24 February 2021

ASX Announcement

FDA ORPHAN DRUG DESIGNATION FOR AD-214

MELBOURNE Australia, 24 February 2021: AdAlta Limited (ASX:1AD), a clinical stage biopharmaceutical discovery and development company using i-body technology to address challenging drug targets has received Orphan Drug Designation (ODD) from the US Food and Drug Administration (FDA) for its lead product candidate AD-214 for the treatment of Idiopathic Pulmonary Fibrosis (IPF).

The Food and Drug Administration (FDA) created the Orphan Drug Act to encourage and provide special incentives to biopharmaceutical companies that undertake the development of promising potential treatments for rare or 'orphan' diseases that affect fewer than 200,000 people in the United States.

ODD entitles AD-214 to certain benefits during development for IPF including eligibility for seven years market exclusivity post approval, tax credits of 50% of qualified clinical drug testing costs awarded upon approval, additional protocol assistance, reduced review times and waiver of certain marketing authorisation application fees. In addition to bringing novel therapies to sufferers of rare diseases more rapidly, these benefits add additional economic value to AD-214 for AdAlta and its eventual commercialisation partners.

The grant of ODD for AD-214 follows the previous grant of ODD for AD-114, the predecessor molecule to AD-214.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
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Notes to Editors
About AdAlta

AdAlta Limited is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body technology platform to solve challenging drug targeting problems and generate a promising new class of single domain antibody protein therapeutics with the potential to treat some of today's most challenging medical conditions. The i-body technology mimics the shape and stability of a unique and versatile antigen-binding domain that was discovered initially in sharks and then developed as a human protein. The result is a range of unique proteins capable of interacting with high selectivity, specificity and affinity with previously difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases. i-bodies are the first fully human single domain antibody scaffold and the first based on the shark motif to reach clinical trials.

AdAlta is conducting Phase 1 clinical studies for its lead i-body candidate, AD-214. 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 entering collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare to discover i-bodies as diagnostic imaging agents against Granzyme B, a biomarker of response to immuno-oncology drugs.

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 implicated 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: https://adalta.com.au

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