ASX Announcement | 1 April 2026

AdAlta Limited (ASX:1AD)

BZDS1901 clinical update

Tumour shrinkage, clearance in advanced mesothelioma patients treated with BZDS1901 support exploration of higher dosing, further clinical development

Investment highlights

- All **five advanced mesothelioma patients in extension Cohort 1** of the investigator-initiated trial of BZDS1901 have passed at least two months of follow-up.
- **14 mesothelioma patients now treated**: all had either previously not responded to, or relapsed after, chemotherapy or immunotherapy
- **Five of the ten patients** receiving the highest doses of BZDS1901 are **seeing tumour shrinkage** of more than 30% (50% Overall Response Rate)
- **Tumours that were 5cm in size** before BZDS1901 are **now undetectable in two out of ten** of these patients (20%, achieving criteria for a Complete Response) – highly unusual in patients who have already failed prior therapy
- **Response rates are almost double** those seen with current treatments
- Over a quarter of all patients have shown **on-going tumour shrinkage**, providing evidence of CAR-T persistence
- **Updated safety protocols** have allowed higher doses to be given with manageable toxicities
- These positive clinical results continue to support exploration of higher dosing and future studies

AdAlta Limited (ASX:1AD) ("AdAlta" or **"the Company")**, developer of next generation cell and protein therapeutic products, through its cell therapy subsidiary, AdCella Pty Ltd ("**AdCella**") has received further positive clinical results from ongoing investigator-initiated trials ("**IITs**") of its first-in-class CAR-T therapy, BZDS1901 in advanced mesothelioma. The studies are being conducted by Shanghai Cell Therapy Group Co Ltd ("**SHcell**") in China. These latest results show improving response rates to treatment with AdCella's preferred Generation 2 (Gen 2) version of BZDS1901, strengthen confidence in both the effectiveness and safe delivery of BZDS1901 and support the potential to increase doses in future clinical studies.

14 patients with advanced mesothelioma have now been treated with AdCella's preferred Generation 2 (Gen 2) version of BZDS1901. All of these patients have previously relapsed or failed to respond to at least one course of chemotherapy or immunotherapy or both. Current treatment options for these patients are usually associated with poor outcomes. Typically 50% of these patients will survive less than 9 months (median overall survival ("**mOS**") duration).[1] Only 11-29% of patients will experience meaningful tumour shrinkage, known as Overall Response Rates ("**ORR**").[2] Complete disappearance of the tumour on a CT scan, known as Complete Response ("**CR**"), is highly unusual.

At the highest doses of Gen 2 BZDS1901 tested to date, five out of ten patients are experiencing tumour shrinkage of more than 30%, representing a 50% ORR, more than double current treatment options. Impressively, tumours can no longer be detected by CT imaging in two out of ten patients, representing a highly unusual 20% CR rate. In one of these patients, two 5 cm tumours became undetectable three months after treatment and remain undetectable 18 months later (Figure 1). Of the 14 mesothelioma patients treated

[1] A Scherpereel *et al*, Nivolumab or nivolumab plus ipilimumab in patients with relapsed malignant pleural mesothelioma (IFCT-1501 MAPS2): a multicentre, open-label, randomised, non-comparative, phase 2 trial, *Lancet* (2019) 20(2) 239; NCT02716272

[2] A complete response (CR) describes a response to treatment where there is no longer any measurable disease presence; a partial response (PR) describes a response to treatment where tumour volumes shrink by 30% or more; stable disease (SD) describes a response to treatment where tumour volumes shrink or grow by less than 30%; progressive disease (PD) describes an absence of response to treatment where tumour volumes expand by more than 30%; overall response rate (ORR) is the sum of CRs and PRs.

with Gen 2 BZDS1901, four (28.6%) have survived more than 12 months and a further five (35.7%) are alive but have not yet reached the 12 month assessment point.

AdAlta CEO and Managing Director, Tim Oldham said:
"These latest results further strengthen our confidence in BZDS1901's potential to make a real difference for patients with advanced mesothelioma. We remain focused on progressing this program so that Australian patients can be the first outside China to access this promising new therapy."

