7 October 2021

ASX Announcement

BTB FUNDING AGREEMENT TRANSFERRED TO AD-214 INHALED PROGRAM

Key points

- **AdAlta was awarded A$1 million in funding from the Medical Research Future Fund's (MRFF) Biomedical Translation Bridge (BTB) program in December 2019**
- **Initial funding (A$0.22 million) was used to develop a radiolabelled version of AD-214, AdAlta's lead asset, for PET imaging to optimise clinical development**
- **Insights from use of the radiolabelled product led AdAlta to alter AD-214 clinical program; much of the original grant funding was allocated to activities now no longer needed**
- **AdAlta and MTPConnect (who deliver the BTB program) have agreed to reallocate A$0.76 million in unspent grant funds to developing an inhaled version of AD-214 while also improving the intravenous formulation**

MELBOURNE Australia, 7 October 2021: AdAlta Limited (ASX:1AD) is pleased to announce an amendment to its funding agreement with MTPConnect under the Australian Government's Medical Research Future Fund's (MRFF) Biomedical Translation Bridge (BTB) program, with support from BTB partner, UniQuest. The amended BTB agreement will see A$0.76 million in matched funds, originally allocated to other workstreams, transferred during FY2022 to support the development of inhaled and improved intravenous formulations of AdAlta's lead product AD-214 for Idiopathic Pulmonary Fibrosis (IPF) and other fibrotic diseases.

AdAlta's CEO and Managing Director, Tim Oldham, commented:

"Insights generated from the BTB grant funding to date have been of significant value in shaping AdAlta's clinical strategy. The development and use of a radiolabeled version of AD-214 for PET imaging provided us with insights that could not have been obtained in any other way. These have informed and guided our clinical development strategy. We are very grateful for the continued support of the BTB program as we seek to bring a much-needed new therapeutic option to patients suffering the debilitating effects of Idiopathic Pulmonary Fibrosis."

Background

In December 2019, AdAlta announced that it had been awarded A$1 million in matched funds under the BTB program. The funding was to support the development and clinical evaluation of a radiolabelled version of AdAlta's lead asset, AD-214. The radiolabelled version, RL-AD-214, was successfully developed and used in preclinical studies to show, through PET imaging, where AD-214 was distributed in animal models.

Insights from these studies using RL-AD-214, as well as findings from the recent Phase I AD-214 clinical trial, led AdAlta to shift the focus of its IPF clinical program from intravenous administration to a likely more cost effective and patient convenient inhaled formulation. Work is also commencing to modify the intravenous formulation to improve its suitability for use in other fibrotic indications.

With the change of focus, much of the original funding was allocated to activities no longer needed. To date, A$0.22 million has contributed to the development of RL-AD-214 under the BTB agreement. AdAlta and MTPConnect have now agreed an amended program of development under which the BTB program will reallocate $0.76 million in matched funds in FY2022 towards the development of an inhaled formulation and alternate intravenous formulations of AD-214. This is intended to prepare AD-214 for inhalation toxicology studies to commence during the second half of calendar 2022.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
October 2021

Notes to Editors
About the Biomedical Translation Bridge program

The Biomedical Translation Bridge program is an initiative of the Australia Government's Medical Research Future Fund. The BTB program can provide up to A$1 million of funding over a maximum two-year year period to help eligible organisations fund and nurture early-stage health and medical research to reach proof-of-concept with potential to attract further capital and support. The BTB program is delivered by MTPConnect, in partnership with BioCurate (University of Melbourne and Monash University), UniQuest (University of Queensland through its drug discovery initiative QEDDI), the Medical Device Partnering Program (MDPP, led by Flinders University), and the Bridge and BridgeTech programs (Queensland University of Technology); all pre-eminent organisations engaged in the translation and commercialisation of health and medical research.

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 has completed Phase I clinical studies for its lead i-body candidate, AD-214, that 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 co-develop i-bodies as diagnostic imaging agents against Granzyme B, a biomarker of response to immuno-oncology drugs, a program now in preclinical development. It also has a collaboration with Carina Biotech to co-develop precision engineered, i-body enabled CAR-T cell therapies to bring new hope to patients with cancer.

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

For more information, please contact:

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