ASX Announcement | 21 January 2026

AdAlta Limited (ASX:1AD)

AdCella milestones and regulatory progress

New US FDA manufacturing requirements align with AdCella strategy, first contracted payment to SHcell completed, additional RDTI rebate received

Investment highlights

- New US FDA requirements support AdCella's manufacturing scalability and automation strategy
- AdCella has made a first payment of US$0.5 million (A$0.75 million) due to Shanghai Cell Therapy Group ("**SHcell**")
- AdAlta Group receives additional $0.15 million Research and Development Tax Incentive refund in respect of FY2025, being the first in respect of overseas expenditure for AdCella's "East to West" cellular immunotherapy strategy

AdAlta Limited (ASX:1AD) ("AdAlta" or **"the Company")**, developer of next generation cell and protein therapeutic products, believes that new US Food and Drug Administration ("**FDA**") requirements for manufacturing of cell and gene therapy products aligns with, and further enables, AdCella's "East to West" cellular immunotherapy strategy. AdCella has now made the first milestone payment due under the recently executed development collaboration agreement for BZDS1901 with Shanghai Cell therapy Group ("**SHcell**") and the group has now received an additional $0.15 million Research and Development Tax Incentive (**"RDTI"**) refund in respect of BZDS1901.

New FDA guidance on manufacturing requirements for cell and gene therapies facilitate AdCella's manufacturing strategy

AdCella, AdAlta's cellular immunotherapy subsidiary, adds value to its products (such as BZDS1901) by delivering two outcomes at the end of Phase 1 clinical trials:

1. Clinical proof of concept: evidence that supports the potential for each product to have substantially superior efficacy and/or imporved safety over existing standards of care; and
2. Manufacturing proof of concept: evidence that the manufacturing process is capable of being scaled to tens of thousands of patients per year with reproducible outcomes, limited dependence on manual (human performed) processes and low cost and can be readily migrated between manufacturing sites and equipment.

The US FDA has announced increased flexibility on manufacturing and control requirements for cell and gene therapies throughout their lifecycle.[1] Reducing burdens like full cGMP compliance prior to Phase 2 and 3 clincial trials, employing more adaptable product specification expectations and streamlining process validation requirements will, in AdCella's opinion, provide greater flexibility to introduce continuous process improvement over time and reduce the cost and time to transition from Phase 1 to Phase 2 studies. This will in turn reduce the cost of and accelerate AdCella's manufacturing proof of concept work, enhancing the commercial viability and partnerability of its pipeline.

AdAlta's CEO and Managing Director, Dr Tim Oldham said:
"Demonstrating scalability and portability of cellular immunotherapy manufacturing processes is critical to support commercial viability of these products and requires continuous adoption of new technologies. Making this feasible requires recognizing that these products are not defined by the process used to make

[1] https://www.fda.gov/news-events/press-announcements/fda-increases-flexibility-requirements-cell-and-gene-therapies-advance-innovation and https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/flexible-requirements-cell-and-gene-therapies-advance-innovation

them and the FDA's announcement confirms regulators are moving in this direction, making our task achieveable with greater speed, lower cost and more efficient use of capital."

First milestone paid in respect of BZDS1901 and additional RDTI refund received

AdCella has paid the first instalment of US$0.5 million (~A$0.75 million) towards the first milestone due to SHcell under the BZDS1901 development collaboration agreement announced on 2 January 2026. The payment was made using funds invested by AdAlta Ltd in return for an anticipated increased share of AdCella post the initial third party financing that is currenty being finalized.

AdAlta has also received an additional $0.15 million Research and Development Tax Incentive ("RDTI") refund in respect of the financial year to 30 June 2025 (**"FY2025"**). The refund was paid following a favourable Advance Overseas Finding ("**AOF**") in respect of certain offshore research expenses for CAR-T cell therapy products in the Company's "East to West" cellular immunotherapy pipeline and is in addition to the $0.78 million received in December 2025.

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

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

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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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