



# NEW HOPE FOR MESOTHELIOMA PATIENTS

**BZDS1901 CAR-T: OVERVIEW AND PATIENT CASE STUDY  
RESTRICTED**

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# ADALTA'S BZDS1901 CAR-T PRODUCT ADDRESSES A US\$4.2B MARKET OPPORTUNITY FOR MESOTHELIOMA, POTENTIAL IN 10+ OTHER CANCERS

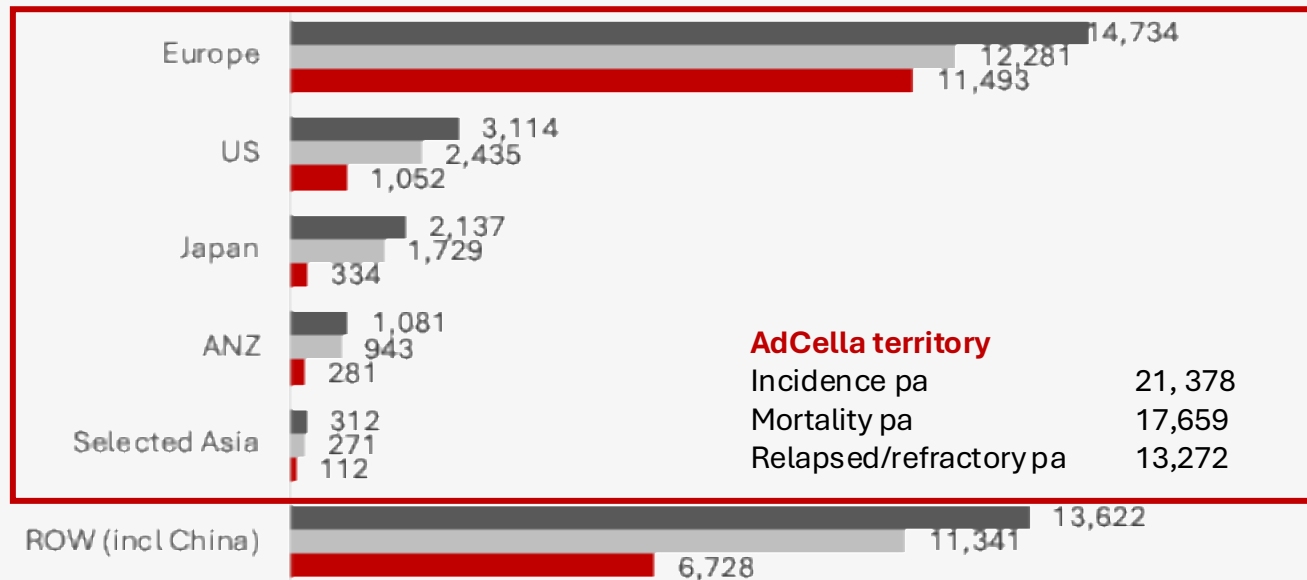
## Mesothelioma

- Rare cancer of the membranes surrounding lungs, heart, abdominal organs
- Asbestos exposure (fibres and dust) is key risk factor (10-60 years later)

### Mesothelioma market size: incidence and mortality(1)

Number of patients

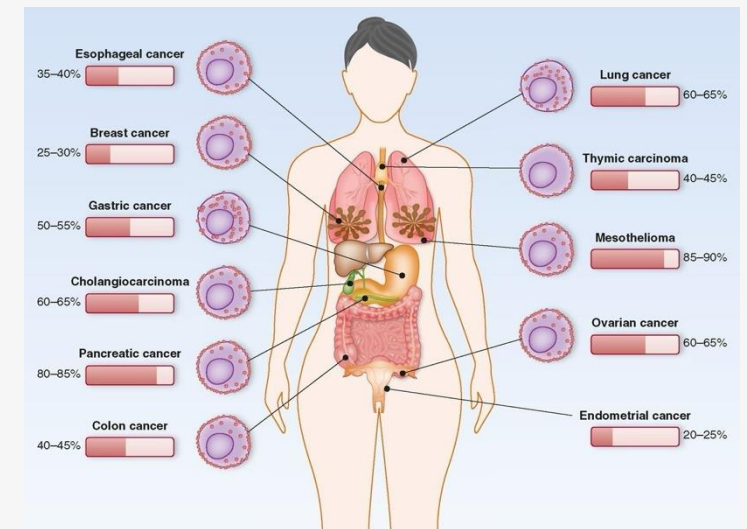
■ Incidence ■ Mortality ■ Relapsed/refractory



US\$12.2bn  
US\$4.2bn

Total market forecast for mesothelioma drugs by 2034<sup>2</sup>  
BZDS1901 addresses relapsed, refractory market<sup>3</sup>

Many other cancers, especially gynecological cancers, express the same target that BZDS1901 CAR-T cells seek

