ASX Announcement | 2 January 2026

AdAlta Limited (ASX:1AD)

AdCella and Shanghai Cell Therapy Group Co Ltd launch global collaboration on groundbreaking cancer therapy

First-in-class PD1 armored MSLN CAR-T anchors “East to West” cellular immunotherapy pipeline

Investment highlights

- AdAlta and its AdCella subsidiary have executed a Development and Collaboration Agreement (“**DCA**”) to co-develop Shanghai Cell Therapy Group Co Ltd (“**SHcell**”)’s BZDS1901 for all markets outside greater China
- BZDS1901 is a highly differentiated clinical stage, first-in-class armored CAR-T product targeting mesothelin (“**MSLN**”) with demonstrated complete responses in difficult to treat advanced mesothelioma patients and a low cost, scalable manufacturing process
- AdCella is financing BZDS1901 development outside greater China via third party investors and will be responsible for establishing a manufacturing platform and conducting a Phase 1 clinical trial in mesothelioma and other solid cancers in Australia
- AdCella will acquire a share of the proceeds of any commercialization event at the completion of Phase 1 clinical trials

Melbourne, Australia and Shanghai, China: AdAlta Limited (ASX:1AD) (“AdAlta” or **“the Company”)**, developer of next generation cell and protein therapeutic products, and its cellular immunotherapy subsidiary, AdCella Pty Ltd (“**AdCella**”) has signed a major development agreement with Shanghai Cell Therapy Group Co Ltd **(“SHcell”)** to bring an innovative cancer treatment, BZDS1901, to markets outside China. This partnership marks the official launch of AdCella’s “East to West” strategy, leveraging Chinese innovation and Australian expertise to accelerate global access to next-generation cell therapies.

AdAlta CEO and Managing Director, Tim Oldham said: "*We have been very impressed by the innovation, rigor and discipline SHcell have brought to BZDS1901 and are delighted to be working with them to globalize this important product. BZDS1901 exemplifies many features we believe are important for successfully bringing the potential of CAR-T cell therapy to solid cancer patients: established target, armoring to overcome immune suppression and a lower cost and short manufacturing process. We are delighted that Australian patients will be the first outside China to be able to access BZDS1901, particularly those with advanced mesothelioma for which there are very limited treatment options today. This is what our “East to West” cell therapy strategy was established to do.”*

SHcell’s CEO and Board Chairman, Qijun Qian said: "*BZDS1901 is the most advanced CAR-T product in our pipeline. AdCella’s innovative collaboration model and integration of Australia’s world class CAR-T cell capabilities represent a force multiplier for SHcell. AdCella’s investment enables us to advance BZDS1901’s global development faster and more cost effectively than would otherwise have been possible, allowing us share in the future growth of BZDS1901 while simultaneously enabling us to allocate more resources to other products in our pipeline.”*

BZDS1901: a breakthrough treatment for mesothelioma and other solid cancers

The therapy, BZDS1901, is a first-in-class CAR-T[1] cell treatment targeting mesothelin (MSLN), a protein found at very high levels in aggressive cancers like mesothelioma, certain lung cancers, and various gynaecological cancers. These are diseases with few effective options and poor survival rates.

[1] 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)

Special features of BZDS1901 include (see also Figure 1):

- **Well established target:** MSLN's high expression on cancer cells and low expression elsewhere makes it an ideal target for CAR-T cell therapies and it is a well-established target for personalized or targeted cancer therapies.[2]
- **Armoured for success where other products have failed:** Unlike conventional CAR-T therapies, BZDS1901 is "armoured" to block PD1, a checkpoint inhibitor that tumours use to shut down immune responses.[3] BZDS1901 CAR-T cells not only target the tumour but also secrete a PD1 blocker, so they don't get switched off by the tumour. This is the first time this armouring strategy has been used and could make BZDS1901 far more effective in solid tumours where other CAR-Ts and treatments have struggled.
- **Proven promise in clinical studies:** BZDS1901 has already demonstrated significant clinical promise in 36 patients with advanced mesothelioma and other solid cancers across three investigator-initiated trials ("**IITs**") in China. An early version of BZDS1901 demonstrated an overall response rate ("**ORR**") of 63.5% in advanced mesothelioma patients, including one complete response ("**CR**").[4] 73% of these (8 out of 11 patients) survived beyond 12 months. This compares with 11-29% ORR and 8.4-8.7 month median overall survival ("**mOS**") for current second line standard of care.[5] The current version of BZDS1901 has already demonstrated responses, including complete responses, at substantially lower doses and without complete dose optimization (see Figure 1). Complete responses in this patient population are a significant achievement.
- **Faster, cheaper manufacturing:** BZDS1901 can be produced in under two days, compared to 9-10 days for most CAR-T therapies, using a proprietary mRNA delivered enzyme to introduce the CAR modifications thus avoids expensive viral vectors. This makes the process cost-efficient and well down the path to scalability, a critical requirement for CAR-T therapies that are made specifically for each individual patient.

