ASX Announcement

AD-214 Phase I strategy and timing update

Highlights:

- **AD-214 trial protocol to now include both healthy volunteers and IPF/ILD patients and incorporate a radiolabelled version of AD-214**
- **This design is expected to yield strongest data for partnering discussions**
- **Development program to include an additional pre-clinical study**
- **Combination of enhanced trial design and decision to conduct an additional pre-clinical study to slightly delay Phase I trial commencement to mid-2020**
- **The Company has access to sufficient cash reserves to absorb the minor delay**

MELBOURNE Australia, 14 January 2020: Following a strategic review, AdAlta Limited (ASX: 1AD) today provides an update on its lead program, AD-214 – a first in class i-body based therapeutic which is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF).

In December 2019, AdAlta announced it had been awarded a Biomedical Translation Bridge grant of up to $1 million in value by MTPConnect. The grant is designed to provide funding for the Company to develop a radio-labelled tracer that will enable AD-214 to be tracked using PET imaging when delivered to IPF patients. Using this tracer in IPF (and other fibrotic disease) patients is expected to provide strong, marketable data concerning AD-214 localisation, distribution and time on target for commercial discussions with potential pharmaceutical partners, as well as informing more efficient future development plans.

The opportunity provided through this grant has led AdAlta to reassess the design of the overall Phase I clinical program to ensure that maximum clinical insights are generated as quickly as possible. The Company is now working to propose a Phase I program to ethics committees that incorporates an initial single dose component in healthy volunteers to confirm the safety and pharmaco-kinetic profile of AD-214, followed by single and multi-dose components in patients where the radio-labelled version of AD-214 may be used to image disease and track the homing of AD-214 to diseased tissue. The patient components are being designed to include patients with a range of fibrotic interstitial lung diseases (ILDs) of which IPF is one the most common. Broadening the range of eligible patients will improve recruitment and potentially extend the market opportunity for AD-214.

Following an extensive internal review of all pre-clinical data received to date, the Board has determined that an additional pre-clinical study should be conducted in *lieu* of a second half 2019 study that was unable to generate results in any arm of the study including the control and competing product arms. The Company believes that there were technical limitations in the design and

execution of the 2019 study by an external Contract Research Organisation (CRO) and that these can be addressed in this new study.

The Company believes the safety profile of AD-214 is strong, the CXCR4 receptor that AD-214 targets is validated in IPF, other ILDs and other fibrotic diseases and that AD-214 binds very specifically to the CXCR4 receptor with high affinity. Adding to the existing proof of concept data by completing this additional study prior to commencing clinical trials is a prudent step prior to testing AD-214 in healthy volunteers or patients and also better supports partnering.

The combination of the time required conduct the new pre-clinical study and to rework the Phase I human clinical trial to fast-track the radiolabelled version of AD-214 into the study protocol, will lead to a minor (4-5 month) delay to commencement of the Phase I human clinical trial to mid-2020.

AdAlta believes it has access to sufficient cash resources to conduct the additional pre-clinical study, develop the radiolabelled AD-214 imaging agent (subject to finalising the previously announced BTB grant), and complete the healthy volunteer component of the Phase I program.

AdAlta's CEO, Dr Tim Oldham commented, "Reviewing the development plan and complete data set for AD-214 has been an important part of my initial review of the overall AdAlta strategy since joining the Company in October. The strategic review has also included discussions with leading pulmonary physicians, the Company's clinical CRO and several potential licensing partners. There remains a very strong commercial market for fibrosis drugs and a strong pre-clinical data set supporting our view that AD-214 can be compelling to potential pharmaceutical partners.

The key outputs of the review, combined with the BTB grant award, confirm that integrating the radiolabelled AD-214 into the human clinical study and including IPF and other ILD patients is the most compelling strategy. While establishing safety is crucial, establishing that AD-214 reaches and engages with fibrotic tissue in patients is clearly much more powerful and should enable us to have higher-value partnering discussions without unduly extending the time required to obtain these results. The additional pre-clinical data we are now planning will better inform clinical dose ranges and intervals, further supporting the Phase I study design. There is a good return on the minor timeline delay we will incur generating this additional pre-clinical data and commencing clinical testing. We will also use the delay to seek additional regulatory input to our strategy."

Authorised for lodgement by:
Tim Oldham
CEO & Managing Director

-ENDS-

Notes to Editors

About AdAlta

AdAlta Limited is an Australian-based drug development company headquartered in Melbourne. The Company is using its proprietary technology platform to generate a promising new class of single domain antibody protein therapeutics, known as i-bodies, that have the potential to treat some of today's most challenging medical conditions. The technology mimics the shape and stability of a crucial antigen-binding domain, that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, capable of uniquely interacting with previously difficult to access targets such as G-protein coupled receptors and ion channels that are implicated in many serious diseases.

AdAlta is currently preparing for its phase 1 clinical studies for its lead i-body candidate, AD-214. The clinical program is expected to commence in mid-2020 following clinical trial design finalisation and completion of a pre-clinical study to inform dose levels. 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 in collaborative partnerships to advance the development of its i-body platform. It has an agreement with UK-based research organisation, Excellerate Bioscience to collaborate on an undisclosed target of commercial interest and an agreement with GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

AdAlta plans to continue further drug discovery and development directed towards other drug targets and diseases.

Further information can be found at: www.adalta.com.au.

For more information, please contact:

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