

ASX Announcement | 10 August 2026
AdAlta Limited (ASX:1AD)

AdAlta reports ongoing IIT cohort survival in EW-001 mesothelioma study

All five patients on study at March update remain on study in July; emerging trend to longer survival at higher doses

Investment highlights

- **All five patients** remaining on study at AdAlta's previous clinical update remain **alive** and still in follow-up at July 2026, **extending the signal of ongoing survival** across the cohort.
- At higher doses, **three of 10 patients (30%) have now survived at least 12 months**, with three more patients alive and yet to reach the 12 month milestone.
- Taken together, the durability of the first complete response beyond two years (announced previously), and the emerging survival trend at higher doses provide a strong rationale for AdAlta's **planned evaluation of higher EW-001 dosing in its upcoming Australian Phase 1 study**.
- AdAlta will continue to follow all patients in the study and report additional survival and response data as they emerge.
- The Company is advancing the **transfer of EW-001 manufacturing to Cell Therapies Pty Ltd in Australia** and progressing preparations for a **pre-IND meeting with the US FDA**, with both milestones anticipated in **H2 CY2026**.

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of next generation cellular immunotherapies for solid cancers, in a further update on the Investigator Initiated Trial ("IIT") of its lead CAR-T cell therapy,¹ EW-001 (formerly BZDS1901) in China, is able to report continued survival as at July 2026 of all patients that were on study at the previous update (March 2026).

Continued survival of all patients remaining on study

All five patients who remained on study when AdAlta last reported follow-up, as at March 2026, **remain alive and on study** as at July 2026.

Among the 10 patients treated at higher EW-001 doses:

- **Three patients (30%) have now survived for at least 12 months.**
- A further three further patients remain alive and yet to reach that point.
- Five patients achieved a Complete Response ("CR", no tumour can be detected after treatment, n=2) or Partial Response ("PR", tumour shrinkage greater than 30%, n=3) for an **Overall Response Rate to EW-001 therapy of 50%**.

AdAlta CEO and Managing Director, Dr Tim Oldham said:

"Every one of the five patients still on study in March remains alive, and the higher the EW-001 dose, the better patients have done. Combined with two patients achieving complete tumour clearance also at these higher doses, something almost never seen in advanced mesothelioma, this supports our plan to evaluate even higher doses in our Australian Phase 1 study. For patients with advanced mesothelioma, who today have very few options, EW-001 offers real new hope – and for our shareholders it strengthens the value we are building in this program."

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. CAR-T cell therapy has the potential for a single dose to have durable effects and to be potentially curative.

Response rates exceed benchmarks; survival rates trending favourably

Mesothelioma is a rare but rapidly fatal cancer of the membranes surrounding the lungs, heart and gastrointestinal organs, usually linked to asbestos exposure. Patients are typically treated initially (first line) with chemotherapy or immunotherapy. Once the disease has returned or progressed following these treatments, therapeutic options (second line) are limited and clinical outcomes are generally poor.

Achieving and maintaining a **Complete Response** is associated with the potential for durable disease control and is an important outcome for patients, regulators and prospective commercial partners. In advanced (second line and later) mesothelioma patients this is **almost never achieved with current therapies** – the major published studies report Complete Response rates of 0% - which is why **the EW-001 Complete Response results to date (reported 5 August 2026) stand out**.

Clinical outcomes from current second line therapies represent the benchmark that EW-001 is designed to eventually exceed. Table 1 summarises key response and survival rates to date. **Complete and Overall Response rates to EW-001 treatment compare favourably with both current first and second line therapeutic options**. Survival rates are trending towards current second line survival rates with a significant number of patients still alive.

Table 1: EW-001 results to date compare favourably with current first line and second line (advanced) mesothelioma treatment options, noting patient numbers remain small

Outcome measure	First line therapy ²		Second line therapy ³		EW-001 (BZDS1901) ⁴	
	Chemo-therapy	Immuno-therapy	Placebo	Immuno-therapy	All patients (n=14)	Higher doses (n=10)
Complete Response Rate (complete tumour clearance)	0%	2.6%	0%	0%	14%	20%
Overall Response Rate (tumour shrinkage)	44.0%	39.6%	1%	11% [^]	43%	50%
1 year survival rate	58%	68%	~30%	~45%	21% so far [#]	30% so far [#]
2 year survival rate	27%	41%	18%	25%	7% so far [*]	10% so far [*]

[#] A further 21% of patients (30% of those receiving higher doses) remain alive and on study and yet to reach 12 months follow-up.

