24 August 2021

ASX Announcement

AdAlta and Carina Biotech to develop next-generation CAR-T cancer therapeutics

Highlights

- AdAlta and Carina Biotech enter a collaboration agreement to develop i-body enabled CAR-T cancer immunotherapies against up to five solid tumour antigen targets
- Combining Carina's advanced CAR-T platform technologies with AdAlta's i-body targeting capability aims to create unique, next-generation bi-specific CAR-T cells
- Significant market potential with cellular immunotherapies market forecast to grow at 20% per year.[1]
- Agreement delivers on AdAlta's corporate strategy and contributes to the goal of having 5 pipeline products by end CY2021
- Joint AdAlta/Carina investor briefing to be held tomorrow at 2:30pm AEST

Melbourne and Adelaide, Australia, 24 August 2021
AdAlta Limited (ASX:1AD) and Carina Biotech Pty Ltd have entered a collaboration agreement to develop next-generation i-body enabled CAR-T cells, with the potential to bring CAR-T cell therapy to treat a far greater range of cancers than the small number of blood cancers that has been achieved today.

CAR-T cell therapy is a fast-emerging form of cancer therapy that modifies a patient's immune system to recognise and attack cancer cells that have resisted standard treatments such as chemotherapy and radiation.

AdAlta's CEO, Dr Tim Oldham commented, *"We believe that by combining our i-bodies with Carina's world-class CAR-T platform, we can make this important new therapeutic approach accessible to more patients and a greater range of cancers than is possible today. We are well past the starting line, having worked previously on the first two targets selected for our collaboration, and with Carina on one of these."*

Carina's CEO, Dr Deborah Rathjen commented, "*This collaboration with AdAlta gives us the capability to generate bi-specific CAR molecules and then next-generation CAR-T cell products with enhanced cancer targeting and efficacy – something we are very excited about. The collaboration is off to a great start with Carina having already successfully inserted an AdAlta i-body into a CAR-T cell with functional cancer killing capability."*

About the collaboration
Under the Collaboration Agreement, AdAlta will discover and optimise panels of i-bodies

[1] Grandview Research, T-cell Therapy Market Size, Share & Trends Analysis Report 2021 – 2028, Feb 2021

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that bind to designated solid tumour antigen targets, from which Carina will generate bi-specific CAR-T cells and identify optimal CAR-T product candidates. Carina and AdAlta will jointly fund pre-clinical proof of concept studies in mouse tumour models.

The Collaboration Agreement contemplates commencing work on up to five tumour antigen targets during the next two years and will continue until completion of research on the final target. The first two targets have been selected enabling research to commence within the next three months. AdAlta's initial contribution will leverage its established laboratory resources and is not anticipated to have a material impact on current cash runway.

AdAlta and Carina will jointly own the products developed through the collaboration. On a product-by-product basis: the companies may elect to continue to co-develop any product; out-license any product to third parties; or either company may exercise an option to license the other party's share of the collaboration assets.

Dr Tim Oldham continued, *"A core part of AdAlta's strategy is to enter collaborations with partners where we can further the use of our i-bodies to address disease targets previously thought undruggable. The i-body-directed CAR-T cells will be the second example of this, complementing our collaboration with GE Healthcare where i-bodies are being used to deliver a PET imaging agent. The Carina collaboration contributes multiple potential products to our pipeline expansion goals."*

AdAlta and Carina will host a Webinar to discuss the collaboration results at 2.30pm AEST Wednesday, 25 August 2021. Register here:

https://us02web.zoom.us/webinar/register/WN_D9rF0gIEQN--qzeohAXAGQ

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
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About CAR-T cell therapy

Chimeric antigen receptor T cell (CAR-T) therapy is a revolutionary and targeted cancer treatment option that harnesses a patient's own immune system to fight their cancer, providing a personalised cancer treatment. It was named by the American Society of Clinical Oncology (ASCO) as its Advance of the Year in 2018.

Chimeric antigen receptors (CARs) are human-engineered molecules expressed on the surface of a patient's T cells – key cells of the immune system. These CAR molecules are "targeted" at molecular markers on cancer cells. T cells armed with CARs (CAR-T cells) can more easily "home in" on cancer cells and destroy them.

There are already five approved CAR-T therapies available in the US today. These are generating transformational outcomes for patients with a small number of blood cancers that have failed multiple prior lines of therapy. Even with these limited early applications, the market is forecast to grow at 20.2% per year, and to be worth $20.3 billion by 2027.[2]

[2] Grandview Research, T-cell Therapy Market Size, Share & Trends Analysis Report 2021 – 2028, Feb 2021

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Revenues from solid tumour CAR-T cell therapies are forecast to exceed revenues from blood cancer CAR-T cell therapies by 2030.[3]

About i-bodies

i-bodies are an example of a "next-generation antibody". Antibodies are large protein molecules playing a key role in the immune system's response to the presence of a foreign substance (antigen). Next generation antibodies are smaller proteins engineered to replicate key functions of full-sized antibodies and are predicted to have a major impact on human health, particularly in oncology, autoimmunity and chronic inflammatory diseases.[4]

AdAlta's proprietary i-bodies are approximately one tenth of the size of conventional monoclonal antibodies. They were engineered using a human protein backbone and synthetic antigen binding regions to mimic small, very stable "single domain antibodies" found in sharks. The result is a range of unique and versatile proteins capable of interacting with high selectivity, specificity and affinity with previously difficult-to-access targets in the human body that have been implicated in many serious diseases.

Benefits of combining CAR-T and i-bodies

The small size and unique targeting of i-bodies provides greater flexibility and design options for CAR-T cells and are ideally suited for the production of bi-specific CARs with increased precision and efficacy. i-bodies can be utilised as the binding domain of a CAR receptor that engages the tumour antigen. i-bodies are approximately half the size of traditional binding domains and are capable of accessing and engaging antigens in unique ways.

About AdAlta

AdAlta Ltd is a clinical stage drug development company headquartered in Melbourne, Australia. Using its proprietary i-body technology platform, AdAlta aims 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.

AdAlta has completed Phase I clinical studies for its lead i-body candidate, AD-214, 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.

For more information visit: www.adalta.com.au

About Carina Biotech

Carina Biotech Pty Ltd is developing CAR-T and other adoptive cell therapies for the treatment of solid cancers from its headquarters in Adelaide. Using its proprietary chemokine receptor platform, Carina aims to improve access to, and infiltration of, solid

[3] Polaris Market Research, CAR-T Cell Therapy Market Share, Size, Trends, Industry Analysis Report 2021 – 2028, June 2021
[4] https://www.nature.com/articles/nrd.2017.227

cancers by CAR-containing cells to create more potent and specific cancer cell killing and reduced off-target effects. Carina has a fully integrated, proprietary manufacturing process that has both reduced manufacturing time and improved CAR-T cell quality capable of delivering robust CAR-T cells to patients.

Carina has a deep pipeline of CAR-T programs and is progressing its lead product against a cancer stem cell antigen, LGR5, through IND-enabling activities with the aim of commencing clinical trials in patients in 2022. Carina successfully out-licensed its first CAR-T product against novel solid tumour antigen nfP2X7 to Biosceptre (UK).

For more information visit: www.carinabiotech.com

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