ASX Announcement | 17 November 2026

AdAlta Limited (ASX:1AD)

US FDA Orphan Drug Designation for EW-001 in mesothelioma assigned to AdAlta

AdAlta now holds a valuable US regulatory asset for its lead CAR-T therapy, following its first pre-IND meeting with the FDA

Investment highlights

- The US Food and Drug Administration ("FDA") **Orphan Drug Designation** for EW-001 for treatment of mesothelioma has been **assigned to AdAlta** by partner Shanghai Cell Therapy Group ("SHcell").
- Orphan Drug Designation brings **extended US market exclusivity** after approval, waiver of FDA application fees and other development incentives including tax credits for commercialisation partners.
- The assignment follows AdAlta's **pre-IND meeting with the FDA**, which supported the potential to use preclinical and clinical data from **all prior and current manufacturing variants** of EW-001 in an IND submission.
- The constructive pre-IND meeting covered manufacturing, testing, preclinical and clinical trial design questions, and **raised no issues AdAlta had not already considered**.
- Formal FDA meeting minutes are **expected in early December 2026**; AdAlta will update the market once received.

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of next generation cellular immunotherapies for solid cancers, today announced that Shanghai Cell Therapy Group Co Ltd ("SHcell") has assigned to AdAlta the US Food and Drug Administration ("FDA") Orphan Drug Designation ("ODD") for EW-001 (formerly BZDS1901) in the treatment of malignant mesothelioma. EW-001 is AdAlta's lead CAR-T cell therapy for advanced mesothelioma and other mesothelin-expressing cancers. The assignment follows AdAlta's first pre-IND meeting with the FDA on EW-001, held on 3 November 2026 US time (4 November 2026 AEST).

The FDA grants ODD to medicines being developed for rare diseases – those affecting fewer than 200,000 people in the United States – to encourage investment in treatments for patients with few options. SHcell, which originally developed EW-001, first obtained the designation in February 2023. AdAlta, which holds the rights to EW-001 outside Greater China, **now holds it in its own name**.

AdAlta CEO and Managing Director, Dr Tim Oldham said:
"Orphan Drug Designation is one of the most valuable regulatory assets a cancer therapy can hold in the United States. Extended market exclusivity after approval, together with fee waivers and tax incentives, materially strengthens the commercial case for EW-001 – for AdAlta, and for the larger biopharmaceutical companies we expect to partner with.

Just as important is what sits behind the assignment. Our pre-IND meeting supported the potential to use the totality of preclinical and clinical data generated across EW-001's manufacturing variants to open our IND. That means years of laboratory work and patient experience in China can work for us as we prepare for clinical trials in Australia."

Why Orphan Drug Designation matters
ODD does not change the evidence needed to show that EW-001 is safe and effective, but it brings significant incentives:

- **Market exclusivity.** Once EW-001 is approved for malignant mesothelioma, the FDA generally cannot approve the same medicine from a competitor for the same disease for seven years – protection that is separate from EW-001's patents.
- **Lower costs.** Exemption from the FDA's marketing application fee (currently more than US$4 million), and tax credits on qualifying US clinical trial costs that may benefit commercialisation partners.
- **Support.** Eligibility for FDA orphan product grants and FDA assistance in planning development.

Because AdAlta's strategy is to develop products for licensing to larger biopharmaceutical companies, these incentives add directly to what EW-001 is worth to a future partner.

Pre-IND meeting held
A pre-IND meeting lets a company test its development plan with FDA reviewers before the most expensive work is committed. IND stands for "Investigational New Drug" – the application the FDA must accept before clinical trials can begin under its oversight. AdAlta's meeting covered four areas:

- **Manufacturing** – technology transfer from SHcell to Cell Therapies Pty Ltd ("CTPL") in Melbourne, and planned process optimisation.
- **Testing** – analytical strategies: the tests that confirm each batch of EW-001 is consistent, potent and safe.
- **Preclinical package** – whether existing laboratory and animal data are suitable to support the IND, including data from previous manufacturing variants combined with the clinical studies conducted in China.
- **Phase 1 clinical trial design** – the design of AdAlta's planned Phase 1 clinical trial in Australia.

Like many cell therapies, EW-001 has been made using successive versions of SHcell's manufacturing process, from the version used in the earliest clinical studies in China to the rapid, low-cost third generation process now being transferred to CTPL. The meeting **supported the potential to use the totality of preclinical and clinical data generated across all of these variants** in the IND submission.

The discussion was constructive and did not raise any FDA questions about matters or requirements that AdAlta had not previously considered. Formal minutes reflecting the FDA's initial feedback and the discussion are expected in early December 2026, and AdAlta will update the market once they are received.

Next steps and strategic significance
Two near term milestones follow: the FDA's formal pre-IND meeting minutes (expected in early December 2026) and the **first manufacturing run of EW-001 in Australia** at CTPL, scheduled for December 2026.

For shareholders, AdAlta now holds in its own name a US designation that strengthens EW-001's commercial position and appeal to partners, and the program's first formal engagement with the FDA has gone as planned. Both give greater confidence in the path to clinical trials of EW-001 in Australia and show the 'East to West' strategy working as intended.

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

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 EW-001 (formerly BZDS1901)

EW-001 (formerly 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 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 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 commercialisation.

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.

[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

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 optimise the molecule format to enable single dose seasonal prophylaxis.

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

For more information

Join our InvestorHub

Follow us on LinkedIn

Follow us on X (formerly Twitter)