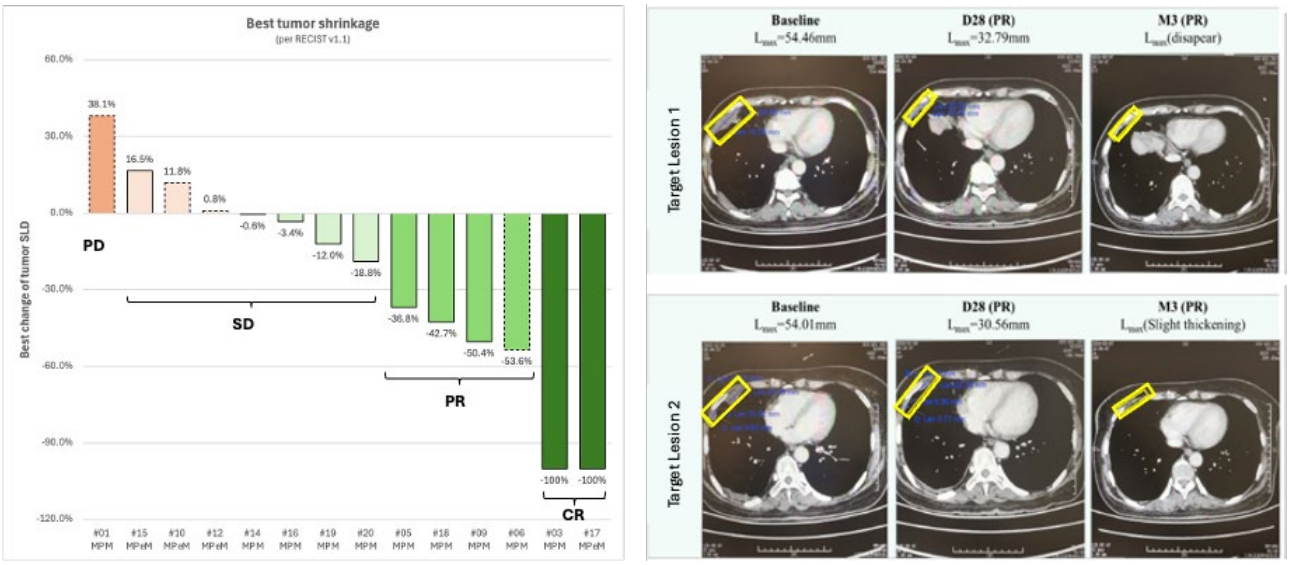

*Figure 1: **Panel A** shows the best change in tumour burden achieved for each of 14 patients treated with Gen 2 BZDS1901. Tumour burden is determined by using CT imaging to measure the sum of the longest diameters (SLD) of pre-selected tumours using a standardised protocol called RECISTv1.1. -100% change of tumour SLD represents a complete response ("**CR**"): tumours that could no longer be detected by imaging. Any change between -30% and -100% is a partial response ("**PR**"). Any change between -30% and +30% is stable disease ("**SD**") and any change greater than +30% is progressive disease ("**PD**"). A patient may achieve tumour shrinkage and then the tumour may grow again – only the best response is shown here. A patient may continue to live with PR, SD or even PD, and so overall survival is an important additional measure of effectiveness. MPM = pleural mesothelioma; MPeM = peritoneal mesothelioma. Patients with dashed outlines received lower doses of Gen 2 BZDS1901 (5-6x10^5 CAR-T cells/kg); all other patients received higher doses (8-10x10^5 CAR-T cells/kg). **Panel B** shows the CT scans of patient #3 (who achieved a complete response) prior to CAR-T treatment (baseline) and at one month (D28) and three months (M3) after treatment showing the progressive disappearance of two target tumours that were more than 5cm at baseline. Patient #3 was assessed as achieving CR between month 3 and month 5 and is still alive with undetectable tumours 23 months after treatment.*

BZDS1901 development progress
BZDS1901 is a first-in-class CAR-T[3] cell treatment targeting mesothelin ("**MSLN**"), a protein commonly found in aggressive cancers like mesothelioma, certain lung cancers, and various gynaecological cancers. Current second line treatment options (after initial chemotherapy or immunotherapy has failed) for advanced mesothelioma typically produce response rates of only 11-29%, and median overall survival ("**mOS**") of less than 9 months.[4] Complete responses are highly unusual in this setting.

