ASX Announcement | 29 April 2026

AdAlta Limited (ASX:1AD)

AdAlta executes first Australian manufacturing Work Order for BZDS1901 CAR-T therapy

BZDS1901 treatment has resulted in frequent responses in advanced mesothelioma, including patients demonstrating complete tumour clearance; Australian manufacturing is major value milestone

Investment highlights

- **AdAlta and Cell Therapies sign first Work Order to bring BZDS1901 manufacturing to Australia**, advancing the program toward Australian Phase 1 clinical trials
- **BZDS1901 has delivered multiple responses in patients with advanced and refractory mesothelioma, including two patients who have achieved complete tumour clearance (Complete Response)** – a rare and highly significant clinical outcome in this disease setting
- **One Complete Response patient remains alive 22 months after BZDS1901 treatment**, with no tumour recurrence reported to date
- **Manufacturing is mission-critical for patient-specific CAR-T therapies** and successful transfer to Australia materially strengthens BZDS1901's partnering and licensing value
- **Australian manufacturing site to become global reference facility** supporting future multinational development and commercialization
- **BZDS1901 targets an estimated US$4.2 billion segment of the advanced mesothelioma market**, within a total mesothelioma market forecast to reach US$12.2 billion by 2034

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or **"the Company"),** developer of next generation cellular immunotherapies for solid cancers, today announced that it has signed its first Work Order with Cell Therapies Pty Ltd ("**CTPL**") to commence transfer of manufacturing for AdAlta's lead CAR-T[1] program, **BZDS1901**, to Australia.

This milestone follows encouraging early clinical data from studies in China, where **BZDS1901 has already demonstrated multiple tumour responses including two cases of complete tumour clearance (Complete Response, CR) in patients with advanced mesothelioma. These responses have been seen in** patients whose cancer had previously progressed after both chemotherapy and immunotherapy.

For patients with relapsed mesothelioma, a Complete Response is exceptionally uncommon. In one BZDS1901-treated patient, tumours became undetectable after treatment and **patient remains alive 22 months after treatment**, with no tumour recurrence reported to date.

The manufacturing transfer to Australia is a critical next step toward local clinical trials and a major value driver for future commercial partnerships.

AdAlta CEO, Dr Tim Oldham said:
"BZDS1901 has already delivered the type of outcome every cancer therapy aims for but few achieve 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.

advanced mesothelioma – complete tumour clearance in patients who had exhausted prior options. This highlights the exceptional potential of BZDS1901.

At the same time, for CAR-T therapies, manufacturing is inseparable from the product itself. A robust, scalable Australian manufacturing process is essential for trials, but it is also a major source of value for future partners. We are delighted to be working with CTPL, one of the most experienced global manufacturers in the field."

A rare and meaningful clinical result in a difficult cancer
Mesothelioma is a rare but rapidly fatal cancer of the membranes surrounding lungs, heart and gastrointestinal organs that is usually linked to asbestos exposure.

The market for drugs treating mesothelioma is forecast to reach US$12.2 billion by 2034,[2] and the advanced mesothelioma market addressable by BZDS1901 is estimated at US$4.2 billion.[3] In addition, BZDS1901 may have application in more than ten other cancers.

Patients diagnosed with mesothelioma today are typically treated with surgery if possible and then initial or first line drug treatments are chemotherapy or immunotherapy. Current first-line treatments typically deliver: [4]

- Tumour shrinkage (Overall Response) in only **40-44%** of patients
- **Complete tumour clearance (Complete Response) is rare and seen in less than 3% of patients**
- Median survival (at which point 50% of patients will have died) often only **14-18 months**, with tumours beginning to grow again typically after only **7 months**

Once a patient has relapsed after initial therapy, treatment options are even more limited and outcomes are much poorer. Current second-line and later treatments for these advanced mesothelioma patients typically deliver:[5]

- Tumour shrinkage in only **11–29%** of patients
- **Complete tumour clearance is extremely rare**
- Median survival often only **8–10 months**

By contrast (see Table 1), BZDS1901 clinical studies in relapsed or advanced mesothelioma patients in China have reported:

- **Up to 50% Overall Response rate** (tumour shrinkage)
- **Up to 20% Complete Response rate** (complete tumour clearance) – diagnostic imaging confirming tumour clearance in the two patients achieving complete responses to date are shown in Figures 1 and 2
- 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.

