AdAlta
next generation protein therapeutics

ASX Announcement

AdAlta receives Orphan Designation for its lead drug candidate targeting patients with idiopathic pulmonary disease

MELBOURNE Australia, 18 January, 2017 - AdAlta Limited (ASX: 1AD), today announced it has received Orphan Drug Designation from the United States Food and Drug Administration (FDA) for AD-114, a novel first-in-class drug candidate for the treatment of idiopathic pulmonary fibrosis (IPF).

There is growing global interest in promising new treatments for fibrosis, especially for idiopathic pulmonary fibrosis, which has a 50 to 70 per cent mortality rate and affects 135,000 people in the US every year. Current therapies for the treatment of IPF 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.

Orphan Drug status allows for significant R&D tax credits, new drug application fee waivers and a seven year period of market exclusivity from the US Food & Drug Administration (FDA) after approval. Companies pursuing orphan treatments are usually granted accelerated development and regulatory timelines as well as premium pricing.

AdAlta Chief Executive Officer Sam Cobb said, "Securing Orphan Designation for our lead program represents an important step in our strategy for the rapid commercial development of AD-114 for the treatment of idiopathic pulmonary disease. We expect this orphan designation, when combined with our pre-clinical package of AD-114, will help accelerate our commercial development path."

"AdAlta remains on track to meet its stated clinical development milestones and management remains focused on expediting AD-114 into Phase 1 human clinical trials for idiopathic pulmonary fibrosis by early 2018."

More recently AdAlta also demonstrated broad fibrotic application of AD-114, demonstrating the potential of AD-114 for the treatment of other fibrotic diseases including the liver (NASH) and eye (wet-AMD).

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

Notes to editors

About AdAlta Limited

AdAlta Limited (ASX:1AD) 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 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. 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 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.

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*

Orphan Drug Designation

The Orphan Drug Designation program provides orphan status to drugs which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders that affect fewer than 200,000 people in the US, or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan Drug Designation qualifies the sponsor for seven-year FDA-administered market Orphan Drug Exclusivity (ODE) on successful approval of the drugs. It also qualifies the sponsor for various regulatory and financial support measures as the treatment progresses through pre-clinical and clinical development in the US.

NASH

Nonalcoholic steatohepatitis (NASH) is liver inflammation and damage caused by a buildup of fat in the liver, inflammation and fibrosis. NASH can get worse and the progressive fibrosis or scarring of the liver leads to cirrhosis. NASH affects 70-90% of obese or diabetic populations, and overall, NASH affects 3-5% of the US population, for which there are no treatments currently approved.

Wet-AMD

Infection or inflammation of the eye results in impairment of visual function and can ultimately lead to fibrosis. Eye fibrosis diseases include diabetic retinopathy and age related macular degeneration (AMD). AMD is the commonest cause of severe visual impairment in people over the age of 50 years in the developed world. It is estimated that in 2010, there were 1.023 million Australians and 2.07 million Americans with AMD and these figures are expected to double by 2050. In Australia, AMD is the most common cause of blindness contributing to 50% of all blindness. Globally, diabetic retinopathy is one of the most significant causes of visual loss and a principal cause of impaired vision in patients aged between 25 and 74 years of age. According to the US National Institutes of Health National Eye Institute, it was estimated that there were 7.7 million Americans affected by diabetic retinopathy in 2010. The numbers of people with these diseases is predicted to increase due to demographic ageing.

Contact:

At AdAlta Limited

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
E: adalta@instinctif.com

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