ASX Announcement I 4 February 2026

AdAlta Limited (ASX:1AD)

Increasing patient access to CAR-T cell therapies in Australia and SE Asia: ANZ Biologics Festival presentation

AdAlta Limited (ASX:1AD) ("AdAlta" or **"the Company")**, developer of next generation cell and protein therapeutic products is presenting at ANZ Biologics Festival on 4 February 2026.

AdAlta's CEO and Managing Director, Dr Tim Oldham will present a paper titled "Increasing patient access to CAR-T cell therapies in Australia and SE Asia" in which he will:

- Outline the current barriers that exist for patients to maximise access to CAR-T cell therapies
- Propose a blueprint to improve that access
- Highlight how AdCella's "East to West" cellular immunotherapy strategy is aligned with this blueprint to bring these ground breaking therapies to more Australian and SE Asian patients

Presentation details are:

ANZ Biologics Festival 2026
Wednesday, 4 February 2026
3:40 – 4:05 pm AEST
Crown Promenade, Melbourne

A copy of the presentation is attached and shareholders may comment and ask questions by visiting AdAlta's InvestorHub here: https://investorhub.adalta.com.au/link/egBBvy

This ASX announcement has been authorised for release by the CEO 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

For more information

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AdAlta

IMPROVING PATIENT ACCESS TO CAR-T CELL THERAPY IN AUSTRALIA AND SE ASIA

Tim Oldham
CEO and Managing Director, AdAlta Ltd

ANZ Biologics Festival
4 Feb 2026

ADALTA: NEXT GENERATION CELL & PROTEIN THERAPEUTICS

AdAlta - a clinical stage biotech:

- Growth powered by AdCella "East to West" cellular immunotherapy spin-out
- Monetising other valuable assets

"East to West" cellular immunotherapy strategy for growth

AdCella

Bringing the potential of cellular immunotherapies to solid cancer patients: 90% of cancers, untapped opportunity leveraging existing success in blood cancers and Asian innovation

First asset a potential breakthrough treatment addressing US$4b segment of mesothelioma market: BZDS1901 is clinical stage first in class armoured CAR-T product

Delivering both clinical and manufacturing proof of concept: Leveraging regional ecosystem and technology partnerships to deliver what larger pharma companies need

Capital efficient business model: buying into majority share or short investment horizon projects, leveraging rapid Asian innovation, world class manufacturing partnerships, R&D Tax incentive

Two other valuable pipeline assets for monetisation

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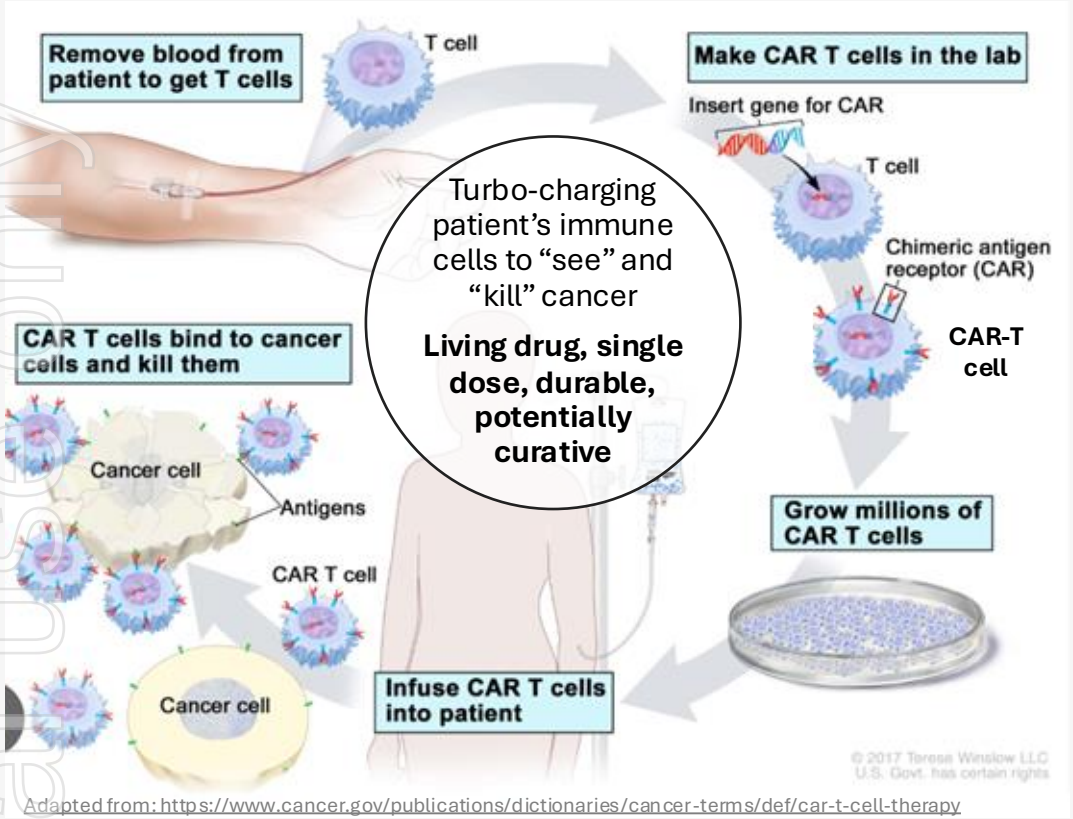
First in class anti-fibrotic protein, AD-214, with strategic partners sought for continued development into Phase II outside the company