To date, BZDS1901 has been administered to 36 patients with advanced mesothelioma and other solid cancers across three IITs in China. Generation 1 (Gen 1) of BZDS1901 demonstrated response rates of 63.5% in advanced mesothelioma patients. 73% of these (8 out of 11 patients) survived beyond 12 months.

Gen 2 of BZDS1901 features a short (less than two day), lower cost manufacturing process and is administered at lower doses than Gen 1, representing a substantial improvement in scalability. 15 advanced mesothelioma patients have now received Gen 2 of BZDS1901. 14 were able to be evaluated for efficacy including five patients in IIT extension Cohort 1 that was initiated at AdCella's request. Since initial results

[3] Chimeric Antigen Receptor-T (CAR-T) cell: a type of patient immune cell (T cell) that has been engineered in a laboratory to express a CAR that binds to a protein on the surface of a cancer cell (in the case of BZDS1901 this protein is mesothelin)
[4] A Scherpereel *et al*, Nivolumab or nivolumab plus ipilimumab in patients with relapsed malignant pleural mesothelioma (IFCT-1501 MAPS2): a multicentre, open-label, randomised, non-comparative, phase 2 trial, *Lancet* (2019) 20(2) 239; NCT02716272

were announced on 2 January 2026,[5] two additional patients have completed at least two months follow-up, and additional follow-up data is now also available on two other patients.

Improving response rates at lower doses
Across all patients receiving Gen 2 BZDS1901, nearly half have responded to treatment and complete responses are being maintained despite much lower cell doses (just 5-10% of the Gen 1 doses). At the highest Gen 2 doses used to date, results are approaching those seen with the Gen 1 product. Continued tumour shrinkage in some patients suggests the CAR-T cells remain active in the body for extended periods.

- In the whole 14 patient cohort, ORR is now 42.9% (previously 38.5%) with CR 14.3%. Both new patients achieved stable disease ("**SD**") but with demonstrable tumour shrinkage.
- Of ten patients receiving higher doses of Gen 2 BZDS1901 (8-10x10^5 CAR-T cells/kg), five responded (50% ORR) including two complete responses (20% CR).
- Just over one quarter of all patients (26.3%) showed continued tumour shrinkage over a period of 2-4 months, including one patient improving from partial response ("**PR**") to CR and another from SD to PR.
- mOS has not yet been reached but remains greater than 6 months, with 8 patients (57.1%) still alive. 4 patients (28.6%) have survived more than 12 months.

Encouraging safety profile
The extension study used an updated safety management protocol more closely aligned with recent protocols applied in Australia and the United States.

Importantly:
- No dose limiting toxicities were seen in the extension cohort using the higher BZDS1901 doses under these protocols
- No cases of severe cytokine release syndrome were observed
- One serious neurological side effect occurred but resolved quickly after treatment and the patient achieved a complete response

This improved safety profile with state of the art safety management supports the potential for further Gen 2 BZDS1901 dose increases in future studies.

Next steps
Planning is underway for an additional extension cohort of up to five additional patients, subject to agreement with the clinical partner. Additional follow-up data will continue to be collected from existing patients.

AdCella remains focused on progressing BZDS1901 toward Western clinical development.

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

This ASX announcement has been authorised for release by the Board of AdAlta Limited (ASX:1AD).

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[5] https://investorhub.adalta.com.au/announcements/7320663

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 subsidiary company, AdCella Pty Ltd's '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.

AdCella 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.

AdCella 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. AdCella 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.

AdCella's first asset, BZDS1901, is a first in class CAR-T cell therapy for mesothelioma and other solid cancers including lung and gynaecological cancers. BZDS1901 is the first CAR-T product for mesothelioma to secrete its own immune checkpoint inhibitor "armouring" to help overcome tumour immune suppression, is manufactured in less than two days without expensive viral vectors, and has demonstrated clinical potential, including difficult to achieve complete responses in advanced mesothelioma in China.

Separately, 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. AdAlta's first in class i-body®, WD-34, is a discovery stage asset being advanced through partnering as a potentially transformational prophylaxis and treatment for malaria.

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

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