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ASX Announcement | 2 September 2026

AdAlta Limited (ASX:1AD)

AdAlta's partner to provide BZDS1901 CAR-T therapy to advanced mesothelioma patients under a special access scheme in China

Approval follows an independent assessment of safety and possible efficacy, brings new hope to patients with very few options, and gives AdAlta a growing source of real-world data on its lead product

Investment highlights

- AdAlta's partner **SHcell has received official approval** to provide BZDS1901 to eligible advanced mesothelioma patients in China's **Hainan Boao Lecheng** special access zone.
- Patients will receive BZDS1901 manufactured using SHcell's **first generation manufacturing process**; AdAlta's EW-001 contains the same engineered armoured CAR-T features but will use a faster, lower cost **third generation manufacturing process** in Australia for Western markets.
- Approval followed an **independent assessment of BZDS1901's safety and possible efficacy** by Hainan's health and medicines regulators.
- Treatment will be provided at **Ruijin Hospital, Hainan**, a top tier (Grade A tertiary) hospital in the zone.
- SHcell and AdAlta will **continue to receive data** on the number of patients treated and their safety and treatment outcomes, providing **real-world evidence** supporting BZDS1901/EW-001 development in China and around the world.

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of next generation cellular immunotherapies for solid cancers, announces that its co-development partner, Shanghai Cell Therapy Group Co Ltd ("**SHcell**"), has received official approval to provide BZDS1901 to eligible patients with advanced mesothelioma under a special access scheme in China's Hainan Boao Lecheng International Medical Tourism Pilot Zone ("**Boao Lecheng**"). BZDS1901 is as China version of EW-001 AdAlta's lead CAR-T[1] cell therapy containing the same engineered features..

BZDS1901, made using SHcell's first generation manufacturing process, will be available under special access arrangements to qualifying patients at Ruijin Hospital, Hainan, affiliated to Shanghai Jiao Tong University School of Medicine – a Grade A tertiary (top tier) hospital in the zone. Approval was granted only after Hainan's provincial health and medicines authorities **independently assessed the evidence for BZDS1901's safety and possible efficacy**.

For patients with mesothelin positive, advanced malignant mesothelioma, who today face a median survival of only eight to ten months once their disease returns, this creates a **genuine new option**. For AdAlta, it creates a growing flow of real-world safety and outcome data on its lead product – evidence that supports AdAlta's EW-001 development program in Australia, the United States and other Western markets. EW-001 is engineered to include the same active CAR and armouring technology as BZDS1901, but using a third generation, faster and lower cost manufacturing process.

[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 find and kill cancer. As a living drug, CAR-T cell therapy has the potential for a single dose to have durable effects and to be potentially curative.

AdAlta CEO and Managing Director, Dr Tim Oldham said:
"Two things stand out for us. First, an independent group of regulators has examined the BZDS1901/ EW-001 safety and efficacy data and concluded that the therapy can be offered to patients outside a clinical trial. That is a meaningful external endorsement of a product we have believed in from the outset.

Second, patients with advanced mesothelioma have almost nothing available to them. Every patient treated at Ruijin Hospital, Hainan, is a patient who now has real hope – and every one of them adds to the body of evidence providing confidence and momentum behind development of EW-001, and that is exactly what our East to West strategy is designed to convert into value for shareholders."

What SHcell has been approved to do
Boao Lecheng is a special zone within China's Hainan Free Trade Port, created to give patients earlier access to promising new medicines and medical technologies that are **ethically sound and have been shown to be safe and potentially effective**. New biomedical technologies used in the zone are **independently approved** by Hainan's provincial health and medicines authorities[2] under the zone's own rules, rather than centrally by China's National Medical Products Administration ("**NMPA**"). BZDS1901 qualified on the strength of completed investigator-initiated trials ("**IITs**") in advanced mesothelioma in China, and of the NMPA's approval for BZDS1901 to enter formal Phase I/II clinical trials.

In practical terms, the approval means that:

- eligible patients with advanced mesothelioma can apply to be treated with BZDS1901 at Ruijin Hospital, Hainan;
- treatment is provided outside a clinical trial, under the zone's "clinical translation and application" pathway; and
- hospitals in the zone may charge patients for approved technologies at prices registered with, and published by, the Hainan authorities.

What the approval does not change
Equally important is what this approval does not do:

- **Scope.** It permits BZDS1901 to be provided to selected patients within **one zone in one Chinese province**. It is expressly distinct from full NMPA marketing approval, and separate from China's national rules governing investigator-initiated studies.[3]
- **Product.** Patients in Hainan will receive BZDS1901 made with SHcell's **first generation manufacturing process**.[4] AdAlta is separately establishing SHcell's faster, lower cost **third generation process** in Australia for EW-001.
- **Regulatory path.** It does not replace the approvals AdAlta needs in the United States, Europe or Australia, which will continue to require AdAlta's own clinical trial program.

What the approval does add is evidence. SHcell will continue to receive information from the treating hospital on the number of patients treated, any side effects they experience and how well they respond. This real-world experience will not have the rigour of a controlled study, but it is drawn from the same disease and patient population AdAlta intends to study. It will be **supportive of, rather than directly predictive of**, AdAlta's own results, but it **strengthens the global evidence base** for EW-001, may be submitted in support of a future Chinese registration, and reduces uncertainty for AdAlta, for regulators and for prospective commercial partners.

AdAlta does not receive revenue from patients treated in Hainan. Greater China is SHcell's territory under the parties' Development and Collaboration Agreement, and AdAlta's rights to develop and commercialise EW-001 in markets outside Greater China are unaffected.

Next steps and strategic significance
AdAlta's own program continues on plan. Transfer of manufacturing to Cell Therapies Pty Ltd is progressing, with first Australian manufacturing runs expected in the second half of calendar 2026, and a pre-IND meeting

[2] The Hainan Provincial Health Commission and the Hainan Provincial Medical Products Administration.
[3] China's national requirements for investigator-initiated clinical studies are set out separately, in State Council Decree No. 818 (October 2025). Approval for clinical translation and application in the Boao Lecheng pilot zone is a distinct pathway.
[4] The EW-001 clinical results supporting this approval are from two completed investigator-initiated trials in China that used SHcell's first generation manufacturing process. Later generation processes, including the third generation process AdAlta is establishing in Australia, are being evaluated in ongoing investigator-initiated trials in China; see for example AdAlta's ASX announcement of 5 August 2026.

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with the US FDA is anticipated in the same period. Together these steps pave the way for AdAlta's Australian Phase 1 study.

For shareholders, the significance of today's announcement lies in three things:

- **Validation.** An independent regulatory authority has assessed EW-001's safety and possible efficacy and found it good enough to offer to patients.
- **Data.** The safety and efficacy date from these additional patients adds to the evidence AdAlta will present to the US FDA and to prospective partners, at no cost to AdAlta.
- **Momentum.** Clinician and patient demand in China is a real-world signal of the need EW-001 is designed to meet, and of the value of connecting Asian innovation in cellular immunotherapy with Western regulated markets.

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

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: [5,6]

- 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)
- 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.

[5] 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
[6] See for example CONFIRM study (nivolumab against placebo): DA Fennell et al, Lancet Oncol 2021 (22) 1530

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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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