World first pan-strain inhibitor of malaria parasites, WD-34, with strategic partners sought to advance to proof of concept

OVERVIEW

- **CAR-T cell therapies are revolutionizing outcomes in cancer, autoimmune diseases and other fatal diseases**
- **However access to these groundbreaking therapies remains restricted, particularly in small markets like Australia, SE Asia**
  - ✗ Financial barriers include reimbursement and margin/cost pressure across the supply chain
  - ✗ Operational barriers include supply chain complexity and delivery system capacity
- **Actions Australia and SE Asia can take to overcome these barriers include:**
  - ✓ Seeking out and developing products with access in mind
  - ✓ Facilitating commercial product licensing
  - ✓ Increasing clinical development, leveraging ”advantage Australia”
  - ✓ Facilitating “home grown” products – carefully
  - ✓ Implementing enablers across the value chain: regulatory, automation, education/models of care and reimbursement/incentives

CAR-T THERAPIES ARE REVOLUTIONIZING DISEASE OUTCOMES



Turbo-charging patient's immune cells to "see" and "kill" cancer

Living drug, single dose, durable, potentially curative

Adapted from: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy

7 FDA-approved CAR-T therapies for blood cancer

2 FDA-approved T cell therapies for solid cancer in 2024,[3] autoimmune coming

>US$2.6B earned in 2022[1]

50% of US$20.3B forecast cellular immunotherapy revenue for 2028[4]

Complete response rates:[2]

83% r/r pALL

51-65% r/r LBCL

78% r/r MM

FORBES > INNOVATION > HEALTHCARE

Newly Approved Cell Therapy For Advanced Melanoma, Amtagvi, Is A Potential Breakthrough

The Boundless Potential of CAR T Cell Therapy, From Cancer to Chronic and Common Diseases: A Q&A with Carl June

August 22, 2023 I by Meagan Raeke

HEALTH AUGUST 21, 2023

Chimeric Antigen Receptor (CAR) T cell therapy: A remarkable breakthrough in cancer treatment

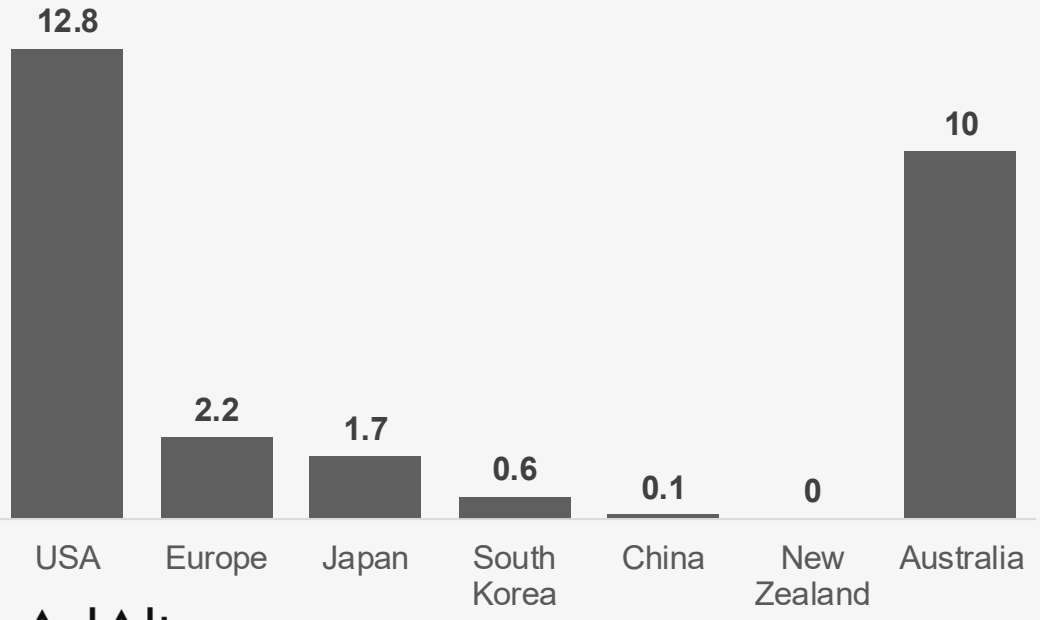
1. Company websites and financial filings; 2. Kymriah, Yescarta and Carvytki prescribing information; r/r = relapsed/refractory; pALL – paediatric acute lymphoblastic leukemia, LBCL = large B cell lymphoma, MM = multiple myeloma; 3. https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/amtagvi; https://www.fda.gov/vaccines-blood-biologics/aucatzyl; 4. Grandview Research, "T-cell Therapy Market Size, Share & Trends Analysis" Feb 2021; Polaris Market Research, "CAR-T Cell Therapy Market Share, Size, Trends, Industry Analysis Report", June 2021