Significant unmet need for therapeutics targeting MLSN

More than 35,000 new cases of mesothelioma are diagnosed each year, more than 29,000 deaths and 20,000 relapsed or treatment refractory patients.[6] There are limited treatment options once chemotherapy fails. 85-90% of patients have high levels of MSLN expression, however MSLN therapies, including MSLN-CAR-T's, have had limited success to date. The global market for mesothelioma-related drugs alone is forecast to reach $12.2 billion by 2034.

MSLN is also highly expressed in other hard-to-treat cancers like non-small cell lung cancer (50-65%), ovarian cancer (60-65%), and pancreatic cancer (80-85%), opening up significant market opportunities.

[2] Z Tang *et al*, The role of mesothelin in tumour progression and targeted therapy, *Anticancer Agents Med Chem* (2013) 13(2), 276
[3] The immune system uses "brakes" to avoid attacking healthy cells. One of these brakes is a protein called **PD1** on immune cells. Cancer cells exploit this by sending signals that press the PD1 brake, shutting down immune attack. Blocking PD1 is like cutting the brake cable, enabling immune cells to stay active and can keep fighting the cancer.
[4] 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 tumours 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.
[5] 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
[6] GlobalData, Mesothelioma Epidemiology and Market Size (2023); Ferlay *et al*, *Global Cancer Observatory: Cancer Today* (2024)

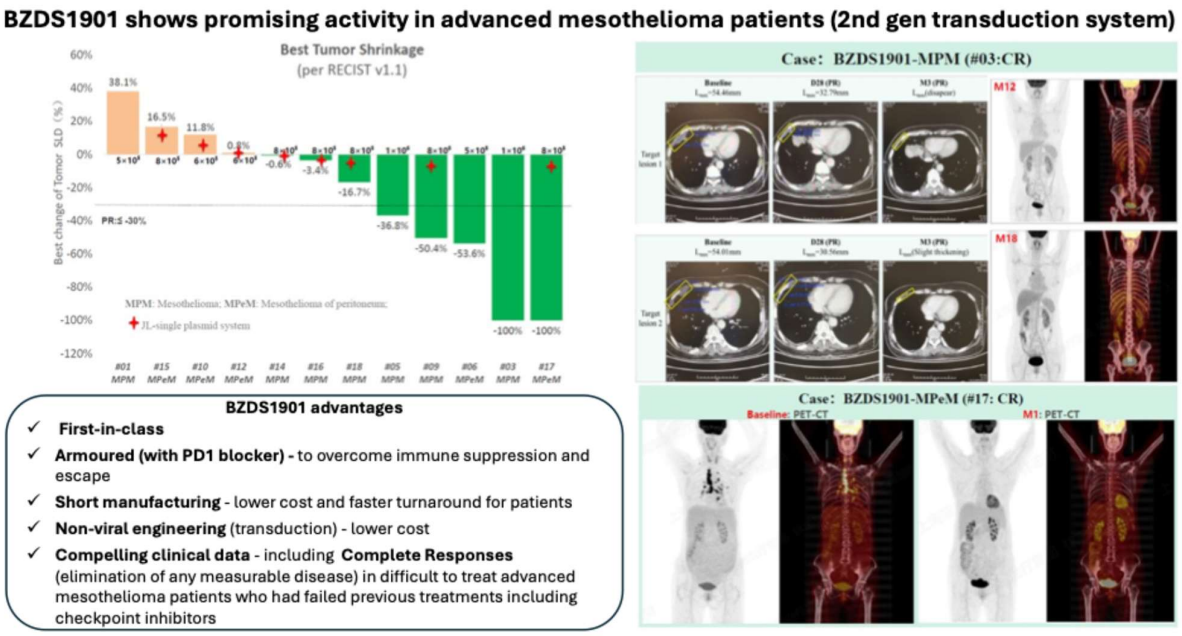

Figure 1: BZDS1901 shows promising activity in advanced mesothelioma patients

Development and Collaboration Agreement: capital efficient asset financing model
The DCA utilizes a novel asset financing, co-development model. By financing and executing the next stage of clinical development, AdCella acquires a share of the economic value of BZDS1901, SHcell's retained share can grow in value, and SHcell can deploy its resources on efficiently developing further products in its pipeline utilizing China's speed and cost advantages.

