ASX Announcement | 26 November 2026

AdAlta Limited (ASX:1AD)

AdAlta receives critical proprietary materials for first Australian manufacture of EW-001

These materials enable the first manufacturing technology transfer run of EW-001 at Cell Therapies in Melbourne, scheduled before the end of 2026

Investment highlights

- Shanghai Cell Therapy Group ("SHcell") has supplied the first batch of **critical proprietary materials** required to manufacture EW-001 in Australia.
- The materials are the genetic **"blueprints" and tools** used to engineer a patient's own immune cells into cancer-fighting EW-001 CAR-T cells, and are available only from SHcell.
- **All materials and components are now on hand** for the first manufacturing technology transfer run at AdAlta's Australian manufacturing partner, scheduled before the end of 2026.
- These materials replace the costly viral vectors most CAR-T therapies require, supporting EW-001's **low cost manufacturing**.

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of next generation cellular immunotherapies for solid cancers, today announced that it has received from its co-development partner, Shanghai Cell Therapy Group Co Ltd ("SHcell"), the first batch of critical proprietary raw materials required to manufacture EW-001 (formerly BZDS1901) in Australia. EW-001 is AdAlta's lead CAR-T cell therapy for advanced mesothelioma and other mesothelin-expressing cancers. The quantities received are sufficient to enable manufacturing technology transfer runs at Cell Therapies Pty Ltd ("CTPL"), AdAlta's contract manufacturing partner in Melbourne, and mean that all materials and components required for the first of those runs are now on hand.

CAR-T therapies are made individually for each patient from their own immune cells. Turning those cells into EW-001 requires two specialised materials: the genetic "blueprint" that tells the cell what cancer-fighting machinery to build, and the tool that writes that blueprint permanently into the cell. Both were designed, and are made, by SHcell. The technology transfer runs they enable are complete manufacturing runs that confirm the process transferred from SHcell performs as expected using CTPL's equipment, staff and procedures.

AdAlta CEO and Managing Director, Dr Tim Oldham said:
"Receiving these materials is what turns our Australian manufacturing plan into actual manufacturing. Cell Therapies can now begin making EW-001 in Melbourne, and the first run is on track before the end of the year.

These are not materials that can simply be bought. They are proprietary to SHcell, and they are what allow EW-001 to be made without the expensive viral vectors most CAR-T therapies depend on. Receiving them is a critical milestone in moving a clinically proven Chinese innovation, together with the materials and know-how to manufacture it, into an Australian facility that can supply Western regulated markets."

What AdAlta has received
The two materials received are:

- **Plasmid DNA – the blueprint.** A circular piece of DNA carrying the genetic instructions for the two proteins that define EW-001: the mesothelin-targeting CAR (chimeric antigen receptor), which allows the T cell to recognise and attack cancer cells carrying the mesothelin protein, and an anti-PD1 VHH protein, a small antibody fragment the cell releases to block a key defence cancers use to switch T cells off.

- **Transposase mRNA – the tool that makes it permanent.** Instructions for an enzyme that integrates the plasmid DNA into the T cell's own genome, so the new instructions are passed on each time the cell divides inside the patient.

Most CAR-T therapies use modified viruses, known as viral vectors, to carry genetic instructions into cells. Viral vectors are expensive and in limited global supply, and EW-001's transposase approach avoids them entirely – a significant part of why EW-001 can be manufactured at substantially lower cost than conventional CAR-T products. Because the two materials are available only from SHcell, receiving them has been a defined step in manufacturing technology transfer to CTPL.

Next steps and strategic significance
The next steps are manufacturing technology transfer runs, which are designed to demonstrate the ability to replicate the SHcell process in Australia and to set a baseline for further process optimisation; the first run is scheduled for December 2026 with analytical results expected early in 2027.

For shareholders, this delivery from SHcell turns a contractual right into first physical supply in Melbourne of critical manufacturing materials. Manufacturing is ranked equally with clinical outcomes by investors and large biopharma companies alike, and showing that EW-001 can be made outside China to the standards Western regulators expect is central to what the program is worth to a future commercialisation partner.

To view a summary, and engage in discussion about this announcement visit AdAlta's InvestorHub here: https://investorhub.adalta.com.au/link/PZgp6y

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

[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

- 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.

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

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