AdAlta
next generation protein therapeutics

ASX Announcement

AD-114 safe in non-human primates and manufacturing progress update

MELBOURNE Australia, 18 July, 2017: AdAlta Limited (ASX: 1AD), the biotechnology company advancing its lead i-body candidate towards clinical development, announces the results of two pre-clinical, non-human primate studies evaluating half-life and safety as well as an update on manufacturing progress.

Pre-clinical toxicology studies

Significant progress has been made with the completion of a number of pre-clinical toxicology studies, core to AdAlta's human trials of AD-114.

Single dose, pharmacokinetic study

The Company's first non-human primate study, reviewing the pharmacokinetic activity of the i-body when delivered via two routes of administration, subcutaneous (SC) and intravenous (IV), has been completed ahead of time.

The primary focus of the single dose study was to further understand the pharmacokinetics, or the way AD-114 is processed in the body via the different routes of administration. Preliminary clinical pathology safety readouts were also obtained. These measurements all demonstrated that the i-body was safe when dosed via either route.

Ascending dose safety study

Preliminary data from a second non-human primate safety study has been received, also ahead of time. The second study was designed to find an appropriate dose range for the i-body when used in AdAlta's planned Phase I human clinical trial.

This study evaluated three ascending doses of AD-114, measuring several safety parameters, including various hematology / blood evaluation readouts. The pharmacokinetic profile and receptor occupancy of AD-114 were also evaluated at the increasing doses. The drug was well tolerated and there were no adverse effects with increased doses of the i-body in non-human primates. Furthermore, no study mortalities or clinical signs relating to the increasing doses of AD-114 were observed.

AdAlta Limited
15/2 Park Drive
Bundoora VIC 3083 Australia

T +61 3 9479 5159
E enquiries@adalta.com.au
ABN 92 120 332 925

adalta.com.au

Importantly, AdAlta confirmed in both completed non-human primate studies, that AD-114 does not mobilise stem cells, unlike all other drugs which work by antagonizing the CXCR4 receptor pathway. This result is a potential advantage of AD-114 for long term treatment in diseases such as fibrosis. This data demonstrates that the long loop of the i-body has a distinct activity and AD-114 is differentiated from competing CXCR4 antagonist products.

AdAlta's Managing Director & CEO, Sam Cobb commented, "We are very pleased to be able to release the topline data from AdAlta's first two pre-clinical toxicology studies. In each study, we've seen that AD-114 has the expected half-life and performs in line with our safety expectations and most importantly, that the i-body has been shown to have no off-target effects. These results are very promising and we look forward to releasing further pre-clinical data soon."

A third study is well progressed which focuses on evaluating the safety of the i-body with a daily dosing regimen at increasing doses for AD-114. Data from this study is expected to be released shortly.

Manufacturing progress and Phase I trial update

On 12 September 2016, AdAlta announced that it had appointed FujiFilm Diosynth Biotechnologies to manufacture AD-114. Subsequent to that announcement, the material manufactured for use in the Company's pre-clinical toxicology studies has been shown to be active, have no adverse on or off target effects and sufficient materials have been provided to complete the pre-clinical toxicology studies outlined above.

Fuji has informed AdAlta that production of the next batch and completion of formulation studies required for the final non-human primate study, will be scheduled for the second half of 2017. This is expected to result in a short delay to the Company's Phase I trial, which is estimated to now be completed in the second half of 2018.

Managing Director & CEO, Sam Cobb continued, "Through the work completed to date we have been able to demonstrate that we can successfully manufacture the i-body and we've been pleased with the way the material has performed. These outcomes represent significant achievements within the AD-114 program.

We are ahead of schedule with the completion of the first two non-human primate studies, but will now incur a small delay to the start of our Phase 1 trial with this news from our manufacturer. The team is working hard to move things along as quickly as possible."

Notes to Editors

About AdAlta

AdAlta Limited is an Australian based drug development company headquartered in Melbourne. The Company is focused on using its proprietary technology platform to generate i-bodies, a new class of protein therapeutics, with applications as therapeutic drugs to treat disease.

I-bodies are a promising, novel class of drugs that offer a new and more effective approach to treating a wide range of human diseases. They are identified and developed using our proprietary technology platform.

We have pioneered a technology that 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, now known as i-bodies, for use in treating serious diseases.

AdAlta is developing its lead i-body candidate, AD-114, 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 also plans to continue further drug discovery and development directed towards other drug targets and diseases with its i-body technology platform.

Further information can be found at: www.adalta.com.au.

For more information, please contact:

AdAlta Limited
Sam Cobb, CEO
Tel: +61 (0)3 9479 5159
E: s.cobb@adalta.com.au