ASX Announcement/Press Release | 10 October 2024
AdAlta Limited (ASX:1AD)

AdAlta appoints AD-214 Clinical Advisory Board

The newly-created Clinical Advisory Board, which includes some world-leading Idiopathic Pulmonary Fibrosis (IPF) experts, will help support AdAlta's efforts to progress AD-214 towards Phase II trials and, ultimately, to commercialisation

Investment highlights

- AdAlta has established Clinical Advisory Board for AD-214, the Company's lead i-body® enabled drug candidate
- The Board's members are renowned experts in the field of pulmonary medicine and fibrosis, and possess a wealth of experience in IPF-specific clinical trials
- AdAlta has also engaged a specialist adviser for IPF translational science

AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company") is pleased to announce the formation of a Clinical Advisory Board (CAB) and the appointment of an additional adviser for its lead asset AD-214, which is being developed to treat Idiopathic Pulmonary Fibrosis (IPF). These strategic appointments are part of the Company's ongoing preparations for upcoming Phase II clinical trials of AD-214, which, pending the completion of financing arrangements, would aim to build on the positive results observed in Phase I studies.

The newly created CAB represents another milestone in the broader strategy of AdAlta's subsidiary, AdSolis, to advance the development and commercialisation of AD-214, a first-in-class molecule that has shown promise to improve outcomes for the more than 500,000 IPF patients worldwide for whom the disease is terminal.

AdAlta CEO and Managing Director, Tim Oldham said: "*Our efforts to develop AD-214 have taken a further significant step forward with the creation of our Clinical Advisory Board and the appointment of a specialist adviser for translational science. As a group, these highly skilled healthcare professionals are not just experts in the treatment of Idiopathic Pulmonary Fibrosis, they are also passionate about advancing therapeutic options for this debilitating disease and collectively have immense experience in delivering IPF clinical trials, We welcome them to AdAlta as the Company looks to advance its development of AD-214.*"

All members of the CAB are experts in pulmonary medicine and fibrosis

The newly-created Clinical Advisory Board includes internationally recognized experts in the field of pulmonary medicine and fibrosis. Importantly, these individuals also, all bring a wealth of experience from their involvement in multiple IPF clinical trials. The members of the CAB are:

- *Professor Tamera Corte*: Professor Corte is affiliated with both the Royal Prince Alfred Hospital in Sydney and the University of Sydney. She is currently the Chief Investigator on the Centre of Research Excellence for Pulmonary Fibrosis and founding Chair of the Steering Committee for the Australian Idiopathic Pulmonary Fibrosis Registry, the Australasian Interstitial Lung Disease Registry. She has extensive experience in IPF research and clinical trials, contributing significantly to the understanding and treatment of the latter disease.
- *Professor Toby Maher:* Currently at the Keck School of Medicine, University of Southern California, Professor Maher is a renowned respiratory physician and researcher whose work has focused on

innovative treatments for IPF. He has been Global Chief Investigator for multiple commercial trials for IPF and other interstitial lung diseases and has recruited more than 1,000 subjects to 35+ clinical studies over the past eight years.

- *Professor Marlies Wijsenbeek-Lourens:* Based at Erasmus University Rotterdam, Professor Wijsenbeek-Lourens is a leading pulmonologist with a strong track record in IPF and other interstitial lung diseases (ILD) clinical trials and patient care. She is currently chair of the Erasmus MC multidisciplinary ILD and sarcoidosis center, a European ILD reference center.
- *Professor Philip Molyneaux:* Professor Molyneaux is currently the lead consultant for clinical trials in pulmonary fibrosis at Royal Brompton and Harefield Hospitals, and is the director of the NIHR cardiorespiratory clinical research facility. His research has been pivotal in advancing new therapeutic approaches for IPF.
- *Dr Steve Felstead MB ChB*: Dr Felstead will transition from AdAlta's Scientific Advisory Board to the Clinical Advisory Board, bringing his extensive clinical drug development expertise and knowledge of AD-214 to the team. Steve was Vice President, Head of Clinical Research, Pharma-therapeutics Division, Pfizer Inc after being Development Therapeutic Area Head for Allergy and Respiratory medicines. He is currently Chief Medical Officer at Juvenescence Ltd.

Translational Science Adviser also appointed

In addition, AdAlta is pleased to announce the engagement of Professor Gisli Jenkins from Imperial College London as a specialist adviser for translational science. Professor Jenkins currently leads the Margaret Turner Warwick Centre for Fibrosing Lung Diseases at the National Heart and Lung Institute and is an honorary consultant physician at the Royal Brompton Hospital in London. Professor Jenkins' expertise in bridging the gap between laboratory research and clinical application will be invaluable as AdSolis moves forward with AD-214.

The formation of this Clinical Advisory Board together with the appointment of a specialist adviser for translational science underscores AdAlta's commitment to advancing AD-214 through its next stage of development. The collective expertise and global reach these healthcare experts bring to AdAlta will be instrumental in guiding AD-214's Phase II clinical trial preparations and ensuring the trial's success.

For a video summary of this release and opportunity to engage in a virtual discussion see: https://investorhub.adalta.com.au/link/lPdzqe

This ASX announcement has been authorised for release by the Board of AdAlta Limited (ASX:1AD).

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About AdAlta Limited

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 enabled protein and cell 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's lead i-body® enabled candidate is AD-214. At any time, 500,000 patients with lung fibrosis (IPF) face death from inability to breath, despite spending US$4.3 billion per year on pharmaceutical therapies. Fibrosis can affect all organ systems and around 45% of all western country deaths have a fibrotic disease component. AD-214 is taking a wholly new approach to treat IPF and other fibrotic diseases. AD-214 is a first in class (first to utilize this mode of action) molecule and has been shown to be safe in Phase I clinical studies and effective in multiple animal and laboratory models of fibrotic disease. In accord with its business model, AdAlta is creating a private, unlisted subsidiary called AdSolis to advance AD-214 into Phase II clinical trials through licensing and/or third party investment.

AdAlta believes that the i-body® technology is ideally suited for use in the creation of advanced cellular immunotherapies for cancer and that this field represents an opportunity to expand its clinical stage pipeline. It has entered a Memorandum of Understanding with SYNthesis BioVentures to investigate the formation of a jointly owned entity, to be called AdCella, that, once established, will provide innovative cellular immunotherapies originating in Asia with a pathway to western regulated markets via Australian clinical trials and further enhancement with AdAlta's i-body® technology. It has appointed Cell Therapies Pty Ltd, Australia's leading manufacturer of cell and gene therapies, as AdCella's preferred manufacturer.

The Company is also entering collaborative partnerships to advance the development of its i-body® platform. It has a collaboration with Carina Biotech to codevelop precision engineered, i-body® enabled CAR-T cell therapies (i-CAR-T) to bring new hope to patients with cancer. It has an agreement with GE Healthcare to co-develop i-bodies as diagnostic imaging agents (i-PET imaging) against Granzyme B, a biomarker of response to immuno-oncology drugs, a program now in preclinical development.

AdAlta's strategy is to maximise the products developed using its next generation i-body® platform by 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.

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