



ASX Announcement | 5 October 2026
AdAlta Limited (ASX:1AD)

EW-001 Joint Development Committee approves FDA briefing pack and manufacturing technology transfer plan

AdAlta and its partner Shanghai Cell Therapy Group have formally approved the next two steps on the path to clinical trials of EW-001 in Australia

Investment highlights

- The latest EW-001 **Joint Development Committee** meeting with Shanghai Cell Therapy Group ("SHcell") was held in Shanghai in late September 2026.
- The committee **approved the briefing pack** now submitted to the US FDA for AdAlta's pre-IND meeting on 4 November 2026 (AEST).
- The committee also **approved the plan to transfer** SHcell's EW-001 manufacturing process to AdAlta's Australian manufacturing partner.
- Both are formal governance steps that must be passed under the parties' Development and Collaboration Agreement.
- Two advanced mesothelioma patients continue in follow-up in the ongoing China clinical study, including the **second complete responder**, with next formal assessments expected in early calendar 2027.

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of next generation cellular immunotherapies for solid cancers, today announced that the Joint Development Committee ("JDC") for EW-001 (formerly BZDS1901), AdAlta's lead CAR-T cell therapy for advanced mesothelioma and other mesothelin-expressing cancers, has approved two important next steps in the program: the content of the briefing pack for AdAlta's upcoming pre-IND meeting with the US Food and Drug Administration ("FDA"), and the plan to transfer EW-001 manufacturing technology from Shanghai Cell Therapy Group Co Ltd ("SHcell") to Cell Therapies Pty Ltd ("CTPL") in Melbourne.

The JDC brings AdAlta and SHcell, the company that originally developed EW-001, together to oversee the program. Under the parties' Development and Collaboration Agreement, key steps must be approved by the JDC before they proceed. The meeting in Shanghai in late September approved both of the steps AdAlta needs to take next.

AdAlta CEO and Managing Director, Dr Tim Oldham said:

"These are the approvals we needed to take EW-001 to its next stage. SHcell has endorsed both what we will discuss with the FDA in November and how EW-001 will be made in Melbourne, so we can now move ahead with both."

What the JDC approved

- **FDA briefing pack.** Before a pre-IND meeting, the FDA reviews a detailed document describing how EW-001 is made and tested, what is known about its safety and effectiveness, and the Phase 1 clinical trial AdAlta proposes to run. Much of that information comes from SHcell, so the JDC's formal approval confirms that both partners stand behind the proposals and data being put to the FDA. The briefing pack has now been submitted on schedule to the FDA. As previously announced, the meeting is scheduled for 3 November 2026 US time (4 November 2026 AEST).
- **Manufacturing technology transfer plan.** The plan sets out how SHcell's rapid, low cost third generation manufacturing process for EW-001, together with its testing methods and know-how, will be transferred to CTPL. Making EW-001 in Australia to the standards the FDA expects is an essential step before Phase 1 clinical trials can begin.

Update on patients in China

In July 2026, AdAlta reported that all five patients then remaining on study in SHcell's investigator-initiated trials ("IITs") of EW-001 in China were alive. Further details about these patients are now available. Two of those patients remain on study (meaning progress is formally and regularly monitored and documented). How long each patient stays on study is set by the study protocol. As a result:

- the first patient to achieve a complete response, having completed the final study assessment point two years after treatment with no evidence of cancer returning, has **completed the study**;
- two patients were assessed as having progressive disease (their cancer had grown relative to baseline pre-treatment) having previously achieved a partial response and stable disease respectively and, as per protocol, were withdrawn from formal follow-up; and
- two patients **remain on study with planned follow-up**: the second complete response patient, who, as previously reported, has passed one year of survival and is next due for assessment at 18 months, and a patient whose disease remained stable (tumours not growing) at their six month assessment.

The next formal assessments of both patients remaining on study are expected in the first quarter of calendar 2027. No patients have yet been treated under the Hainan Boao Lecheng special access approval announced in September 2026.

Next steps and strategic significance

AdAlta will submit the approved briefing pack to the FDA ahead of the pre-IND meeting. The FDA generally issues formal written minutes two to four weeks after the meeting, and AdAlta will update the market as appropriate. In parallel, AdAlta, SHcell and CTPL will proceed with the approved technology transfer plan, with first Australian manufacturing runs anticipated in the second half of calendar 2026.

For shareholders, the significance is simple: the partnership with SHcell is working as intended. Both partners have now formally agreed on what will be put to the FDA and on how EW-001 will be made in Australia – the two foundations of AdAlta's planned Phase 1 clinical trials and of the value AdAlta aims to create by bringing EW-001 to Western patients and partners.

To view a summary, and engage in discussion about this announcement visit AdAlta's InvestorHub here: <https://investorhub.adalta.com.au/link/PR1g3r>

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.

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

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

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