ASX Announcement | 25 May 2026

AdAlta Limited (ASX:1AD)

AdAlta engages sector-leading advisors to support US FDA engagement for BZDS1901 CAR-T therapy

Early engagement with the US Food and Drug Administration is expected to improve the efficiency and quality of clinical trial preparation and support access to potential accelerated regulatory pathways

Investment highlights

- **AdAlta has engaged Dark Horse Consulting Group, Inc ("DHC"),** a leading specialist in cell and gene therapy development, **to support regulatory engagement with US Food and Drug Administration ("FDA")** for its BZDS1901 CAR-T therapy
- **Initial work will focus on preparing for a near-term pre-IND meeting with the FDA** to ensure manufacturing technology transfer to Australia and Phase 1 clinical trial preparation are aligned with FDA expectations
- DHC will also advise AdAlta on **potential advanced regulatory designations and accelerated pathways** that may provide enhanced FDA engagement, shorter review timelines and other commercial advantages for future partners
- **BZDS1901 has delivered multiple tumour responses (shrinkage)** in patients with advanced and refractory mesothelioma, including two patients who have **achieved complete tumour clearance (Complete Response)** that remain ongoing at 6 and 22 months after treatment respectively. BZDS1901 targets an estimated **US$4.2 billion** segment of the **advanced mesothelioma market**

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or **"the Company"),** developer of next generation cellular immunotherapies for solid cancers, today announced that it has engaged Dark Horse Consulting Group, Inc ("**DHC**"), a leading cell and gene therapy consulting firm, to initiate regulatory engagement with US Food and Drug Administration ("**FDA**") for AdAlta's lead CAR-T[1] program, **BZDS1901**.

The engagement is intended to help ensure that BZDS1901 manufacturing technology transfer to Australia, process optimisation, preclinical studies and planned Australian Phase 1 clinical trial design are **aligned with FDA expectations** before formal regulatory submissions are made. Early engagement with the FDA, particularly through a pre-IND meeting, is **widely regarded as an important step in improving the quality and efficiency of future IND applications and reducing the risk of delays** from additional information requests.

The engagement will also help AdAlta **assess and prioritise potential expedited and enhanced regulatory pathways** that may be available to advanced therapies such as CAR-T cell therapies and treatments for rare cancers including mesothelioma.

BZDS1901 is a first-in-class CAR-T cell therapy that has already demonstrated multiple tumour responses, including two cases of complete tumour clearance (Complete Response, CR), in patients with advanced mesothelioma. Complete Responses are rarely achieved in advanced mesothelioma and both responses remain ongoing at 6 and 22 months respectively (monitoring continues). These responses were observed in

[1] CAR-T (chimeric antigen receptor-T cell) therapy is a living drug manufactured from a patient's own immune cells by engineering them in a laboratory to incorporate a receptor that can bind to a molecule found on the surface of a cancer, enabling the immune cells to be able to find and kill cancer. As a living drug, CAR-T cell therapy has the potential for a single dose to have durable effects and to be potentially curative.

patients whose cancer had previously progressed despite chemotherapy and immunotherapy treatment. The addressable advanced mesothelioma market is estimated at US$4.2 billion per year. [2]

AdAlta CEO, Dr Tim Oldham said:
"Early engagement with the FDA is an important step in ensuring that our clinical, manufacturing and regulatory strategy for BZDS1901 is aligned with the expectations of the world's leading regulator for cell therapies.

By engaging Dark Horse Consulting Group, Inc, we are adding highly specialised expertise with deep experience in CAR-T and cell therapy development. Their guidance will help us prepare efficiently for clinical trial approvals and position BZDS1901 to take advantage of potential regulatory pathways that could accelerate development and increase the attractiveness of the program to future partners."

Early US FDA engagement can improve efficiency of Phase 1 clinical trial preparation
To commence Australian Phase 1 clinical trials for BZDS1901, regulatory approval is required. AdAlta has elected to seek approval through the US FDA, which can then be automatically recognised by Australia's Therapeutic Goods Administration ("**TGA**"), because the FDA:

- is the world's most experienced regulator for CAR-T cell therapies;
- has an established and widely recognised Investigational New Drug ("**IND**") review process for advanced therapies;
- provides confidence for potential future commercial and strategic partners; and
- regulates the largest and most commercially important CAR-T market globally.

A successful IND application requires sponsors such as AdAlta to submit extensive manufacturing, preclinical and clinical data packages. The requirements for advanced therapies such as CAR-T products are particularly detailed and can involve significant scientific and regulatory judgement.

If regulators identify gaps or deficiencies in the submitted data package, additional studies or information requests may be required, potentially increasing development costs and timelines.

For this reason, early FDA engagement through a pre-IND meeting is considered an important opportunity to obtain feedback on planned studies, manufacturing processes and clinical trial design before the formal IND submission process begins.

Dark Horse Consulting has specialised in the development of cell and gene therapies since 2014 and has supported more than 350 companies globally. The firm typically supports approximately 10–15 pre-IND meetings and 10 IND submissions each year.

A range of enhanced and expedited regulatory pathways may be available for BZDS1901
Regulatory agencies globally, including the FDA, offer a range of programs and designations designed to support therapies addressing rare diseases, significant unmet medical needs and advanced therapeutic modalities such as CAR-T cell therapies.

Depending on eligibility, these pathways may provide benefits including increased engagement with regulators, shorter review timelines, potential for accelerated or conditional approvals, and commercial incentives following approval.

These pathways can materially enhance the value of products such as BZDS1901 for both AdAlta and potential future commercial partners.