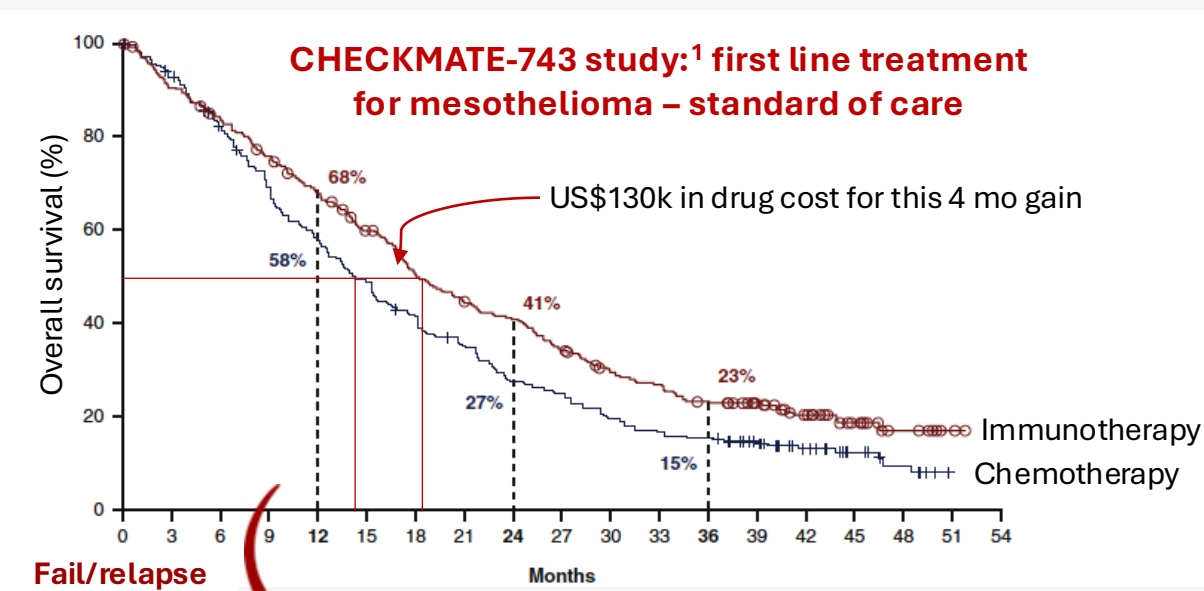


1. Ferlay et al. Global Cancer Observatory: Cancer Today. 2024; GlobalData Mesothelioma Epidemiology and Market Size. 2023 data.; Malaysia National Cancer Registry Report 2012-2016; Hospital-Based Cancer Registry 2016, Thailand; Neilly et al. Breathe. 2024; Kitadai et al BMJ Cancer 21, 294 (2021).; Yip et al. Asian Pac J Cancer Prev. 2011; includes both pleural and peritoneal mesothelioma; regions based on WHO definitions (Europe includes Eastern Europe and Russia; Selected Asia includes Singapore, Malaysia, Thailand and S Korea); AdAlta analysis

2. <https://www.biospace.com/malignant-mesothelioma-market-size-to-reach-usd-12-2-billion-by-2034-impelled-by-increasing-popularity-of-gene-therapy>

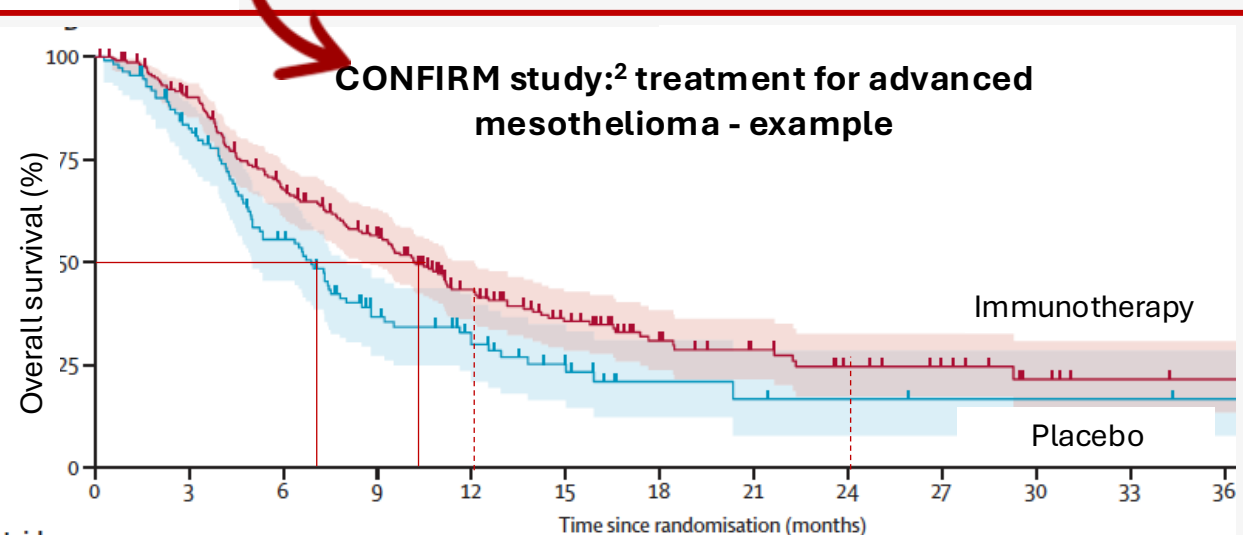
3. Assumes addressable market 90% of relapsed/refractory incidence population is MSLN positive (Servais et al 2021 Human Cancer Bio); and conservative price of US\$250,000 per dose ((South Korea US\$270k; Japan US\$300k; EU US\$350k; Australia US\$400k; US US\$370-450k per literature sources for CD19 and BCMA CAR-T products)