CAR-T ACCESS IS STILL LIMITED, ESPECIALLY OUTSIDE US

"Despite its curative potential … in the US, as well as in European countries where CAR T-cell therapy is available to treat patients with large B-cell lymphoma (LBCL), ***only about two out of 10 eligible patients receive access*** to CAR T-cell therapy"

CAR-T Vision[2]

CAR-T doses per million population 2023(1)



T cell therapies for oncology indications

Product				
Kymriah (CD19 CAR-T, Novartis)	2017	2018	2021	2018
Yescarta (CD19 CAR-T, Kite)	2017	2018		2020
Tecartus (CD19 CAR-T, Kite)	2020	2020		2021
Breyanzi (CD19 CAR-T, BMS)	2021	2022		
Abecma (BCMA CAR-T, BMS)	2021	2021		
Carteyva (CD19 CAR-T, JWT)			2021	
Yorwida (CD19 CAR-T, HeYuan)			2023	
Carvykti (BCMA CAR-T, J&J/Legend)	2022	2022	2024	2023
Fucaso (BCMA CAR-T, IASO)			2023	
Zevor-cel (BCMA CAR-T, CARSgen/Nuocheng)			2024	
Amtagvi (TIL, Iovance)	2024			
Tecelera (MAGE4 TCR-T, US World Meds)	2024			
Auctazyl (CD19 CAR-T, Autolus)	2024	2025		
	9	**7**	**6**	**4**

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1. AdAlta analysis of varied market size, value and pricing reports; Australian estimates via industry survey
2. It's time for CAR-T, CAR-T Vision Report June 2025, https://cartvision.com/

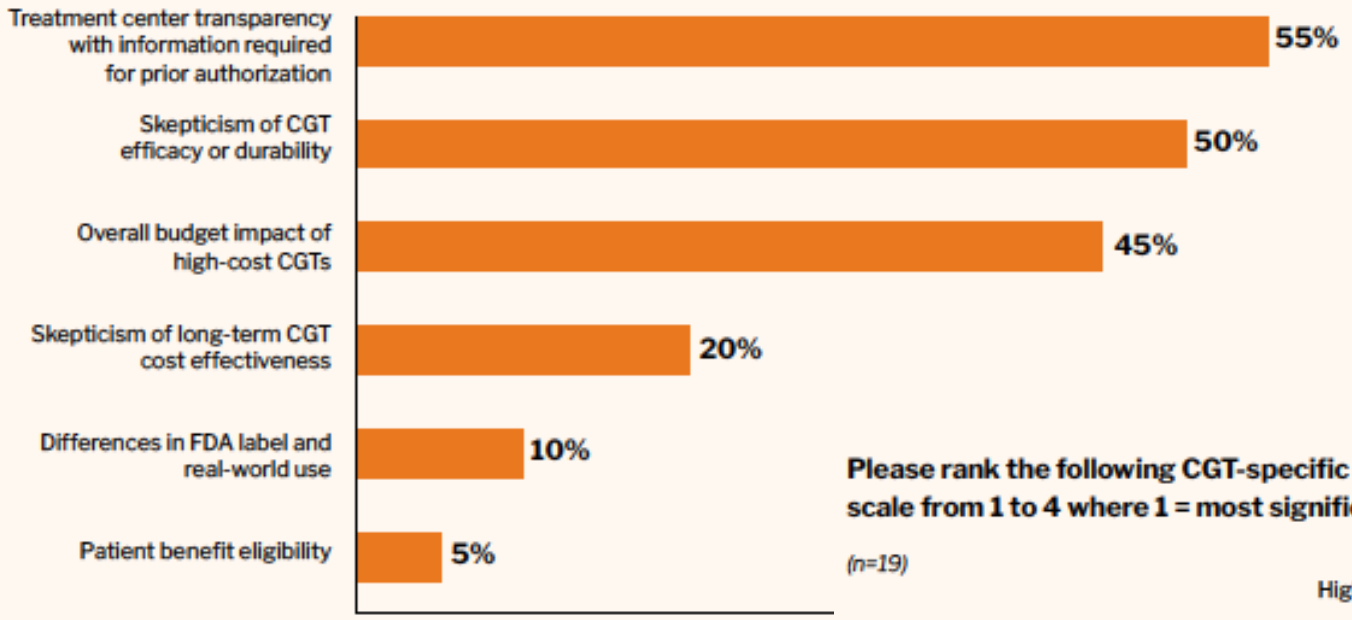
BARRIERS TO CAR-T ACCESS

Deep dive topics

Financial - lack of reimbursement/insurance	• Opacity of system costs • Limited efficacy or durability data • System not geared to "one-and-done" durable treatments
Financial - margin pressure across value chain	• High COGS limits commercial return to most valuable markets • Ancillary treatment costs, especially AE's, put risk on hospital/payor budgets
Operational - supply chain	• Slow turnaround times/limited capacity in centralised facilities • Complex co-ordination between treatment and manufacturing sites • Onerous conditioning and monitoring requirements
Operational - healthcare system capacity	• High burden to become a qualified treatment centre • Limited capacity in haematology departments – complexity of administration • Lack of awareness, comfort (patients and healthcare professionals)

