ASX Announcement | 5 August 2026

AdAlta Limited (ASX:1AD)

AdAlta reports two year survival milestone in EW-001 mesothelioma study

The first complete responder free of cancer recurrence after two years; the second has reached one year survival

Investment highlights

- **Significant durability milestone**: The first patient to achieve **Complete Response** (CR; complete tumour clearance) after a single dose of EW-001 has now passed **two years survival without cancer recurrence,** something few patients can hope for in advanced mesothelioma.
- **Second Complete Responder reaches one year survival milestone**: the second patient who achieved a Complete Response has **now survived more than 12 months** following EW-001 treatment.
- Across the study **EW-001** has delivered CRs in **2 of 10 patients treated at higher doses (20%,** 14% of 14 patients overall**),** a level of complete tumour clearance that is **almost never seen** in advanced mesothelioma where published second line CRs are typically 0%.
- 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, today reported a significant clinical milestone from the ongoing Investigator Initiated Trial ("**IIT**") of its lead CAR-T cell therapy,[1] EW-001 (formerly BZDS1901) in China.

Two patients with Complete Responses achieve survival anniversaries

The first patient to achieve complete tumour clearance ("**Complete Response**" or "**CR**") following a single dose of EW-001 **remains alive and without cancer recurrence two years after treatment**.

A second patient who achieved a CR has **now survived 12 months**. No imaging assessment was performed at the one-year milestone and the patient's current tumour status is therefore not available.

Complete tumour clearance is almost never seen in advanced mesothelioma. In the ongoing IIT study in China, EW-001 has now achieved:

- A **14% Complete Response rate across all 14 evaluable patients** treated with the current generation of EW-001.
- A **20% Compete Response rate** among the 10 patients treated with **higher EW-001 doses**.

[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.

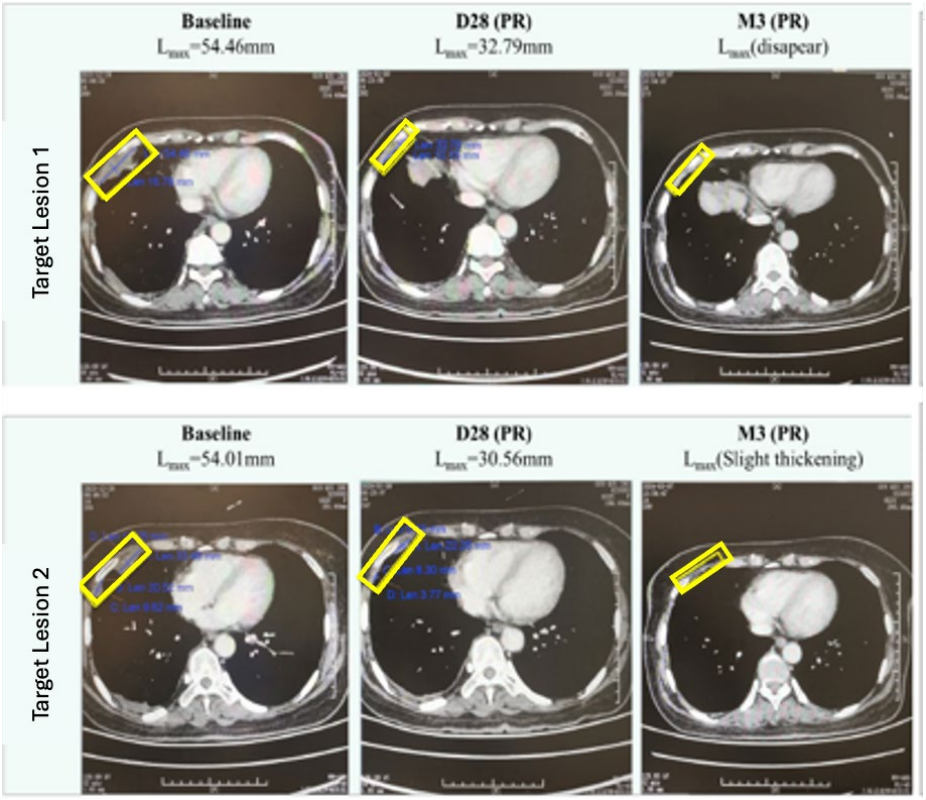

Figure 1: CT scans (measures soft tissue density) from patient #03 showing two large (5cm) tumours (inside yellow boxes) shrinking consistently after treatment to be undetectable three months later. The durability of this response is important: this patient has now passed two years since treatment without signs of cancer recurrence.

Two-year durability represents a significant clinical milestone
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 with chemotherapy or immunotherapy. Once the disease has returned or progressed following these treatments, therapeutic options are limited and clinical outcomes are generally poor.

A Complete Response means that **no tumour can be detected** after treatment. 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 results to date stand out.

AdAlta CEO and Managing Director, Dr Tim Oldham said:
"Complete tumour clearance is almost never seen in patients with advanced mesothelioma. To have achieved it in two (20%) of the ten patients treated at the higher EW-001 doses is highly encouraging – and to see the first of those patients still free of cancer recurrence two years after a single infusion is the kind of result that changes the conversation with patients, regulators and partners."

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:

- **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 the first Complete Response and the additional survival milestone achieved by the second complete responder:

- **Durability.** A single dose of EW-001 has now kept one patient free of an aggressive cancer for two years. Responses measured in years rather than weeks or months are particularly meaningful in advanced cancer and provide important evidence of EW-001's potential durability of response.
- **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/eX127r

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: [2,3]

- 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) is often only 14-18 months for first line and 8-10 months 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)

[2] 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
[3] See for example CONFIRM study (nivolumab against placebo): DA Fennell et al, Lancet Oncol 2021 (22) 1530

- 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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