[2] https://www.biospace.com/malignant-mesothelioma-market-size-to-reach-usd-12-2-billion-by-2034-impelled-by-increasing-popularity-of-gene-therapy
[3] 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)
[4] 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
[5] See for example CONFIRM study (nivolumab against placebo): DA Fennell et al, Lancet Oncol 2021 (22) 1530

Table 1: results of China clinical studies of BZDS1901 compared with current treatment options in advanced (second and later line) mesothelioma[6]

Outcome measure	**Placebo**[5] (111 patients)	**Immunotherapy**[5] (221 patients)	**BZDS1901** (10 patients at minimum predicted therapeutic dose)[7]
Complete Response Rate	0%	0%	**20%**
Overall Response Rate	1%	11%	**50%**
Median Overall Survival	6.9 mo	10.2 mo	Not yet reached (**Gen 1: 25.6 mo**)[8]
1 & 2 year survival rate	~30% & 18%	~45% & 25%	Not yet reached (20% 1 year survival with 50% still alive and not yet at one year)

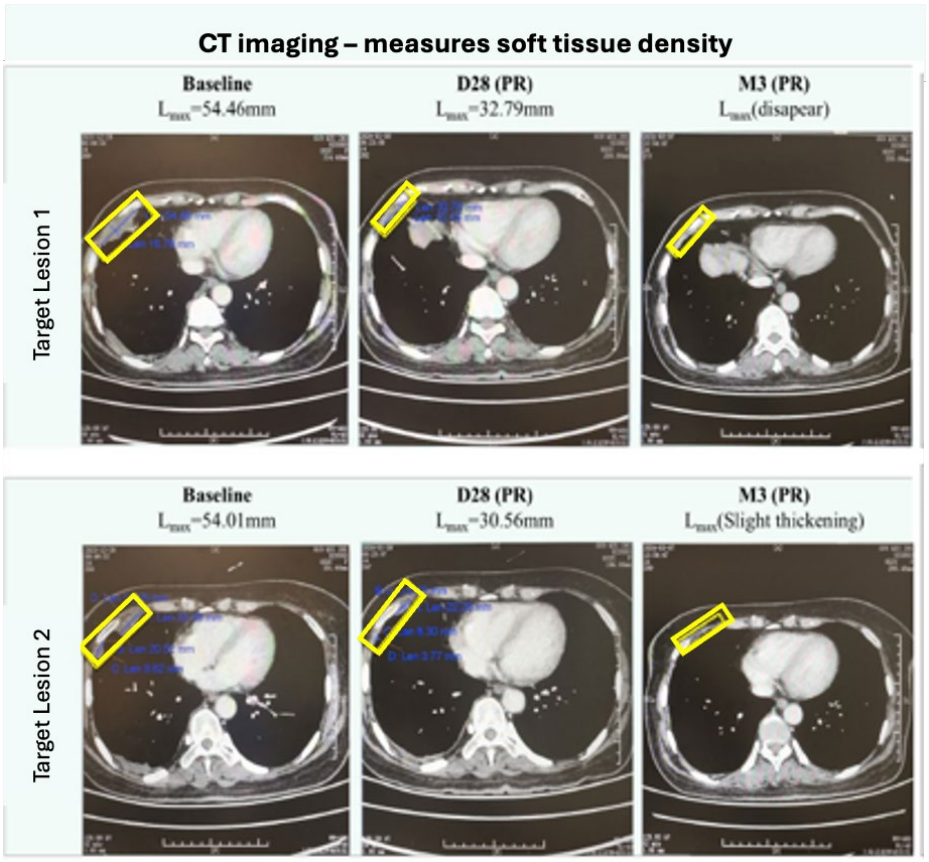

Figure 1: Advanced mesothelioma patient treated with a single dose of BZSD1901 after relapse following first line combination immunotherapy and failure of second line single agent immunotherapy. Two 5cm tumours (inside yellow boxes) shrank consistently after treatment to be undetectable three months later. This patient was still in complete response at the 18 month assessment point and still alive at 20-22 months. The next assessment point is 24 months.

[6] This table compares two independent studies. Potential differences in patient populations and differences in study sizes mean there is no guarantee that the relative performance of the treatments will be maintained in later and larger clinical studies of BZDS1901
[7] Shanghai Cell Therapy Group Company Inc and AdAlta Ltd data on file; patients received 8-10x10^6 CAR-T cells/kg (a further 4 patients received 5-6x10^5 CAR-T cells/kg)
[8] Y Sun et al, Adv Sci 2025 e08754 doi: 10.1002/advs.202508754