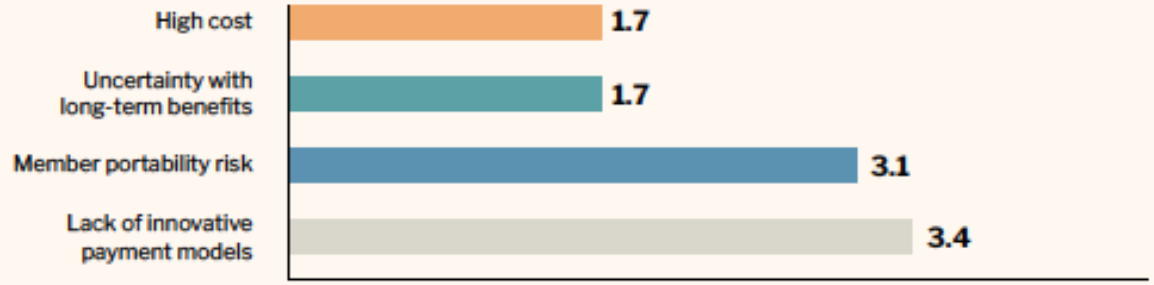
CAR-T CHALLENGES TRADITIONAL REIMBURSEMENT MODELS

What are the primary barriers you face when evaluating coverage decisions for CGTs? (choose all that apply) *(n=20)*



Please rank the following CGT-specific challenges when considering reimbursement on a scale from 1 to 4 where 1 = most significant and 4 = least significant.

(n=19)



TOTAL COST TO DELIVER CAR-T CELL THERAPY IS SUBSTANTIAL

Total cost of CAR-T cell therapy delivery in the US typically ranges from $500,000 to over $1 million per patient

$373,000-$475,000	CAR-T product acquisition cost (list)
$45,000-$600,000 ($160,000 average)	Comprehensive care (apheresis, infusion, hospitalization, side effect management including ICU stays for cytokine release syndrome (CRS), management of neurological events

US CAR T-Cell List Prices

Carvykti	~$465,000–$500,000+
Kymriah	~$475,000
Yescarta	~$373,000–$400,000+
Tecartus	~$373,000
Abecma	~$400,000+ range
Gross margins	**<50-75%**

(cf >95% for proteins and small molecules)

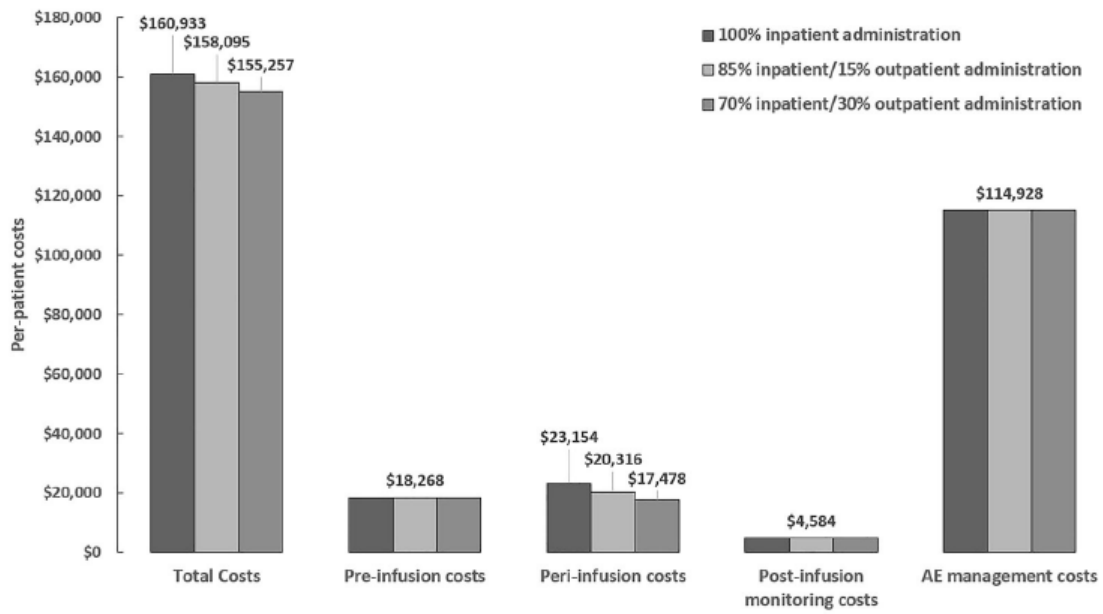
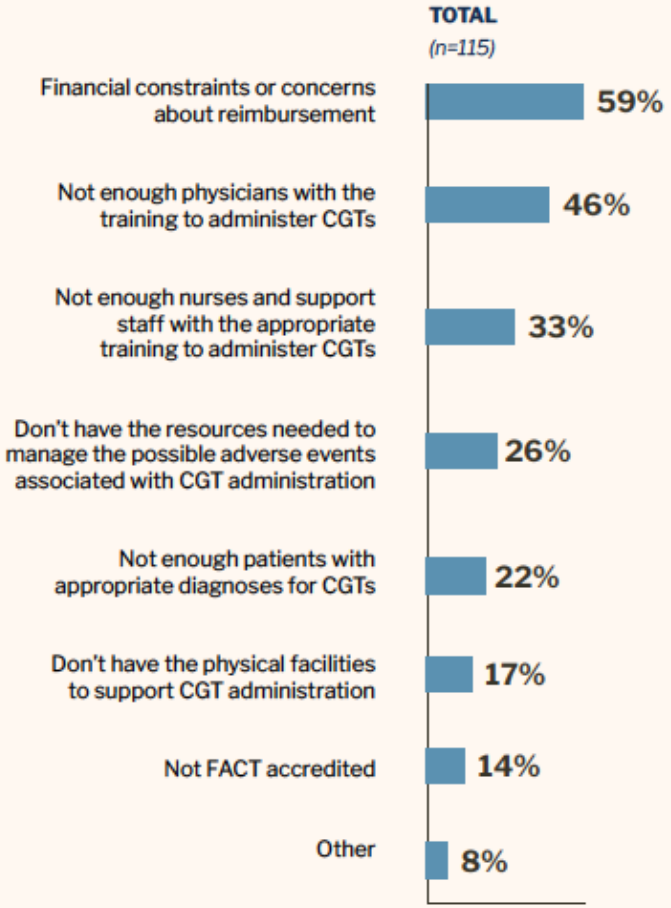