The data requirements and optimal timing for seeking these designations vary significantly. As part of the engagement, DHC will help AdAlta evaluate and prioritise the most relevant opportunities and ensure that the BZDS1901 development plan is appropriately designed to support future applications where suitable.

Next steps and strategic significance
DHC previously supported AdAlta's due diligence and initial development planning for BZDS1901. Under the expanded engagement, DHC will complete a further regulatory gap analysis, review the manufacturing

[2] https://www.biospace.com/malignant-mesothelioma-market-size-to-reach-usd-12-2-billion-by-2034-impelled-by-increasing-popularity-of-gene-therapy; BZDS1901 addressable market assumes addressable market 90% of relapsed/refractory incidence population is MSLN positive (Servais et al 2021 Human Cancer Bio); and conservative price of US$250,000 per dose (compares with typical prices in South Korea US$270k; Japan US$300k; EU US$350k; Australia US$400k; US US$370-450k per literature sources for CD19 and BCMA CAR-T products)

technology transfer program being executed with Cell Therapies Pty Ltd, and assist in preparation for a pre-IND meeting with the FDA, including development of briefing materials and proposed discussion topics.

DHC will also support AdAlta in identifying and assessing potential advanced regulatory designations that may be relevant to BZDS1901.

Together, these activities are intended to support the efficient commencement of Australian clinical trials for BZDS1901 while strengthening the program's strategic value and attractiveness to global oncology partners.

To view a summary, and engage in discussion about this announcement visit AdAlta's InvestorHub here: https://investorhub.adalta.com.au/link/rDEKxP

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

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About BZDS1901

BZDS1901 is a novel, first in class, CAR-T cell therapy designed to treat mesothelioma (a rare but rapidly fatal cancer usually linked to asbestos exposure) and with possible application in more than ten other cancers. CAR-T cell therapies are living drugs manufactured from a patient's own immune cells that are engineered to be able to find and kill cancer. They offer the potential to provide durable cancer control or cure from a single treatment.

Patients diagnosed with mesothelioma today are typically treated with surgery if possible and then initial or first line drug treatments are chemotherapy or immunotherapy. Once a patient has relapsed after initial therapy, second line treatment options are even more limited and outcomes are much poorer. Current treatments typically deliver: [3,4]

- Tumour shrinkage (Overall Response) in only 40-44% of first line patients and 11-29% of second and subsequent line patients
- Complete tumour clearance (Complete Response) is rare and seen in less than 3% of first line patients and almost never in second line patients
- Median survival (at which point 50% of patients will have died) often only 14-18 months first line and 8-10 months second line, with tumours beginning to grow again typically after only half that time.

By contrast, BZDS1901 clinical studies in relapsed or advanced mesothelioma patients (second line and later) in China have reported:

- Up to 50% Overall Response rate (tumour shrinkage)
- Up to 20% Complete Response rate (complete tumour clearance)
- Median overall survival has not yet been reached in the current study cohort, however an earlier generation of BZDS1901 achieved more than 25 months median survival

These early results suggest BZDS1901 may offer an exciting potential new treatment option for patients with few alternatives.

About Dark Horse Consulting

At Dark Horse Consulting ("**DHC**"), we specialize in the development of cell and gene therapy products. Our collective knowledge is extensive, spanning process development, device development, manufacturing, quality systems, preclinical development, regulatory, program management, business development, strategy,

[3] CHECKMATE-743 study (nivolumab + ipilimumab against chemotherapy): S Peters et al, Annals of Oncology, 2022 (33) 488; https://doi.org/10.1016/j.annonc.2022.01.074
[4] See for example CONFIRM study (nivolumab against placebo): DA Fennell et al, Lancet Oncol 2021 (22) 1530

and financing/investor relations. Many of our consultants also bring experience from adjacent, more mature, sectors, including traditional biologics, small molecules, medical devices, and management consulting. As a result, we understand the unique challenges faced by cell and gene therapy developers like none other. We apply best practices from across this and other industries to address the needs of our clients, who range from biopharmaceutical companies to tools and technology providers to venture capital and private equity investors.

For more information, visit https://www.darkhorseconsultinggroup.com/

About AdAlta

AdAlta (ASX: 1AD) is a clinical stage biotechnology business addressing the need for effective cellular immunotherapies for the treatment of solid cancers.

Through its 'East to West' strategy, the Company is integrating Asia's prowess in T cell therapy development with the efficiency and quality of Australia's clinical and manufacturing ecosystem to create a pathway connecting 'Eastern' innovation in cellular immunotherapies with 'Western' regulated markets and patients.

AdAlta in-licenses products from Asian originators and invests to establish US FDA regulated manufacturing and conduct Phase I clinical studies with potential to position each product for on-licensing to larger biopharmaceutical companies for potential registrational studies and commercialization.

AdAlta implements a disciplined approach to asset selection focused on highly differentiated T cell therapy products supported by clinical data in solid cancers. The company adopts a capital efficient business model delivering a rapid return on investment in each project that is replicable and provides opportunities to scale across multiple products.

Solid tumours account for 90% of cancers yet remain underserved by current cellular immunotherapies. AdAlta aims to dominate this high-growth segment. The cellular immunotherapy market is projected to grow at a compound annual growth rate of 34% to reach US$20.3 billion by 2028.

AdAlta's first in class fusion protein, AD-214, takes a whole new approach to fibrotic diseases of the lung and kidney, such as the degenerative and fatal Idiopathic Pulmonary Fibrosis. Following demonstration of efficacy in multiple animal models of disease and two successful Phase I clinical studies, AD-214 is available for partnering.

To learn more, please visit: www.adalta.com.au

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