Under the DCA:

- AdCella receives an exclusive license to develop and commercialize BZDS1901 for all markets outside greater China ("**Territory**").
- AdCella is to establish and optimize manufacturing of BZDS1901 at an Australian CDMO, secure an Investigational New Drug ("**IND**") from the US FDA (including completing certain IND-enabling non-clinical studies), and conduct a Phase 1 clinical trial in up to 18 advanced mesothelioma and gynaecological patients.
- SHcell is to supply transposase materials for production of BZDS1901, treatment additional patients in an ongoing IIT study in China and for the ongoing development of BZDS1901 in China.
- AdCella estimates it will invest up to US$22-31 million over the next four years to advance development of BZDS1901 to the end of Phase 1 clinical trials, inclusive of upfront and milestone payments to SHcell and before the benefit of RDTI rebates (estimated at US$8-12 million). Development costs are substantially less than the cost to conduct similar studies in the US.
- AdAlta will provide management and operational support to AdCella via a services agreement.
- The collaboration will be governed by a Joint Development Committee.

Phase 1 studies are intended to demonstrate clinical proof of concept and manufacturing scalability. On successful completion, the parties may agree to either out-license BZDS1901 (a "**Commercialization Event**") or that either or both of them will continue the development of BZDS1901. AdCella may retain the rights to commercialize BZDS1901 for Australia and New Zealand unless such rights are critical to effective a Commercialization Event in respect of other parts of the Territory.

The Net Economic Proceeds from the Commercialization Event will be shared between two parties and this share and milestones will be adjusted if either both parties continue development beyond Phase 1.

The terms of the DCA are summarized in the Appendix below.

AdAlta to retain a substantial holding in AdCella through and beyond initial milestones
AdAlta plans that AdCella will raise funds directly through private investment to fund development. Discussions with venture capital funds, institutional investors, and family offices for the first funding round, as well as follow-on financing, are ongoing. The final terms of the initial funding will be announced to the ASX once confirmed. It is expected AdAlta will retain majority ownership of AdCella after the initial round of funding.

Funding AdCella through private investment maximizes AdAlta's return on its previous investment. AdAlta's shareholding in AdCella comes from earlier business development and R&D activities that secured BZDS1901, along with a seed investment made from existing cash reserves.

Significant early project goals over the next 9-12 months include:

- Completing a pre-IND meeting with FDA to confirm the technology transfer program and the content of the IND submission;
- Treating a further 2-7 patients with BZDS1901 under an ongoing IIT in China;
- Commencing remaining non-clinical IND-enabling studies;
- Commencing technology transfer; and
- Advancing discussions to in-license a second product for AdCella's pipeline.

"East to West" cellular immunotherapy strategy officially launched
AdAlta's strategy positions it at the forefront of a new wave of cellular immunotherapies, with BZDS1901 as the ideal first product. Execution of the DCA with SHcell is the culmination of almost a year of planning. It also represents SHcell's first expansion of its development programs outside China.

This collaboration combines cutting edge science and clinical results with a capital efficient model to maximize shareholder and partner value and delivers a clear path to global markets for a therapy addressing a very high unmet need. It exemplifies the power of Chinese innovation to create highly differentiated cell therapies and of Australia's cell therapy clinical, manufacturing and translational excellence to accelerate the globalization of these transformational products.

Details of a webinar to discuss this transaction, to be held in mid-January, will be announced separately.

To view a video summary and engage in discussion about this announcement visit AdAlta's InvestorHub here: https://investorhub.adalta.com.au/link/P2z4mP

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

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About SHcell

SHcell is the first and only company in China to cover the entire cell-based healthcare value chain. With more than a decade of industry experience, the company operates across four core areas: cell banking, oncology healthcare services, cell therapy product research and development, and cell empowerment. By integrating proprietary technology platforms—including an AI-empowered nanobody discovery platform, a non-viral gene writing platform, and a nucleic acid synthesis and delivery platform—with established infrastructure such as cell banks, cell factories, a cancer hospital, and medical laboratories, SHcell delivers comprehensive, one-stop cell-based healthcare products and services.

Founded in 2013, SHcell has consistently invested in cell therapy innovation, supported by deep expertise in cell biology, oncology, immunology, aging mechanisms, and clinical medicine. Its closed-loop, complementary business model supports sustainable growth and the efficient development of next-generation products and services. SHcell's pipeline includes BZDS1901, the world's first anti-PD-1 nanobody-armored CAR-T cell therapy candidate intended for the treatment of solid tumors.