Fig. 2 Per-patient average total costs and costs by stage of therapy assuming 100%, 85%, and 70% inpatient administration. Cost is calculated in 2021 USD. *AE* adverse event, *USD* United States dollars

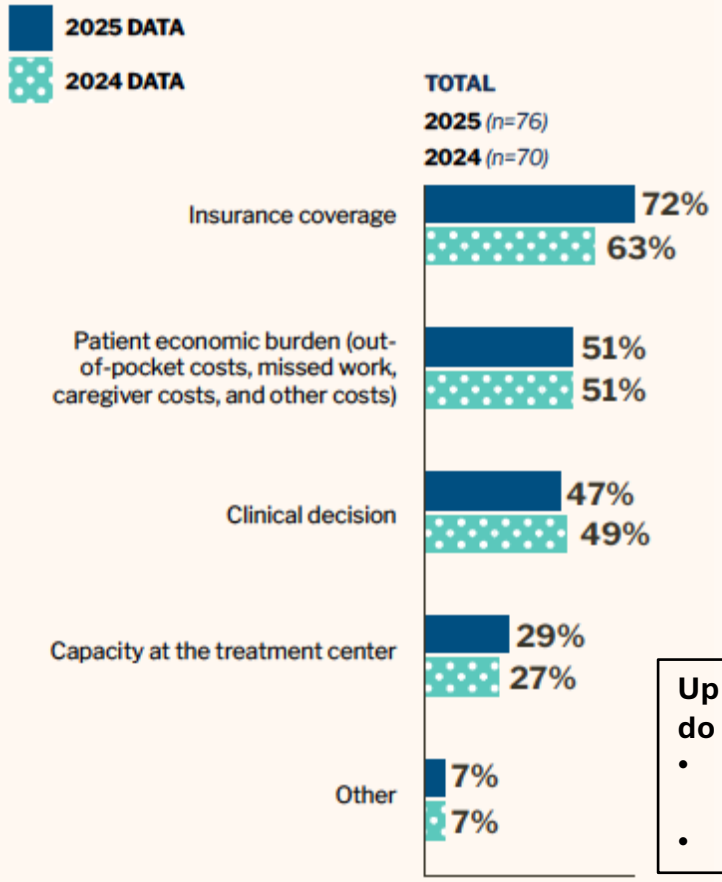
Source: https://doi.org/10.1016/j.jval.2024.04.004; https://doi.org/10.1007/s40487-023-00228-5

INSTITUTIONAL CAPACITY LIMITS ACCESS

What are the barriers limiting your institution's ability to administer CGTs?



