

ASX Announcement | 27 March 2026
AdAlta Limited (ASX:1AD)

AdCella completes first Joint Development Committee meeting for BZDS1901

Identified opportunities to accelerate development timelines and reduce regulatory risk

Investment highlights

- First BZDS1901 Joint Development Committee meeting held with Shanghai Cell Therapy Group – moves development from independent planning to joint execution
- Potential to accelerate manufacturing transfer to Australia by up to six months – reduces risks to development timeline and regulatory approvals
- Two stage US FDA engagement strategy before clinical trial application is submitted – improves quality of regulatory feedback
- Updated clinical results from China Investigator Initiated Trials are pending
- Existing collaboration terms accommodate timeline changes and AdCella resourcing schedule

AdAlta Limited (ASX:1AD) (“AdAlta” or “the Company”), developer of next generation cell and protein therapeutic products, advises that its subsidiary, AdCella Pty Ltd (“AdCella”) has completed the inaugural Joint Development Committee (“JDC”) meeting with Shanghai Cell Therapy Group Co Ltd (“SHcell”) for its first-in-class CAR-T therapy, BZDS1901. BZDS1901 will initially be tested as a treatment for advanced mesothelioma patients (relapsed after first treatment) for whom there are limited clinical options today.

The meeting marks the transition of the collaboration from planning into joint execution and identified opportunities to accelerate development timelines and reduce regulatory risk.

AdAlta CEO and Managing Director, Tim Oldham said:

“This first JDC meeting is an important milestone for the BZDS1901 program, bringing together SHcell’s development experience with AdCella’s Australian clinical and manufacturing plans. The potential to bring manufacturing technology transfer forward significantly strengthens our regulatory and clinical pathway, while the refined FDA engagement strategy is expected to reduce development risk.”



AdAlta CEO and Managing Director, Tim Oldham and Senior Director Operations, Angus Tester touring SHcell’s facilities with Dr H Max Qian, Head of Novel Drug Development Unit at the recent Joint Development Committee meeting in Shanghai

Key outcomes from the JDC meeting held in Shanghai include:

- Manufacturing technology transfer to Australia may be accelerated by up to six months, bringing forward a key development milestone and reducing clinical timeline risk
- Earlier Australian manufacturing enables more effective regulatory engagement. AdCella can now optimize manufacturing from an in-house reference and can conduct final toxicology studies with the same process to be used in clinical trials
- US FDA engagement now planned across two meetings before clinical trial (“IND”) application to improve certainty and reduce regulatory risk. The first meeting, as originally planned, will seek early clarity on IND-enabling and clinical requirements early. The second meeting, following technology transfer, will enable confirmation of AdCella’s manufacturing process acceptability using real comparability data rather than theoretical or proposed comparability assessments
- SHcell’s new plasmid manufacturing facility is in advanced construction, supporting supply of critical starting materials for Australian clinical trials
- China Investigator Initiated Trial (“IIT”) extension Cohort 1 dosing completed (five mesothelioma patients); updated results to be announced when available
- Clinical trial strategy improvement opportunities have been identified for both:
 - Extension Cohort 2 of the China IIT study, and
 - Planned Phase 1 clinical trial in Australia
- Flexibility of the collaboration agreement to accommodate manufacturing and regulatory changes and AdCella’s current resourcing schedule was confirmed.

AdCella does not expect to provide an update following every future JDC meeting, but will announce material developments as they arise.

To view a summary and engage in discussion about this announcement visit AdAlta’s InvestorHub here: <https://investorhub.adalta.com.au/link/PBvo7P>

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 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 commercialization.

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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