# MESOTHELIOMA REMAINS A RAPIDLY LETHAL DISEASE



First line therapy: <2y average survival, tumour clearance very rare

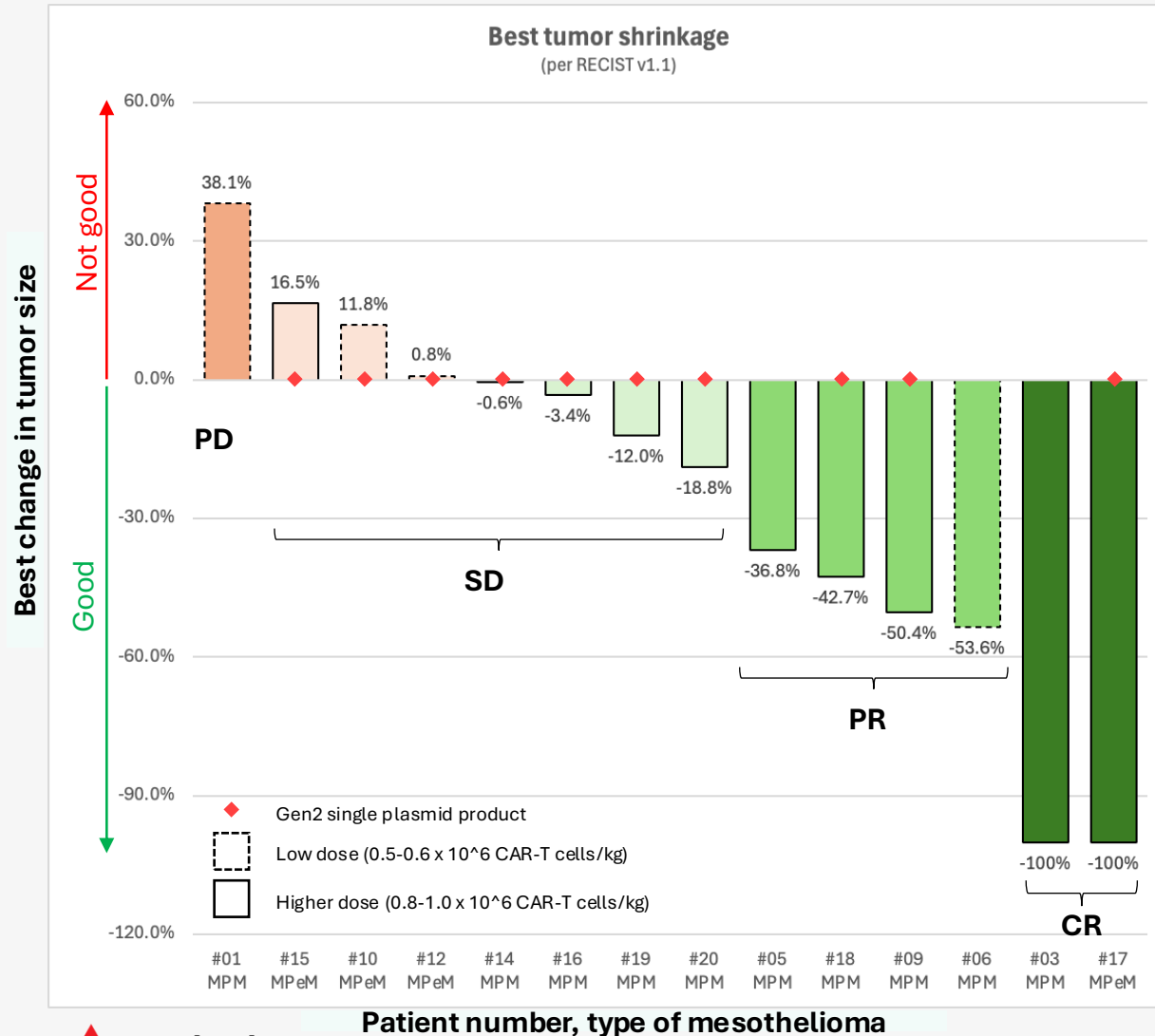
Outcome measure	Chemotherapy	Immunotherapy
Complete Response Rate	0%	2.6%
Overall Response Rate	44.0%	39.6%
Median Overall Survival	14.1 mo	18.1 mo
1 & 2 year survival rate	58% & 27%	68% & 41%
Incremental drug cost		US\$130k



