



ASX Announcement | 23 September 2026
AdAlta Limited (ASX:1AD)

US FDA accepts AdAlta's request for a pre-IND meeting on EW-001 CAR-T therapy

The culmination of substantial data and knowledge transfer from Shanghai Cell Therapy Group, and AdAlta's first significant engagement with the world's most experienced regulator of cell therapies

Investment highlights

- The **US Food and Drug Administration ("FDA")** has accepted AdAlta's request for a pre-IND meeting on EW-001, the Company's lead CAR-T cell therapy for advanced mesothelioma.
- This is **AdAlta's first significant engagement with the FDA** on EW-001 and a **key milestone for the second half of calendar 2026**.
- Review of **hundreds of new documents** from co-development partner Shanghai Cell Therapy Group Co Ltd ("SHcell"), preparation of a **draft Phase 1 clinical trial protocol** and a refined manufacturing strategy underpin confidence in the proposals put to the FDA.
- FDA feedback will provide important input into **manufacturing technology transfer and optimisation**, the **remaining IND-enabling non-clinical studies** and **Phase 1 clinical trial design**.
- Aligning with FDA expectations before a formal submission is made reduces the risk of delays and additional product development work later, helps ensure that the protocol design meets all current safety and efficiency expectations, and supports EW-001's attractiveness to future partners.

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of next generation cellular immunotherapies for solid cancers, today announced that the United States Food and Drug Administration ("FDA") has accepted the Company's request for a pre-IND meeting in respect of EW-001, AdAlta's lead CAR-T cell therapy for advanced mesothelioma and other mesothelin-expressing cancers. The meeting will be AdAlta's first significant engagement with the FDA on EW-001 and is a key milestone for the second half of calendar 2026.

A pre-IND meeting is a formal opportunity to put a development plan in front of FDA reviewers and get their feedback before the most expensive parts of that plan are committed to. IND stands for "Investigational New Drug" – the application a company must have accepted by the FDA before it can begin clinical trials under FDA oversight.

Before such a meeting can be requested, AdAlta needed to prepare a detailed briefing document setting out what the product is, how it is made and tested, what is already known about its safety and effectiveness, and exactly what the Company plans to do next, particularly with regards to evaluation in patients. **Being in a position to prepare that document is the real achievement behind today's announcement.**

AdAlta CEO and Managing Director, Dr Tim Oldham said:

"The FDA agreeing to meet us is the headline. What matters more is what it took to reach the point where we could request the meeting.

Our team has worked through hundreds of documents from SHcell covering how EW-001 is made, how it is tested and how it has performed in patients in China. We have worked with some of Australia's most experienced CAR-T and mesothelioma clinicians to turn that into a draft Phase 1 clinical trial protocol. And we have worked alongside Cell Therapies to finalise manufacturing technology transfer and optimisation plans. A pre-IND briefing document is only possible once all of those pieces exist and fit together, so this is a milestone for the whole program and for our partners, not just for our regulatory team.

Now, consistent with our capital efficient approach, we get to test our thinking with the world's most experienced regulator of cell therapies before we commit to the costliest parts of the program."

Why reaching this point matters

Three separate bodies of work had to come together before the briefing document could be written and to ensure AdAlta's confidence that the proposals being made to the FDA were fully supported. Each was a substantial undertaking in its own right:

- **Data from Shanghai.** Hundreds of new documents have been transferred from SHcell under the parties' Development and Collaboration Agreement. These included detailed manufacturing methods, quality and release testing methods and results, laboratory and animal study reports, and patient-by-patient results from the investigator-initiated trials conducted in China.
- **A clinical protocol for Australia.** Extensive interaction with AdAlta's clinical advisory board, drawn from Australia's leading CAR-T and mesothelioma treatment centres, has produced a draft Phase 1 clinical trial protocol describing which patients would be included, what doses they would receive, how their safety would be monitored and managed, and what clinical outcomes would be measured.
- **A manufacturing process that can run in Melbourne.** Work with AdAlta's contract manufacturer Cell Therapies Pty Ltd ("CTPL") on technology transfer and process optimisation is establishing how EW-001 will be manufactured in Australia to the standards the FDA expects.

None of this work stands alone. What the FDA will be asked to comment on is a single, coherent plan in which the product made in Melbourne, the studies supporting it and the trial proposed for Australian patients all line up. AdAlta's specialist regulatory advisers, Dark Horse Consulting Group, Inc ("DHC"), are supporting preparation of the briefing document and the meeting itself.

What AdAlta expects the meeting to inform

The pre-IND meeting is expected to provide important input across three areas:

- **Manufacturing technology transfer and optimisation** – confirming the testing, comparability and release strategy for EW-001 manufactured in Australia, and the extent to which manufacturing improvements can be made before Phase 1 clinical trials begin.
- **Remaining IND-enabling non-clinical studies** – confirming which laboratory and animal studies are still required, and where existing data generated in China can be relied upon instead.
- **Phase 1 clinical trial design** – the patient population, starting dose and dose escalation scheme, and the safety monitoring arrangements appropriate for a CAR-T therapy in advanced mesothelioma and other solid tumours expressing mesothelin, the protein that EW-001 targets.

Feedback obtained now means any FDA concerns are understood early, so any additional data can be generated and included in the formal IND submission, rather than causing delays and added cost later.

Next steps and strategic significance

The virtual face to face pre-IND meeting is scheduled for 3 November 2026 US time/4 November 2026 AEST. The FDA then generally issues formal written minutes two to four weeks afterwards. Depending on the nature and scope of the feedback received, AdAlta will require further time to work through any implications for its manufacturing, non-clinical and clinical plans. The Company will update the market as appropriate.

For shareholders, the significance is twofold. The meeting itself de-risks the remaining work ahead of Phase 1 clinical trials, testing AdAlta's plans against the expectations of the world's most experienced cell therapy regulator while changes are still inexpensive to make. Just as importantly, being able to hold the meeting at all shows the 'East to West' strategy working in practice: data, know-how and manufacturing capability moved from an Asian originator into a Western regulatory system, on a realistic timeframe and a modest budget. That is the capability AdAlta intends to repeat across its pipeline.

To view a summary, and engage in discussion about this announcement visit AdAlta's InvestorHub here: <https://investorhub.adalta.com.au/link/P3x90y>

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. EW-001 targets a protein called mesothelin that is highly expressed in many cancers. EW-001 is also engineered to produce a protein called a checkpoint inhibitor that is designed to protect the CAR-T cell from a key defensive mechanism used by 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. 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: ^{1,2}

- 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 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)
- Two patients achieving Complete Responses have now reached two and one year survival milestones respectively with no evidence of cancer returning providing evidence of durability of response
- Median overall survival has not yet been reached in the current generation manufacturing process, 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. EW-001 has not yet received regulatory approval for general commercial launch anywhere in the world.

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.

¹ 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>

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

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 other assets include first in class fusion protein, AD-214, that takes a whole new approach to fibrotic diseases of the lung and kidney, such as the degenerative and fatal Idiopathic Pulmonary Fibrosis and WD-34, a novel pan-strain inhibitor of malaria, Babesia and Toxoplasma parasites. Following demonstration of efficacy in multiple animal models of disease and two successful Phase I clinical studies, AD-214 is available for partnering. WD-34 is seeking grant funding to optimize the molecule format to enable single dose seasonal prophylaxis.

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

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