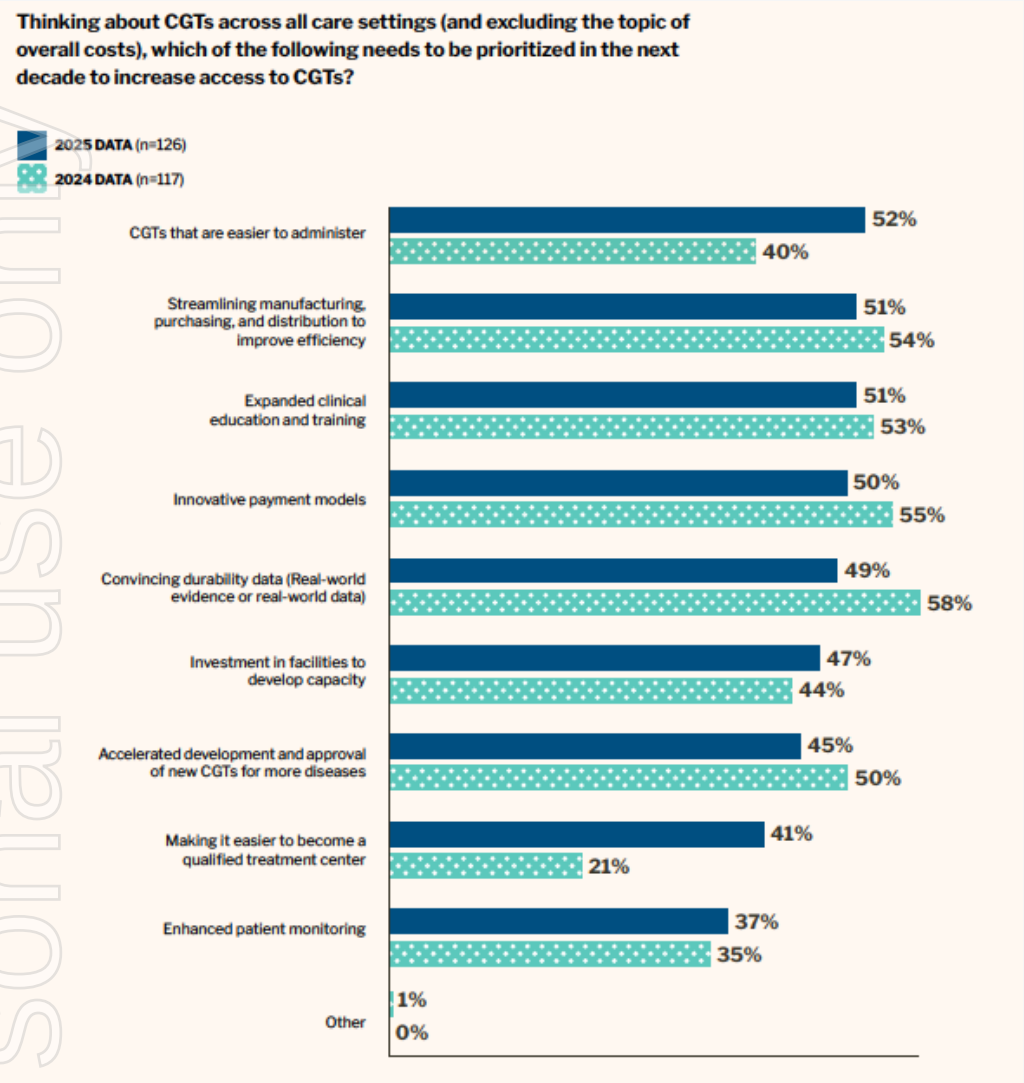
What are the most common reasons why patients who are referred for CGT don't ultimately receive it?



Up to 25% of eligible, approved patients do not receive therapy

- Disease progression prior to product being available
- Failed manufacturing

ACTIONS TO IMPROVE ACCESS IN ANZ/ASEAN



1. Seeking/designing products for access
2. Facilitate commercial product licensing
3. Increase clinical development: advantage Australia
4. Facilitate "home grown" product development - carefully
5. Implement value chain enablers

1. DESIGN PRODUCTS FOR ACCESS*

What can be done?

- Engineer features to enhance efficacy, durability and persistence
- Minimize conditioning regimens and adverse event (AE) profile
- Shorten manufacturing and QC processes
- Establish predictive biomarkers of manufacturing success, clinical response, AE profile
- Enable administration in community/out-patient setting eg 50% of Carvykti today
- Implement allogeneic/*in vivo* strategies

What are the challenges?

- Long term solution implemented product by product
- Dependent on new biology
- Global, industry objective – cannot be done on a regional basis
- Durability comes with experience
- Allogeneic and in vivo strategies yet to be proven, especially in solid cancer

Example: BZDS1901 aPD1-MSLN-CAR-T AdCella

✓ Well established target
Mesothelin (MSLN) is highly expressed on multiple cancers with poor prognosis in advanced mesothelioma

✓ Engineered for success
First product to secrete PD1 blocking molecules to overcome tumour suppression of CAR-T cells and endogenous T cells

✓ Clinical potential for a step change in care
36 patients in 3 IITs; responses 2-3x better than current 2nd line in r/r mesothelioma – including difficult to achieve complete responses

✓ Encouraging safety profile supports lower care/cost
Optimised lymphodepletion and predictive markers of adverse immune response

✓ Faster, cheaper manufacturing
Can be manufactured in less than two days without expensive viral vectors

2. COMMERCIAL PRODUCT LICENSING

What can be done?

- Fill local product pipeline gaps
- License commercial products approved elsewhere for delivery in region
- Replicate historical specialty pharma model

What are the challenges?

- Reimbursement/funding certainty
- Managing supply: cost and complexity of technology transfer v long logistics chain competing for scarce capacity in US facilities
- Bridging requirements from non-Caucasian, non-Tier 1 regulatory jurisdictions (China, Sth Korea, etc)
- Global product or multi-local product: comparability, reproducibility and pharmaco-vigilance

Example: Selected products approved offshore but not available here (including selected *ex vivo* gene therapies)

Breyanzi

Abecma (idecabtagene vicleucel) suspension for IV infusion

AMTAGVI (lifileucel)

Tecelra® afamitresgene autoleucel suspension for IV infusion

casgevy® (exagamglogene autotemcel) suspension for IV infusion

zynteglo™ (betibeglogene autotemcel) suspension for IV infusion

IASO FUCASO

FUCASO (Equecabtagene Autoleucel) Clinical Facts and Clinical Handling Guidance

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*This action enhances global access

3. INCREASE CLINICAL DEVELOPMENT: ADVANTAGE AUS

What can be done?