Typical second line/advanced disease therapy: <10 mo average survival; no tumour clearance; very little chance of shrinkage

Outcome measure	Placebo	Immunotherapy
Complete Response Rate	0%	0%
Overall Response Rate	1%	11%*
Median Overall Survival	6.9 mo	10.2 mo
1 & 2 year survival rate	~30% & 18%	~45% & 25%

# BZDS1901 CAR-T RESULTS TO DATE POINT THE WAY TO A BETTER OUTCOME



- **Multiple responses, response rates more than double** benchmark response rates in advanced (second line) disease
- **Complete tumor clearance in two of 14 patients** – very difficult to achieve in advanced mesothelioma – longest **approaching two years survival**
- Tumor shrinkage continuing over 2-4 months in some patients – evidence of durability
- Generation 1 product achieved **Median Overall Survival 25.6 months**

Outcome measure	All patients (n=14)	Higher doses (n=10)
<b>Complete Response Rate</b>	<b>14%</b>	<b>20%</b>
Overall Response Rate	43%	50%
Median Overall Survival	Not yet reached	Not yet reached
1 year survival rate	29% with 36% still alive and not yet at one year	20% with 50% still alive and not yet at one year

# PATIENT #3: 5cm TUMORS CLEARED FOR NEARLY 2 YEARS

## Advanced pleural mesothelioma

### First line treatment

- 4 cycles of combination immunotherapy (nivolumab + ipilimumab)
- Progressed (tumors growing again) after 6 months