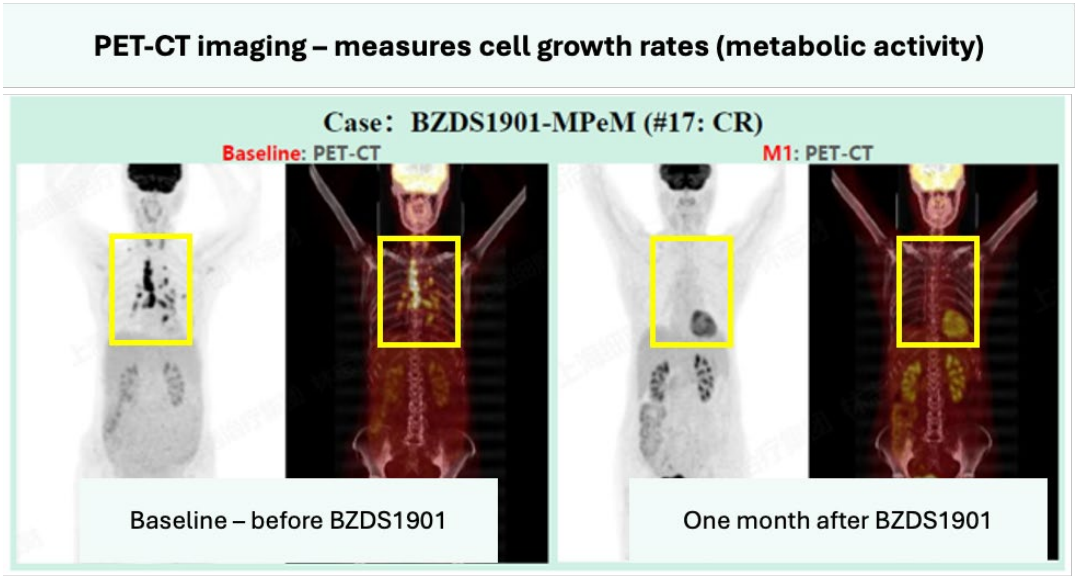

Figure 2: Advanced mesothelioma patient treated with a single dose of BZSD1901 after relapse following first line chemotherapy and single agent maintenance immunotherapy. Multiple tumours visible prior to treatment (dark and bright sopts in yellow boxes) became undetectable one month later. This patient was still in complete response at the 6 month assessment point. The next assessment point is at 9 months.

Why manufacturing matters so much

Unlike conventional drugs, CAR-T therapies are manufactured **individually for each patient using their own cells**. Manufacturing quality, consistency, speed and cost are therefore central to clinical success and commercial viability. Further, for regulatory and logistical reasons, BZDS1901 cannot be manufactured in China for patients anywhere else in the world.

Successfully transferring and optimising BZDS1901 manufacturing in Australia is significant because it:

- Supports planned Australian clinical trials
- Demonstrates the process can be replicated outside China
- Provides confidence in global scalability
- Reduces future supply chain and regulatory risk
- Increases attractiveness to larger pharmaceutical partners evaluating licensing or acquisition opportunities

Manufacturing capability is often one of the most heavily scrutinised areas in CAR-T transactions. Establishing a validated and optimised Australian process can therefore create substantial strategic value beyond enabling Western clinical data alone. Further, BZSD1901 was selected by AdAlta because it already utilises a short (2-day compared with 9-day for traditional CAR-T products) low cost manufacturing technology.

AdAlta's manufacturing partner, CTPL is a leading contract manufacturer of CAR-T cell therapies with more than 20 years' experience in process development, technology transfer and clinical and commercial CAR-T supply and are capable of becoming AdAlta's global manufacturing reference site for BZDS1901. CTPL has completed a technology feasibility assessment on BZDS1901 and helped AdAlta identify several process optimisation opportunities to be implemented as part of technology transfer.

Next steps

The initial CTPL Work Order will cover:

- Transfer of the current manufacturing process from China
- Initial optimisation steps
- Preparation of regulatory documentation to support Australian clinical trials

A subsequent Work Order is expected to qualify the optimised process and enable the commencement of Australian clinical trials.

Strategic significance

AdAlta's "East to West" strategy seeks to acquire promising Asian-developed cell therapies and advance them into global markets.

For BZDS1901, AdAlta is now progressing two of the most important value drivers simultaneously:

1. **Generating compelling early efficacy data**, in both China and, post manufacturing transfer, Australia
2. **Transferable, scalable manufacturing capability**

Together, these milestones can materially enhance the program's 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/yO25dP

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

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About CTPL

Cell Therapies Pty ltd ("**CTPL**") is a commercial contract development and manufacturing organization ("**CDMO**") that has manufactured and delivered advanced cell and gene therapies to patients in Australia and the Asia-Pacific region for more than twenty years.

CTPL provides integrated, phase-appropriate development and GMP manufacturing of cell and gene therapies under one roof, from preclinical concept to commercial supply, minimizing transition risk and preserving critical program knowledge across the cell therapy manufacturing lifecycle. We specialize in the manufacture of cell therapies, ex-vivo gene therapies, and regenerative medicine products.

Our structure was purpose-built to address the evolving needs of cell and gene therapy developers. Embedded within a premier Biomedical Precinct and co-located with a world-class cancer center, the Peter MacCallum Cancer Centre, we maintain close ties to clinical investigators, key opinion leaders, and academic scientists, while running independent GMP-licensed operations.

For more information, visit https://celltherapies.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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