AdAlta
next generation protein therapeutics

ASX / Media Release

AdAlta update on Orphan Drug Designation application for lead drug targeting idiopathic pulmonary fibrosis

MELBOURNE, Australia, 14 October 2016: AdAlta Limited (ASX: 1AD) has received correspondence from the US Food & Drug Administration (FDA) regarding the development path towards Orphan Drug Designation approval for its lead drug candidate AD-114, targeting idiopathic pulmonary fibrosis (IPF).

As part of their review the FDA has requested additional pre-clinical data for its lead i-body candidate AD-114, namely data from an additional animal fibrosis model. The additional animal model requested is already underway and the Company is on track to re-submit its application with the additional data in Q4 2016.

Allowing for a standard 120-day review and response time, AdAlta expects to receive a response from the FDA within Q2 2017. AdAlta is working with a US based specialist in Orphan Drug Designation application to progress this application.

AdAlta Chief Executive Officer Samantha Cobb said, “The AdAlta team remains focused on delivering on our development milestones and advancing lead i-body AD-114 to the clinic. This new data will add to the existing body of data AdAlta already has around AD-114. Importantly we remain on track to file for an Investigational New Drug (IND) application with the FDA in H1 2018”.

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

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.

The i-body is a human analogue of the antigen binding domain of the shark antibody, which combines the advantages of monoclonal antibodies (high target specificity and affinity) with the beneficial stability features of small molecules. In addition to stability, the i-body has a long binding loop that is a feature of shark antibodies not present in either human or next generation antibodies. This feature enables the i-body to recognise and bind to a diverse range of different therapeutically-relevant drug targets, including those that are difficult/intractable to access by current antibody therapies. These include clinically important targets such as G-protein coupled receptors (GPCRs) and ion channels.

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. AD-114 has strong pre-clinical results for IPF, demonstrating both anti-fibrotic and anti-inflammatory activity in human lung tissue and indicating greater efficacy than existing approved IPF drugs.

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

At the Company
Sam Cobb
Chief Executive Officer
AdAlta Limited
Tel: +61 (0) 3 9479 5159
E: s.cobb@adalta.com.au

Media (Australia)
Andrew Geddes
Tel: +61 (0) 408 677 734

Media (International)
Sue Charles/Daniel Gooch
Tel: +44 (0) 20 7866 7905
E: adalta@instinctif.com