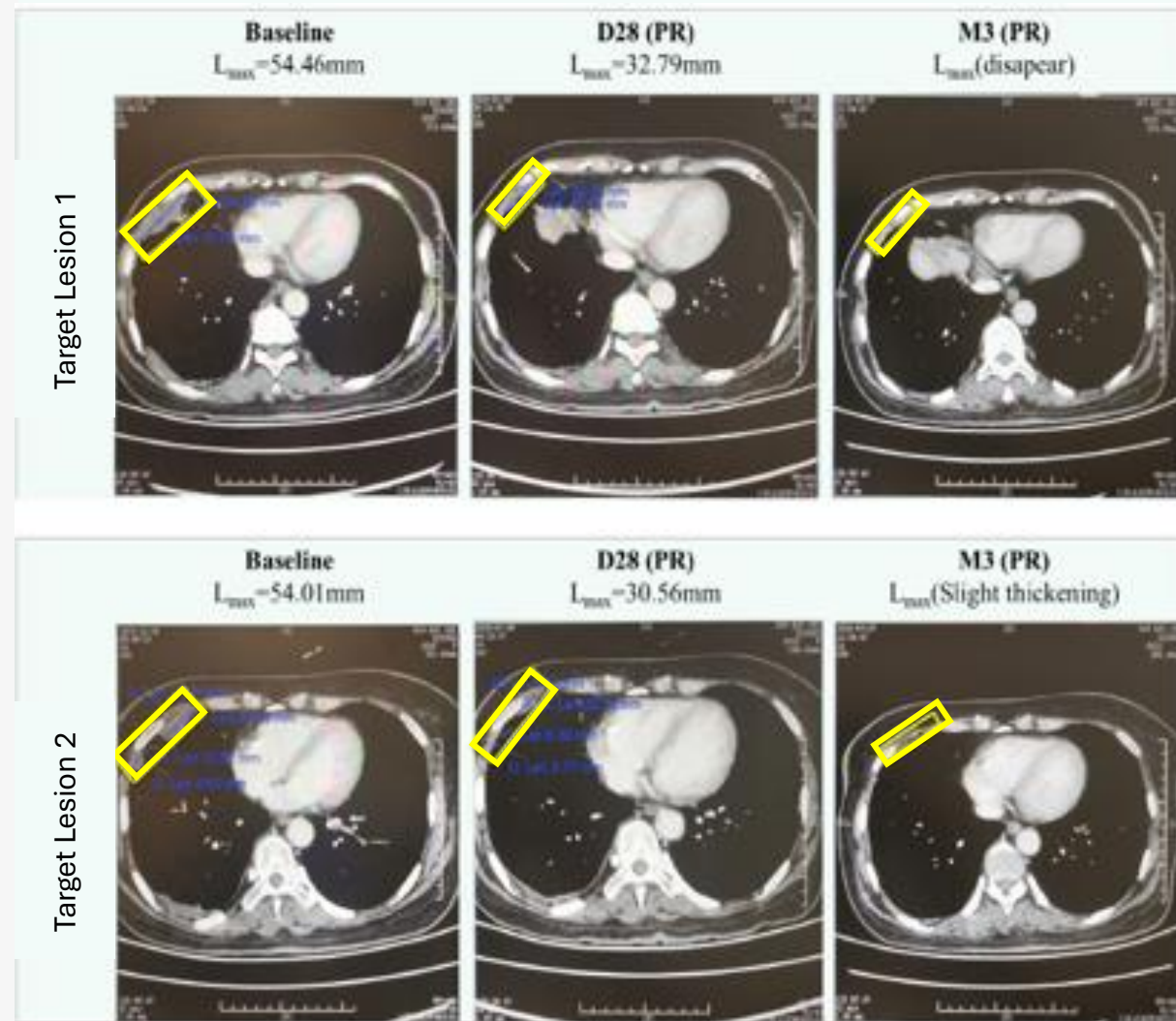
### Second line treatment

- 5 cycles of single agent immunotherapy (nivolumab)
- Tumors not controlled

### Third line treatment with single dose of BZDS1901 intravenous

- 2x 5.4 cm tumors targeted (Baseline – inside yellow boxes)
- 44% reduction in tumor size at 28 days (D28)
- 80% reduction in tumor size at 2 months (M3)
- *Complete response – tumor undetectable – at 3 months*
- *Still in complete response at 18 months, still alive at 20-22 months*
- Manageable side effects: Expected white blood cell, neutrophil reduction; low grade 1 CRS; Grade 3 pulmonary infection

## CT imaging – measures soft tissue density



# PATIENT #17: MULTIPLE TUMORS CLEARED IN ONE MONTH

## Advanced peritoneal mesothelioma

### First line treatment

- 3 cycles of chemotherapy (pemetrexed + cisplatin)
- Progressed (tumors growing again) after 14 months

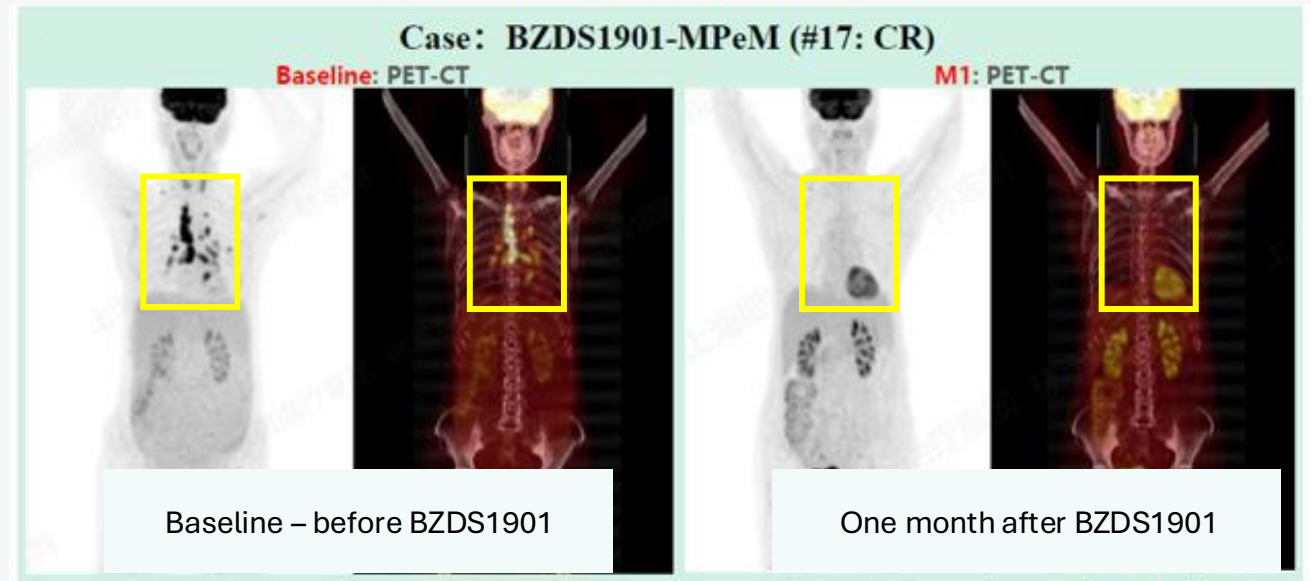
### Followed by

- 1 cycle of single agent immunotherapy (pembrolizumab) as maintenance therapy
- Tumors not controlled

## Second line treatment with single dose of BZDS1901 intravenous

- Multiple tumors visible metabolically active in chest (baseline – dark or bright dots inside yellow boxes)
- *Complete response (all tumors undetectable) at 28 days (M1)*
- *Still in complete response at 6 months*
  
- Manageable side effects: Expected white blood cell, lymphocyte reduction; low grade 1 CRS; Grade 3 infection; Grade 4 ICANS at 2-3 weeks responded well to treatment

