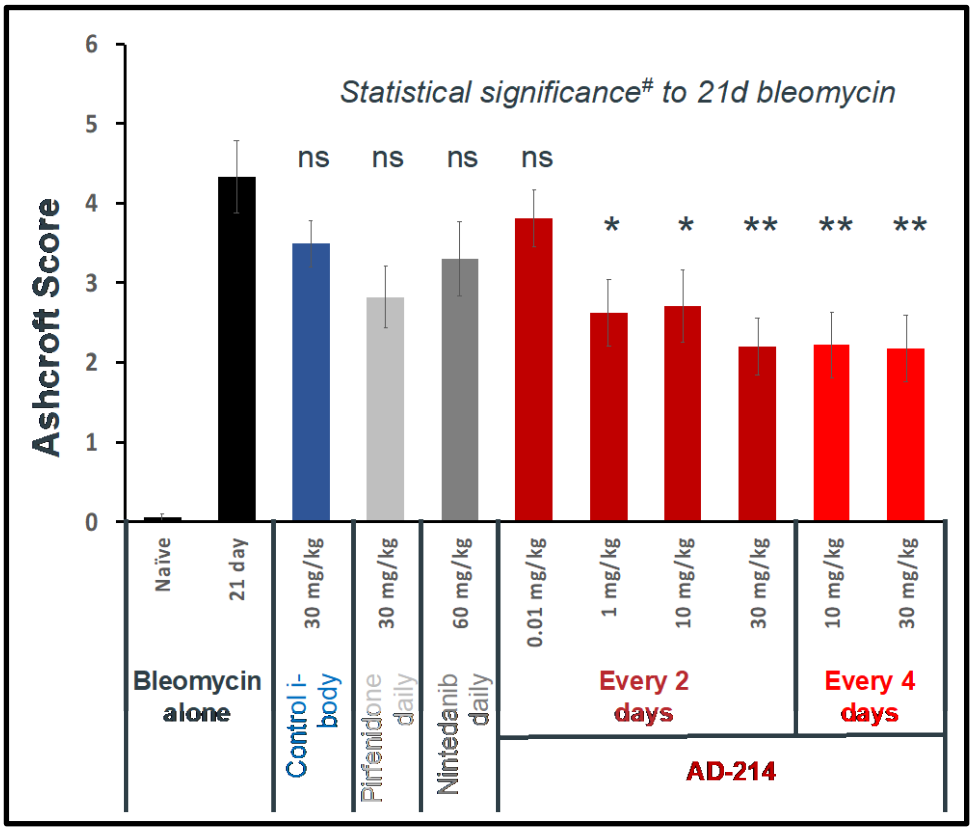

Figure 1: Ashcroft Score of mouse lung fibrosis 21 days after bleomycin administration and varying doses of AD-214, pirfenidone or nintedanib from day eight[1]

CEO Dr Tim Oldham, commented, "In January this year, AdAlta communicated that an additional pre-clinical study was required *in lieu* of a second half 2019 study that was not completed due to non-drug related technical issues. The data reported today is the result of a thorough investigation of the conduct of the previous study. Technical issues relating to the handling and scoring of lung tissue samples were corrected and the Ashcroft Scoring repeated on new samples by both the Contract Research Organisation and an independent laboratory.

"The additional pre-clinical *in vitro* efficacy study is still planned in order to investigate mechanism of action and support partnering efforts however we believe this is no longer a pre-requisite to commencing human clinical studies."

CSO Prof Michael Foley commented, "We are very pleased with the outcome of this study which builds on efficacy data from previous formats of our drug candidate. The mouse bleomycin model is well-recognised for conducting IPF research and AD-214 has been shown in this model to reduce fibrosis and to do so more effectively than current marketed IPF drugs under the conditions tested. With these results suggesting the potential to see activity in humans at doses as low as 1 mg/kg per week, we can now finalise the design and initiate our first-in-human study this year."

AdAlta is on track to commence Phase I human clinical studies of AD-214 in mid-2020.

[1] Statistical significance was determined using ANOVA and post-hoc Dunnett's test: ns = not statistically significant; * = statistically significant with $p < 0.05$; ** = very statistically significant with $p < 0.01$. Error bars represent standard error of the mean for each group.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
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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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