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.

AdAlta's first in class i-body®, WD-34, is believed to be the first protein capable of inhibiting cell invasion by all strains of malaria parasite as well as the parasites causing babesiosis and toxoplasmosis. WD-34 is at pre-clinical development stage, being developed with non-dilutive grant and third party financing, and is available for partnering.

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

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Appendix: Key terms of DCA between SHcell, AdCella and AdAlta

Parties and purpose	AdAlta and AdCella collaborate with SHcell to develop and commercialise SHcell's cellular immunotherapy product known as BZDS1901, a MSLN-targeting, anti-PD1 nanobody-armoured autologous *ex vivo* CAR-T product, for solid tumours (**Product**).
Licence structure	SHcell grants AdCella: • an exclusive royalty free licence to copy, modify, use and exploit, including by sub-licensing, the Product (and any intellectual property in the Product or any improvement to the Product) including three product specific patent families; and • a non-exclusive royalty free licence to copy, modify, use and exploit SHcell background intellectual property, including four enabling patent families related to SHcell's transposase technology; anywhere in the world other than greater China, being China including the Hong Kong and Macao SARs, and Taiwan ("**Territory**"), for the purposes of the development collaboration. AdAlta grants SHcell non-exclusive, non-transferrable and royalty free licence to copy, modify, use and otherwise exploit the AdAlta background intellectual property for the purposes of the development collaboration.
Key SHcell obligations	SHcell will supply transposase mRNA, PD1-MSLN-CAR-T tiniplasmid DNA ("**SHcell Materials**") for IND-enabling and clinical studies, facilitate additional IIT clinical study cohorts and support technology transfer.
Key AdCella obligations	AdCella will be responsible, at its cost, for technology transfer of the BZDS1901 manufacturing process to an Australian CDMO, manufacturing optimization, securing an Investigational New Drug ("**IND**") from the US FDA (including completing certain IND-enabling non-clinical studies), and conducting a Phase 1 clinical trial in up to 18 advanced mesothelioma and gynaecological patients.
Intellectual property ownership	SHcell retains ownership of the Product, the intellectual property in the Product, and the SHcell background intellectual property. AdAlta retains ownership of AdAlta background intellectual property. On termination of the DCA, if SHcell wish to further utilise any data, results or manufacturing locations established or funded by AdCella, the SHcell must negotiate a commercial license to such data, results or manufacturing locations.

Development stages	Stage 1 includes investigational new drug enabling studies, transfer of manufacturing technology from SHcell to AdCella/AdCella's CDMO, and the conducting of phase 1 clinical trials in Australia. Stage 2 includes pursuit and facilitation of a commercialisation event with respect to the Product.
Funding and payments	AdCella is providing financing for the further development of the Product. AdCella commits a minimum of up to US$15 million for Stage 1 of development, inclusive of upfront and milestone payments due to SHcell during Stage 1, and after RDTI cash rebates on eligible R&D expenditure. There is a strict requirement for AdCella to allocate US$3 million to Stage 1 of the development collaboration within 70 days of execution. The balance of the US$15 million commitment must be allocated in accordance with agreed development milestones unless a joint development committee (**JDC**) (comprised of representatives of AdCella and SHcell) agrees otherwise.
Commercialisation	The net economic proceeds of commercialisation of the Product are to be distributed sixty percent to AdCella and forty percent to SHcell at such event. AdCella is granted exclusive rights in Australia and New Zealand to commercialise the Product post Stage 1 (including at grant of a marketing authorisation), provided that if commercialisation in a separate territory requires those rights to be given up, AdCella will do so. SHcell retains exclusive rights to commercialise and retain the proceeds of commercialising the Product in greater China.
Governance and oversight	The JDC oversees development and commercialisation strategy, including monitoring progress against development plans and agreeing key clinical study and technology transfer protocols, any adjustments to development plans and the terms of any Commercialization Event. The JDC will be comprised of representatives from AdCella and SHcell, with each party entitled to appoint 2 members each.
Restrictions on competition	AdCella is restricted from creating, developing, or acquiring a 'Competing Product' during the term of the development collaboration. Similarly, SHcell is restricted from licensing or otherwise commercialising a 'Competing Product' outside greater China during the term of the development collaboration. A 'Competing Product' is defined as any autologous ex vivo CAR-T product that is monospecific in targeting MSLN CAR (including a biparatopic MSLN CAR) and includes PD1 blocker molecule secretion. SHcell must also offer AdCella the opportunity to negotiate a license to certain Follow-on Products (products related to the Product that are not Competing Products) that SHcell may develop.