## PET-CT imaging – measures cell growth rates (metabolic activity)



# USING HUMAN CELLS AS LIVING DRUGS HELPS ACHIEVE THESE OUTCOMES AND IS AT THE CUTTING EDGE OF CANCER CARE

## Treatment goal

### Improve overall tumor response

- Shrinkage = partial response
- Clearance (undetectable) = complete response

### Improve overall survival

- Without tumor growth = progression free survival

2017 -



### Cell therapy (CAR-T, etc)

(accelerate the immune system;  
engineered, living drug)

1990's - 2010



### Immuno- or targeted therapy

(drugs target what is different on cancer;  
remove brakes on immune system)

1940's



### Chemotherapy

(poison cancer faster than the patient)

1920's



### Radiotherapy

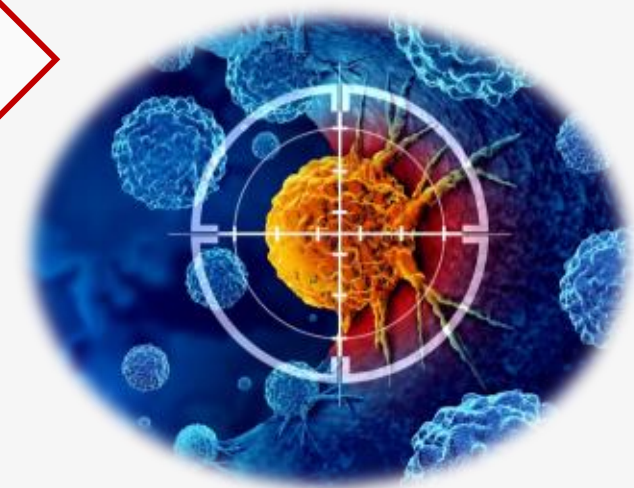
(poison cancer faster than the patient)

Late 1800's



### Surgery

(physically remove tumor)



# CAR-T REVOLUTION: LIVING DRUGS OFFERING DURABLE, POTENTIALLY CURATIVE OUTCOMES

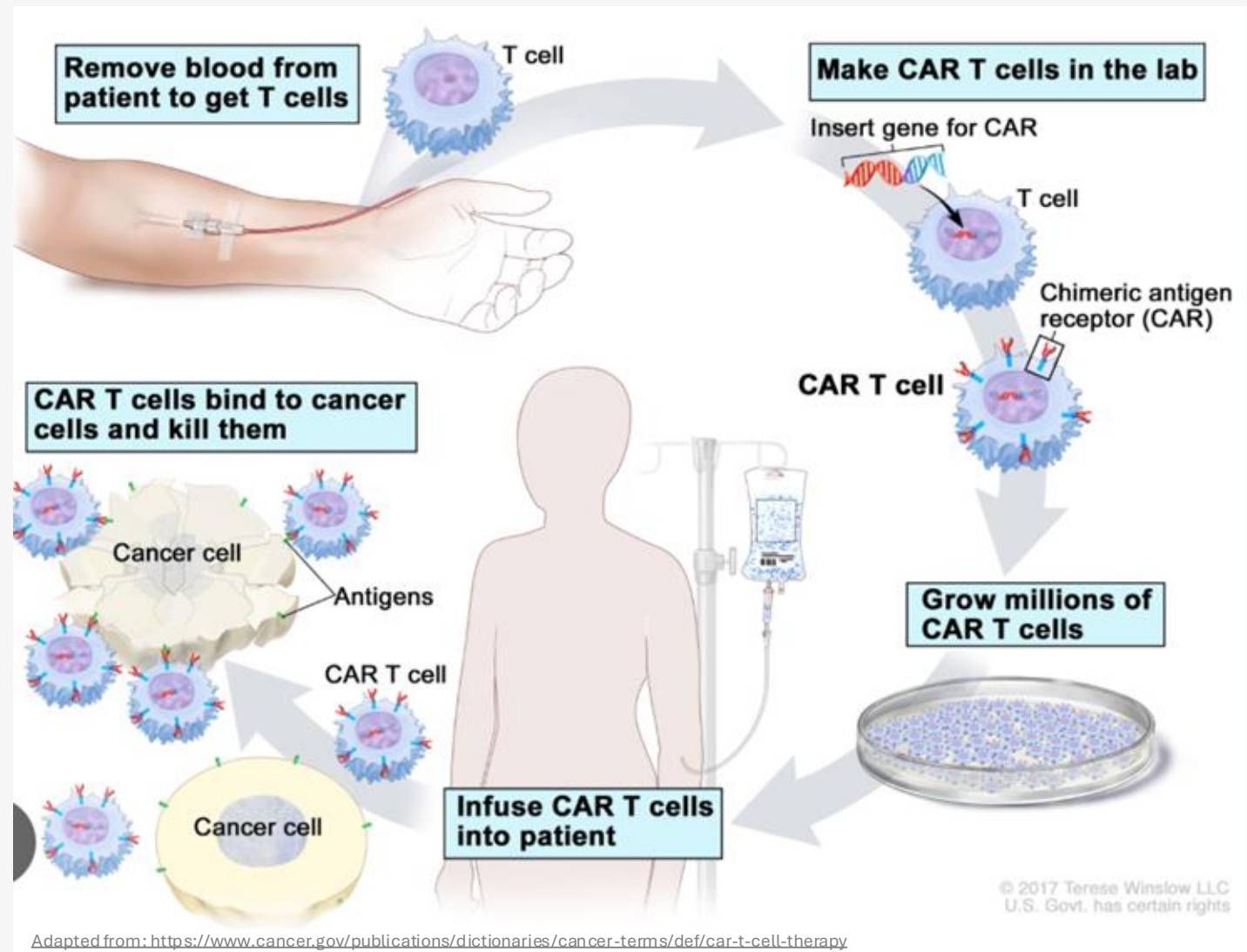
*Turbo-charging patient's immune cells to "see" and "kill" cancer*

