24 May 2021

ASX Announcement

ADALTA AND GE HEALTHCARE ADVANCE GRANZYME B I-BODIES INTO PRE-CLINICAL DEVELOPMENT, EXTEND COLLABORATION

Highlights

- AdAlta and GE Healthcare progress collaboration to next stage
- Multiple AdAlta i-bodies selected to progress from discovery into pre-clinical development of PET imaging agent for immunotherapy
- Collaboration extended: AdAlta to support manufacturing and some *in vitro* testing, generating additional revenue
- Leading PET imaging agents generate US$400m in annual sales in US$6.4b diagnostic radiopharmaceutical market

MELBOURNE Australia, 24 May 2021: AdAlta Limited (ASX:1AD), the clinical stage biotechnology company developing novel therapeutic products from its i-body platform is pleased to announce that its commercial agreement with GE Healthcare (see ASX announcements dated 16 September 2019 and 26 September 2019) is now moving to the next phase, following the successful identification of multiple i-bodies to be advanced into pre-clinical development for use as a potential PET diagnostic imaging agent. AdAlta's role is being expanded.

PET – or Positron Emission Tomography – imaging plays a vital role in the development and use of cancer immunotherapies by non-invasively measuring patient response before, during and after treatment. For this reason, the diagnostic radiopharmaceuticals market is forecast to be worth US$6.4 billion by 2027,[1] with the largest PET imaging agents generating annual sales of more than US$400 million.[2]

The PET diagnostic under development by AdAlta and GE Healthcare is designed to show whether immune cells produce an enzyme called granzyme B in tumours, and therefore whether cancer immunotherapies, such as checkpoint inhibitors are working effectively to reactivate the immune system that the tumour has suppressed.

Dr Paul Evans, Head of Global R&D, GE Healthcare Pharmaceutical Diagnostics said: *"Granzyme B is a key target for PET imaging of immune cell activity in cancer that can indicate whether certain cancer therapies are working. This could provide vital early information to help with assessing the next steps in a patient's treatment regime. We are very pleased with the progress of our collaboration with AdAlta and look forward to our expanded association as we progress further into development."*

Dr Tim Oldham, AdAlta's Chief Executive Officer, said: *"Co-developing i-body products with leading partners like GE Healthcare is a core part of AdAlta's strategy to build a strong and diverse pipeline. We are proud to have ticked a significant milestone as this diagnostic moves from discovery to pre-clinical development and also to contribute our growing manufacturing expertise to accelerating development of this important product."*

[1] Global Industry Analysts, Imaging Agents: Global Market Trajectory and Analytics, April 2021
[2] AD Nunn, J Nucl Med (2007) 169

The small size of the i-body makes it ideal as an imaging agent. AdAlta has now successfully completed the discovery and lead optimisation process to identify and characterise i-bodies suitable for further development. GE Healthcare have now selected multiple i-bodies binding to granzyme B and with other required properties to be progressed into pre-clinical development, marking the next step in the collaboration. Assuming pre-clinical proof of concept is established, candidates will be selected to advance into clinical development.

GE Healthcare and AdAlta have agreed an amendment to their collaboration agreement under which AdAlta will now provide support for i-body manufacturing for both pre-clinical and clinical testing of these candidates, as well as conducting certain pre-clinical studies. AdAlta will earn additional research fees funding this additional support ahead of the next milestone payment due, assuming technical success, on achieving pre-clinical proof of concept (and selection of a lead i-body candidate).

Initially a granzyme B PET imaging agent would support pharma companies as a research tool to enhance clinical trials, improving speed-to-market for immunotherapies. Subsequent regulatory approval could enable the product to be used as a routine diagnostic and patient stratification tool.

The agreement between AdAlta and GE Healthcare is an example of AdAlta's strategy to develop external assets for partners and collaborators alongside development of its own internal pipeline assets. AdAlta's lead internal pipeline asset is AD-214, which is progressing through Phase I human trials as a promising new approach for the treatment of Idiopathic Pulmonary Fibrosis.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
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Notes to Editors

About granzyme B and the immuno-oncology market

The market for immuno-oncology drugs is forecast to reach US$95 billion by 2026.[3] These drugs work by reactivating the immune system that has been suppressed by cancer. Only 20-40% of cancer patients respond to these novel therapies.[4] Non-invasive techniques such as PET imaging help identify responders and appropriate therapies earlier in treatment and so improving outcomes, reducing costs and unnecessary side effects and, when used during clinical trials, accelerating development of new drugs. Since granzyme B is released by activated T cells as part of an immune response to cancer, it is a very attractive target for PET imaging.

[3] ResearchandMarkets.com, Immuno-Oncology - Market Analysis, Trends, Opportunities and Unmet Needs - Thematic Research, March 2021
[4] P Sharma, *et al*, Cell 168(4) 707 (2017)

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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