- Leverage Australia's excellent cell and gene therapy ecosystem, cost advantages and R&D Tax Incentive to make Australia an early destination for global clinical trials
- Brings innovative products to Australian/regional patients early

What are the challenges?

- CTN not available for ex vivo gene modified cell therapies
- Manufacturing/supply chain

Example: AdCella's "East to West" cellular immunotherapy strategy

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*This action enhances global access

4. FACILITATE “HOME GROWN” CAR-T PRODUCTS - CAREFULLY

What can be done?

- Enable academic/not for profit production of CAR-T products at individual hospital centres for administration in that centre
- Lowers cost(?) and reduces turnaround time to patient
- Enables rapid iteration of product design and development

What are the challenges?

- Basis for regulatory approval/oversight and funding: hospital exemption, approved product, “generic” or “copy” product, perpetual clinical trial
- Standards of quality and efficacy to be met
- Basis for differential regulatory treatment cf commercial products
- Intellectual property protection; impact on commercial development
- Site-to-site quality consistency (production, QC)
- True cost of production rarely reflected in costings

Example: multiple countries experimenting with hospital exemption and “hub and spoke” manufacturing models

2018 National Plan for Advanced Therapies

- Hospital exemption pathway for PoC manufacturing
- Centralised funding, patient allocation
- Hub-and-spoke manufacturing
- Centralised patient registry

2025 Modular manufacturing and point of care amendment UK; CLIC Canada

- Allows C&GT to be manufactured on site/nearby site
- Sites must meet licensing, quality standards
- Complements existing hub-and-spoke network of delivery hospitals for commercial product

Public-private partnership for indigenous CAR-T

- Locally manufactured viral vector, cells at 1<0% of US list price: IIT Bombay, Tata Memorial, ImmunoACT
- Central manufacturing hub, 80 delivery centres
- Move towards kits provided by central platform for distributed manufacturing

Public supported ”sovereign capability” plan

- Pre-approved pricing, abbreviated regulatory path
- Academic development (Malaghan), commercial CDMO and delivery centre (bioOra)
- Automation (Cocoon), medical tourism for scale

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*This action enhances global access

5. VALUE CHAIN ENABLERS

Deep dive topics

Regulatory	• CTN pathway for *ex vivo* gene modified cell therapies; conditional approvals • Reduced certification, risk management, monitoring requirements • Manufacturing flexibility: process ≠ product
Automation	• Encourage early adoption of high levels of manufacturing and QC automation • Manufacturing intensity, process development/transfer efficiency, adaptability • Increase digitisation and data … and share across products, patients
Education and models of care	• Cross-disciplinary care models between haematology and oncology, immunology eg cell therapy fellowships, institutional procedures • Enabling regional/out-patient delivery
Reimbursement/incentives	• Funding pathway clarity • DRGs for CAR-T procedures, AE management • Incentives (pricing, support) for tech transfer and local manufacturing

REGULATORY ENVIRONMENT MOVING IN FAVOUR OF ADAPTIVE MANUFACTURING STRATEGIES

Regulators, industry historical mindset: "product is the process"

- Starting material is bigger driver of process outcomes than process itself

The Applicant has established comparability between (b) (4) Iovance Biotherapeutics Manufacturing LLC, so (b) (4) sites can be used to manufacture AMTAGVI. However, the protocol used to establish analytical comparability between (b) (4) Iovance Biotherapeutics Manufacturing LLC is not adequate to assess the impact of major manufacturing changes. The Mechanism of Action (MOA) of AMTAGVI is not well-characterized, and the Applicant has not identified product quality attributes with established relevance to the product's clinical efficacy. Thus, it will be very challenging for the Applicant to complete a convincing comparability exercise to support a major manufacturing change, and additional clinical studies may be necessary. This concern is

FDA NEWS RELEASE

FDA Increases Flexibility on Requirements for Cell and Gene Therapies to Advance Innovation

What is the US FDA allowing?

- **Faster to clinic**: Full cGMP compliance (21 CFR 211) no longer required for Phase 2 trials
- **Streamlined scale-up**: Removal of the rigid "3-lot Process Performance Qualification (PPQ)" requirement
- **Dynamic specifications**: Commercial release criteria can now be "permissive" initially and tightened post-approval
- **Removed REMS** (Risk Evaluation and Management Strategies): reduces hospital certification, compliance burden

How does it impact the sector?