**Living drug**

**Single dose**

**Durable**

**Potentially curative**



# FROM BLOOD CANCERS TO SOLID CANCERS

**7 FDA-approved CAR-T therapies**  
Transforming blood cancer outcomes since  
2017

**>US\$2.6B earned  
in 2022<sup>1</sup>**

**Two T cell therapies for solid  
cancer approved by FDA in 2024<sup>3</sup>**

**CAR-T for solid cancer to be 50%  
of US\$20b cellular  
immunotherapy market by 2028<sup>4</sup>**

## 6yo girl with aggressive ALL (leukaemia)

16 mo of chemo, 2 relapses, ineligible for bone marrow transplant, considered terminal  
Single dose of CAR-T made from her own cells – **cancer free 13 years later**



Complete (cancer free), durable response rates in many advanced blood cancers:<sup>2</sup>  
**83% r/r paediatric ALL (leukaemia)**   **51-65% r/r LBCL (lymphoma)**  
**78% r/r MM (myeloma)**

HEALTH AUGUST 21, 2023

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

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

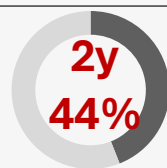
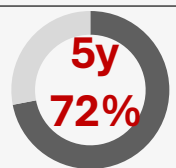
August 22, 2023 | by Meagan Raeke

**AdAlta is striving to bring this same hope to solid cancer patients**

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/aucaatzyl>
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

# POTENTIAL VALUE AT EXIT: PHASE I CAR-T LICENSING TRANSACTIONS

Global top 25 oncology pharma companies investing in autologous cell therapy (licensing, M&A, CVC)



73 *In vivo* CAR-T assets at end of 2024  
5 *In vivo* CAR-T assets in clinic in 2025

Will be seeking proven payloads for optimized delivery systems

Date	Drug(s)	Licensor	Licensee	Deal stage	Lead indications	Total value (US\$m)	Upfront (US\$m)
Nov-25	GCC/CD19 bispecific CAR-T	ICT Innovative Cellular Therapeutics	Lyell™	Phase 1 (completed; US)	mCRC	894*	74*
Oct-24	CD19/CD20 logic gated CAR-T	IMPACT BIO	Lyell™	Phase 1/2 (ongoing; US)	r/r B cell lymphoma; other lymphomas	780-1,030*	(Acquired)
May-24	MAGE-A4 targeting TCR T cell therapy	Adaptimmune	Galapagos	Phase 2 (ongoing; global)	Head & neck cancer	665	85
Nov-23	DLL3 targeting autologous CAR-T cell therapy	LEGEND BIOTECH	NOVARTIS	Phase 1 (ongoing; US)	SCLC, LCNEC	1,110	100
May-23	CD20 and CD19/20-directed autologous CAR-T cell therapy	CBMG Cellular Biomedicine Group	Janssen	Phase 1 (completed; China)	B-cell NHL, Follicular lymphoma, mantle cell Lymphoma, DLBCL	n/a	245
Jan-23	CART-ddBCMA	ARCELLX	Kite A GILEAD Company	Phase 2 (ongoing; US)	Multiple myeloma	n/a	325
Dec-22	Anti-BCMA CAR-T cell therapy	Hadasit הדסית	NEXCELLA NEXT GENERATION CELL THERAPIES	P1b (ongoing; Israel)	Multiple myeloma	34.55	1.5
Dec-20	Mesothelin-targeted autologous and allogeneic CAR-T cell therapy	ATARA BIO	BAYER	Phase 1 (ongoing for autologous therapy; US)	Peritoneal / pleural mesothelioma	670	60
<b>MEDIAN</b>						<b>782</b>	<b>85</b>

# ATARA – BAYER DEAL: US\$60M UP FRONT, US\$610M MILESTONES BEFORE ANY PHASE 1 RESULTS

December 07, 2020

Not intended for U.S. and UK Media

Bayer and Atara Biotherapeutics enter strategic collaboration for next generation, mesothelin-targeted CAR-T cell therapies for solid tumors

