



ASX Announcement | 1 July 2026
AdAlta Limited (ASX:1AD)

AdAlta secures key BZDS1901 CAR-T milestones as program advances toward Australian manufacturing and FDA engagement

Milestone payment to SHcell unlocks additional clinical data and secures critical manufacturing materials

Investment highlights

- **AdAlta has made a US\$1 million milestone payment** to Shanghai Cell Therapy Group Co Ltd in respect of **five additional advanced mesothelioma patients treated with BZDS1901 CAR-T cell therapy in China**.
- **AdAlta has now fully complied with its initial financing obligations** under the BZDS1901 Development and Collaboration Agreement with Shanghai Cell Therapy Group Co Ltd.
- The payment gives AdAlta **access to additional clinical data** from investigator-initiated trials of BZDS1901 in China and **secures supply of critical proprietary materials** needed to manufacture BZDS1901 in Australia.
- Technology transfer of BZDS1901 manufacturing continues, with **first Australian manufacturing runs expected in the second half of calendar 2026**.
- AdAlta is also **preparing for a pre-IND meeting with the US Food and Drug Administration ("FDA")**, anticipated in the second half of calendar 2026.
- **First ever solid cancer CAR-T product approval** validates AdAlta's "East to West" strategy.

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of next generation cellular immunotherapies for solid cancers, today announced it has made a further US\$1 million (~A\$1.43 million) milestone payment to its co-development partner, Shanghai Cell Therapy Group Co Ltd ("**SHcell**"), under the Development and Collaboration Agreement ("**DCA**") for BZDS1901, AdAlta's lead CAR-T¹ therapy being developed for advanced mesothelioma. The payment was made in respect of five additional advanced mesothelioma patients treated with BZDS1901 in China, and was funded in part from the Company's recent A\$2.5 million placement.² With this payment, AdAlta has now fully met the initial financing obligations it took on when it entered the DCA³, securing AdAlta's rights to continue developing BZDS1901 for markets outside Greater China under the DCA.

AdAlta CEO and Managing Director, Dr Tim Oldham said:

"This milestone payment gives us access to valuable new clinical data that will support future regulatory submissions, secures the specialised materials we need to manufacture BZDS1901 in Australia, and is the final component of initial financial allocations specified in our collaboration agreement. We are now focused on the next two milestones that matter most to this program's value: building Australian manufacturing and engaging with the US FDA. Completing our initial financial commitment to BZDS1901 reflects the strong support of our shareholders and our disciplined execution of the East to West strategy."

Access to new clinical data and critical manufacturing materials

This milestone payment delivers two benefits. First, AdAlta gains access to additional clinical results from investigator-initiated trials — studies run independently by clinicians — of BZDS1901 in China. These results

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.

² Announced 4 May 2026 and approved by shareholders on 15 June 2026.

³ See ASX announcement 2 January 2026.

include ongoing treatment durability assessments for all patients treated with BZDS1901, and for the five most recently treated patients CAR-T cell expansion and persistence data (top line results announced previously),⁴ detailed safety data tables required for US FDA regulatory submissions, and detailed manufacturing results that will support technology transfer. Together these results are expected to add materially to the evidence supporting BZDS1901's potential in advanced mesothelioma. AdAlta will review this data over the coming weeks and months.

Second, the payment secures supply of critical proprietary materials from SHcell that are essential to manufacturing BZDS1901. These materials, known as plasmid DNA and mRNA transposases, are the genetic "blueprints" and tools used to engineer a patient's own immune cells into the cancer-fighting CAR-T cells that make up BZDS1901. These are proprietary to SHcell and securing supply is a necessary step for transferring manufacturing to Australia.

First ever CAR-T product approval for a solid cancer validates "East to West" strategy

CARsgen Therapeutics has obtained approval to market Satri-cel in China.⁵ Satri-cel is the world's first CAR-T cell therapy product approved for the treatment of solid tumors. In the clinical study supporting Satri-cel's approval, tumour shrinkage (overall response rate) in Claudin18.2-positive advanced gastric/gastroesophageal junction adenocarcinoma (G/GEJA) patients was just 4% in the control arm but was more than 20% in patients who received Satri-cel, including patients who switched to Satri-cel from the control arm at the end of the study. These are significant outcomes for patients otherwise facing five year survival rates of less than 10%.

This approval is significant validation of AdAlta's belief that CAR-T cells can be effective in solid cancers, that achieving any responses in patients unlikely to otherwise achieve them (as BZDS1901 has already demonstrated in advanced mesothelioma) is clinically meaningful, and that China is leading global source of innovation in solid cancer CAR-T cell therapies. For a more detailed discussion see the update on AdAlta's InvestorHub: <https://investorhub.adalta.com.au/activity-updates/epj1XP-solid-cancer-car-t-arrives-world-first-approval-to-carsgen>. Satri-cel does not compete with AdAlta's BZDS1901.

Next steps and strategic significance

With its initial financial commitments met, AdAlta is focused on the next two value drivers that most influence the future value of BZDS1901: reliable Australian manufacturing and regulatory alignment with the US FDA. Technology transfer to Cell Therapies Pty Ltd ("CTPL") continues, with first Australian test manufacturing runs expected in the second half of calendar 2026, and AdAlta is preparing for a pre-IND meeting with the US FDA anticipated in the second half of calendar 2026. Together these steps keep BZDS1901 advancing while reinforcing the capital-efficient execution at the heart of AdAlta's "East to West" strategy.

To view a video summary, and engage in discussion about this announcement visit AdAlta's InvestorHub here: <https://investorhub.adalta.com.au/link/PIJE5e>

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

For further information, please contact:

AdAlta Limited (ASX:1AD)

Tim Oldham
CEO & Managing Director
P: +61 403 446 665
E: ir@adalta.com.au

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 mesothelin expressing cancers. CAR-T cell therapies are living drugs manufactured from a patient's own

⁴ See for example ASX releases on 1 April 2026, 29 April 2026 and 11 May 2026

⁵ <https://www.carsgen.com/en/news/20260622/>

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:^{6,7}

- 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 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

For more information

⁶CHECKMATE-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>

⁷ See for example CONFIRM study (nivolumab against placebo): DA Fennell et al, Lancet Oncol 2021 (22) 1530



Join our [InvestorHub](#)

Follow us on [LinkedIn](#)

Follow us on [X \(formerly Twitter\)](#)