^{*} A further 36% of patients (50% of those receiving higher doses) remain alive and on study and yet to reach 24 months follow-up.

[^] Overall response rates of up to 29% have been reported in some other second line studies.

Stronger responses at higher doses

Measurements of how much EW-001 is present in patients' blood after treatment (known as pharmacokinetics), analysed together with the tumour responses summarised in Table 1, show a consistent trend: **patients who received higher doses tended to respond better**.

This matters because the highest dose given so far remains modest by CAR-T standards and adverse events seen with EW-001 have been well-managed since adoption of best practice CAR-T safety protocols. These data therefore support AdAlta's strategy to **test higher doses in its planned Australian Phase 1 study**, seeking even stronger and more frequent responses.

Next steps and strategic significance

AdAlta will continue to collect follow-up data from all patients remaining on study and anticipates reporting additional survival and durability data periodically as it becomes available.

In parallel, the Company is progressing two important development milestones for EW-001:

² CHECKMATE-743 study (nivolumab + ipilimumab versus chemotherapy): S Peters et al, Annals of Oncology, 2022 (33) 488.

³ CONFIRM study (nivolumab versus placebo): DA Fennell et al, Lancet Oncology, 2021 (22) 1530; other studies have reported ORR up to 29% but no CR

⁴ EW-001 data are from ongoing investigator-initiated trials in China, as at July 2026. Higher doses are 0.8–1.0 x 10⁶ CAR-T cells/kg; the all patients group also includes patients treated at 0.5–0.6 x 10⁶ CAR-T cells/kg.

- **Australian manufacturing transfer:** AdAlta is transferring the EW-001 manufacturing process to Cell Therapies Pty Ltd in Australia. The first Australian manufacturing runs are expected during the second half of calendar 2026.
- **US regulatory engagement:** AdAlta is preparing for a pre-Investigational New Drug (“pre-IND”) meeting with the US Food and Drug Administration, anticipated in the second half of calendar 2026.

Together these steps are intended to establish an Australian manufacturing platform, obtain regulatory guidance and support the planned Australian Phase 1 clinical study of EW-001.

Strategic significance

For shareholders, the value of this update lies in the durability of responders and the broader clinical trend observed across the higher-dose cohort:

- **Durability.** All five patients on study in March have survived a further three months and a single dose of EW-001 has now kept one patient free of an aggressive cancer for two years. Growing duration of responses and survival provide important evidence of EW-001's potential durability of response.
- **Direction.** The stronger responses observed among higher dose patients provide data-driven support for evaluating higher EW-001 doses in the planned Australian Phase 1 study.
- **Evidence development.** Every additional month of patient survival and follow-up strengthens the clinical evidence supporting EW-001 and the information package AdAlta can present to regulators and prospective development or commercialisation partners.

Investigator-initiated trials involve small numbers of patients and are not a substitute for controlled clinical studies. Even so, a signal of this kind in a disease with so few options continues to underpin AdAlta's confidence in EW-001 and in its “East to West” strategy.

To view a summary, and engage in discussion about this announcement visit AdAlta's InvestorHub here: <https://investorhub.adalta.com.au/link/y0VzVr>

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

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About EW-001 (formerly BZDS1901)

EW-001 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: ^{5,6}

- Tumour shrinkage (Overall Response) in only 40-44% of first line patients and 11-29% of second and subsequent line patients

⁵ 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>

⁶ See for example CONFIRM study (nivolumab against placebo): DA Fennell et al, Lancet Oncol 2021 (22) 1530

- 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) is often only 14-18 months for first line and 8-10 months for second line treatment, with tumours beginning to grow again typically after only half that time.

By contrast, EW-001 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 EW-001 achieved more than 25 months median survival

These early results suggest EW-001 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

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