- Bayer takes exclusive, worldwide license to ATA2271 and ATA3271
- **US\$60m upfront** payment to Atara
- **Up to US\$610m** in total development and commercialization milestone payments
- Up to **“low double digit” royalties** on net sales
- ATA2271 autologous PD-1 DNR armored MSLN-CAR-T for high mesothelin expressing tumors such as mesothelioma and lung cancer (NSCLC) – **Phase 1 just commenced (1 patient enrolled, no results)**
- ATA3271 allogeneic version of ATA2271 utilizing Atara’s EBV T cell platform – **IND-enabling studies to go before clinic**

**ATA2271 attracted these terms despite being less advanced, with less compelling data than BZDS1901 has today\***

Outcome measure	Gen 1 ATA2271 + PD-1 combo at time of deal	BZDS1901 today
Patients treated	25 Gen 1 0 Gen 2 – trial initiated	11 Gen 1 <b>15 Gen 2</b>
Gen 1 to Gen 2 changes	Product redesign	<b>Method of manufacturing</b>
Complete Response Rate	0%	<b>14-20% (Gen 2)</b>
Overall Response Rate	12.5%	<b>43-50% (Gen 2)</b>
Median Overall Survival	23.9 mo	25.6 mo (Gen 1)
1 year survival rate	74-83%	29% with 36% still alive and not yet at one year

# ADALTA'S SCALABLE "EAST TO WEST" STRATEGY: BECOMING A VALUATION MULTIPLIER FOR ASIAN PARTNERS



### 3. On-licensing:

- Establish global manufacturing network and on-license to commercialisation partners.
- AdCella and partner share increased value that partner could not achieve on their own

### 2. Build value cost effectively by transferring to "West":

- *Clinical proof of concept*: Phase 1 in Australia under US IND
- *Manufacturing proof of concept*: closed, partially automated, demonstrated portability across platforms and sites; pathway to low cost commercial scale
- 30-50% cheaper than in US, plus 43.5% R&D Tax Incentive rebate
- Creates substantial value inflection; lower transaction cost for big pharma

### 1. In-license market leading assets from Asia ("East"):

- Highly differentiated assets
- Low acquisition cost
- By financing to next inflection point AdCella "buys" a share of the asset at exit

### 4. Regional commercialization for continuous revenue streams:

- Retain regional rights for in-licensed Phase 1 assets
- Acquire regional marketing rights for later stage assets

# NEXT STEPS FOR ADALTA

Milestone/activity	When	Significance
<b>BZDS1901</b>		
➤ US FDA regulatory advice (pre-IND meeting)	H1 FY27	Confirms and de-risks remaining manufacturing and preclinical activities required prior to Phase 1
➤ Manufacturing technology transfer and optimisation	Begin Q1 FY27	Confirms reliable and cost effective “just-in-time” process for making each patient specific dose of BZDS1901; increases attractiveness to larger pharmaceutical partners
➤ Ongoing clinical results from China IIT study	~ Quarterly	Establishes how long BZDS1901 controls tumors and resulting survival benefit; critical indicator of potential for partners
➤ Preclinical IND-enabling studies	Begin H1 FY27	Ensure complete FDA IND (Investigational New Drug) submission to approve Phase 1 trial; supports marketing to partners
<b>Other assets</b>		
❖ Screening additional “East to West” assets	Ongoing	Evaluating opportunities to expand pipeline with additional assets that can be advanced to inflection points rapidly and at low cost; particularly leveraging recent OriBiotech collaboration
❖ WD-34 (malaria) and AD-214 (fibrosis) out-licensing	Ongoing	Monetises previously developed IP

# “EAST TO WEST” GROWTH STRATEGY TO CREATE VALUE



**“East to West” cellular immunotherapy growth strategy addressing largest market:** solid cancer market 10x larger than blood cancers



**Ground breaking CAR-T BZDS1901 addressing \$4b mesothelioma market is first asset:** armoured for success; promise already shown in clinic; low cost, rapid manufacturing



**Multiple near-term catalysts:** clinical, regulatory and manufacturing milestones for BZDS1901



**Solving for manufacturing at scale:** removing significant barrier to commercialisation and exit with technology partnerships



**Scalable: Building pipeline** of highly differentiated cancer therapies leveraging Asian innovation, Australian advantages and capital efficient model to create value; more than 10 assets on “watch list”



**Protein therapeutics available for partnering create option value:** AD214, a new approach to fibrotic disease, heading to Phase II (US\$4.3b IPF market, US\$10b CKD market); WD34, first pan-species antimalarial antibody, preclinical (US\$1b market)



**FOR MORE INFORMATION PLEASE CONTACT:**

**TIM OLDHAM  
CEO & MANAGING DIRECTOR  
+61 403 446 665  
T.OLDHAM@ADALTA.COM.AU**

**IR@ADALTA.COM.AU**

**WWW.ADALTA.COM.AU**