- **Reduces "Manufacturing Death Valley"**
- **Favours automation, continuous improvement approaches"**
- **Enables earlier, more valuable licensing – enhancing confidence for buyers to scale**
- **Increases access: more hospitals able to administer CAR-T with lower monitoring**

Source: Amtagvi Summary Basis of Regulatory Action; https://www.fda.gov/news-events/press-announcements/fda-increases-flexibility-requirements-cell-and-gene-therapies-advance-innovation 11 January 2026

CURRENT MANUFACTURING IS THE BOTTLENECK TO SAVING LIVES

CURRENT REALITY

- Existing CAR-T processes are **manual, expensive, and highly variable**
- **High Cost of Goods (COGs):** Limits patient access and commercial margins
- **Scalability issues:** Difficult to move from R&D to commercial scale without huge workforce investment
- **Slow process development and technology transfer:** Limited in-process analytical insight, moving production between sites (e.g., Asia to US) is slow, costly and variable

FUTURE STATE

- Future CAR-T processes are **automated, less expensive, and very reproducible**
- **Lower Cost of Goods (COGs):** improves commercial viability
- **Scalable:** Limited workforce and facility investment
- **Faster process development and technology transfer:** on board process analytical technology/AI; digital technology transfer

Xuri Wave®

G-Rex®

Prodigy®

Cocoon®

IRO®

Shuttle®

First generation clinical and commercial manufacturing solutions
(Skilled labour intensive, single unit operations, high facility overhead, expensive)

Next generation systems (examples)
(Closed, compact, multiple unit operations digitally enabled, operated by less skilled labour or robots)

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A BLUEPRINT FOR CAR-T ACCESS?

- **CAR-T cell therapies are revolutionizing outcomes in cancer, autoimmune diseases and other fatal diseases**
- **However access to these groundbreaking therapies remains restricted, particularly in small markets like Australia, SE Asia**
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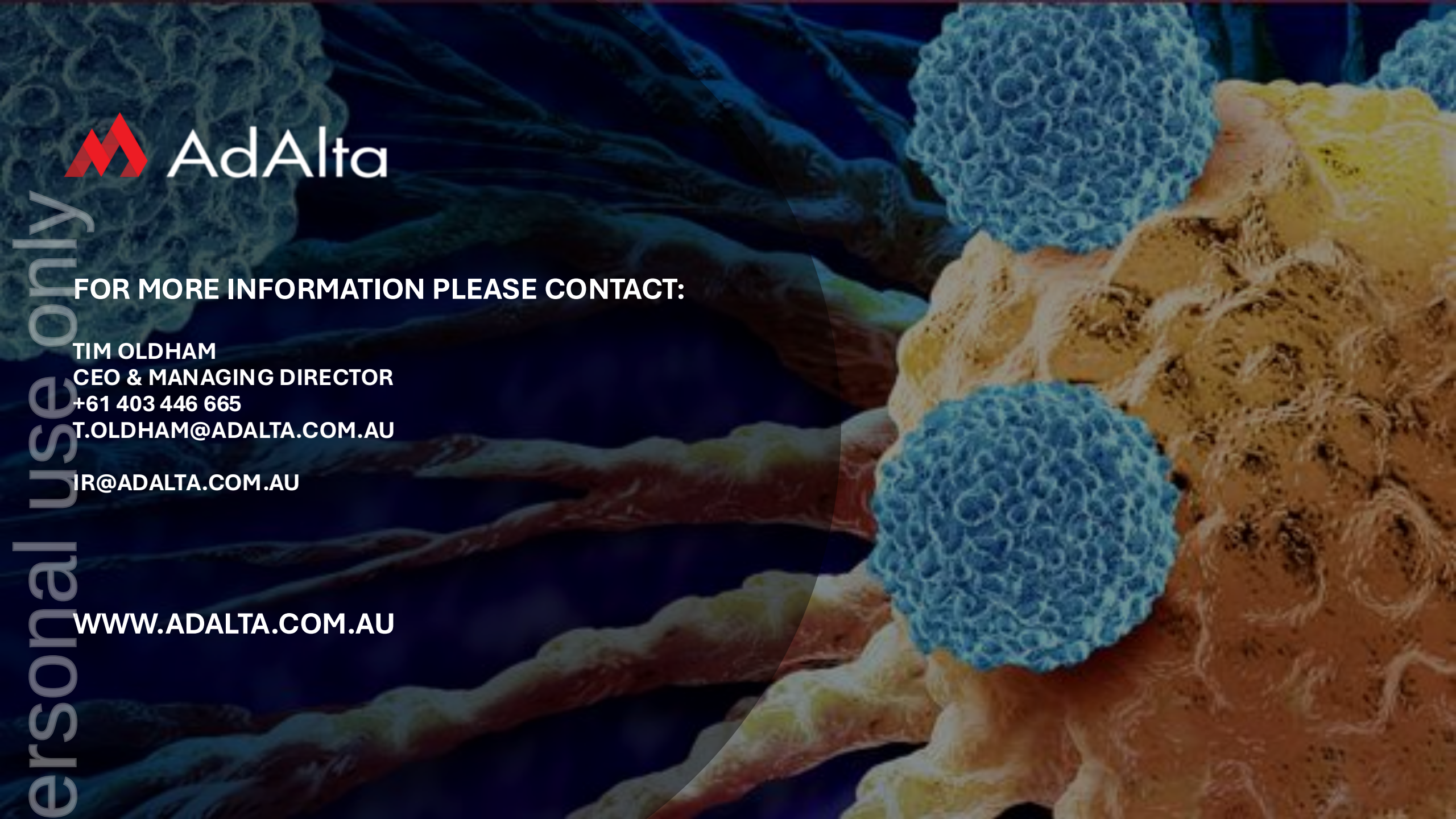

AdAlta

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