



**IMUGENE**

Developing Cancer Immunotherapies

**ASX:IMU**

Investor Presentation  
September 2023

# DEVELOPING CANCER IMMUNOTHERAPIES



Release authorised by the Managing Director and Chief Executive Officer Imugene Limited

# CASH POSITION

Imugene has one of the highest cash balance of ASX biotech

## CASH BALANCE AS AT 30 JUNE 2023

Company	Ticker	Cash [A\$'MM]
Imugene	IMU	153
Telix	TLX	132
Immutep	IMM	123
Mesoblast	MSB	106
Avita	AVH	56
Polynovo	PNV	47
Impedimed	IPD	46
Neuren	NEU	38
Immuron	IMC	17

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Pro-forma cash balance of \$186m

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A\$17 million in July/August relating to azer-cel acquisition

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Provides cash runway for approximately two years

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~75% of overall spend on R&D in Fiscal Year 2023

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15% on total spend on Operational Spend (SG&A) is very modest by industry standards for a clinical portfolio as deep as ours

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10% Other costs including share-based payments

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# INVESTMENT HIGHLIGHTS

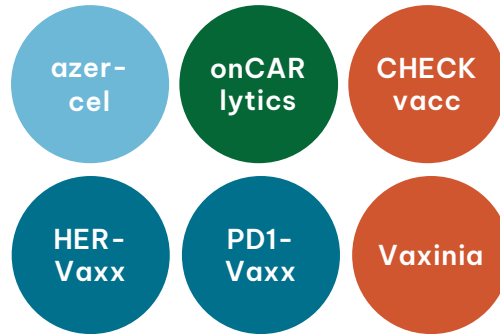
**Market Capitalisation**  
As at 27 September 2023

**A\$358M**

**Cash Position**

**A\$186M** (Pro-forma)

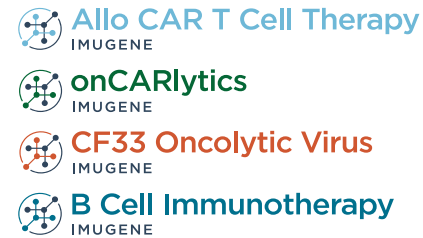
**6**  
**Unique Assets**



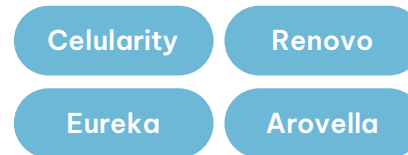
\*Multiple potential platform targets

CF33-CD20	PDL1-Vaxx
TIGIT-Vaxx	CTLA4-Vaxx
LAG3-Vaxx	TIM3-Vaxx

**4**  
**Platform Technologies**

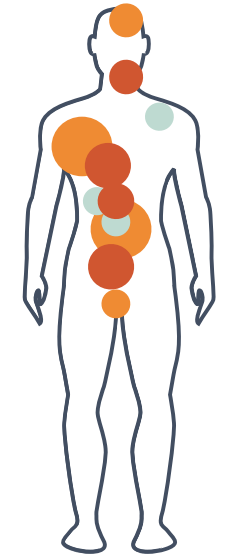


**4**  
**Scientific Collaborations**



**Disease Areas**

- Blood cancers
- Breast (TNBC)
- Lung (NSCLC)
- Gastric
- Gastroesophageal
- Colorectal (CRC)
- Melanoma
- Head and Neck
- Hepatocellular
- Pancreatic
- Glioblastoma (GBM)



**7 FDA IND**

**Clinical Studies**

	FDA IND
AZER-CEL Ph1b/2 registrational DLBCL	✓
IMPRINTER: Ph1 NSCLC	✓
CHECKvacc COH IST: Ph1 TNBC	✓
neoHERIZON: Ph2 Neoadjuvant Gastric Cancer	✓
nextHERIZON: Ph2 Metastatic Gastric Cancer	✓

	FDA IND
MAST: Ph1 Solid Tumors	✓
DOMINICA: Ph1 TNBC	✓
onCARlytics: Ph1 Solid Tumours	✓
neoPolemIST: Ph1 CRC	✓
HERIZON: Ph1b/2 First line Gastric Cancer	✓

**2**

**Supply Agreements**



# FOUR UNIQUE PLATFORMS MAXIMIZE OPPORTUNITIES IN CANCER

Treatments that can be combined with and enhance outcomes of existing standards of care.



**Allogeneic  
CAR T  
Cell Therapy**

**azer-cel**



**onCARlytics**

**onCARlytics**



**CF33  
Oncolytic Virus**

**CHECKvacc & VAXINIA**



**B Cell  
Immunotherapy**

**HER-Vaxx & PD1-Vaxx**

**AZER-CEL CD19  
ALLOGENEIC CAR T  
CELL THERAPY**



# EXECUTIVE SUMMARY

Imugene has licensed a near term potential registrational stage, off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to attack blood cancer. Imugene can also use this drug to combine with its existing onCAR19 to treat solid tumors.

The transaction includes:



Exclusive world-wide license to the **First in Class** product known as azer-cel with over **84 patients** treated in a Phase I trial, demonstrated safety and compelling efficacy **3 additional asset targets**



Encouraging FDA guidance and feedback on manufacturing for a potential **Fast to Market** PHASE 2 registration trial. **Potential for first FDA approved Allogeneic CAR T**



**Completed drug** material and manufacturing process

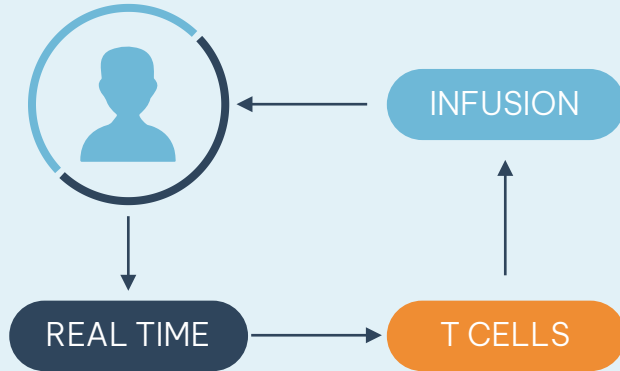


**Manufacturing facility** with a highly **technically** skilled and **specialised** work force

# THE FUTURE OF CELL THERAPY IS OFF THE SHELF

Patients shouldn't have to wait for treatment

## AUTOLOGOUS



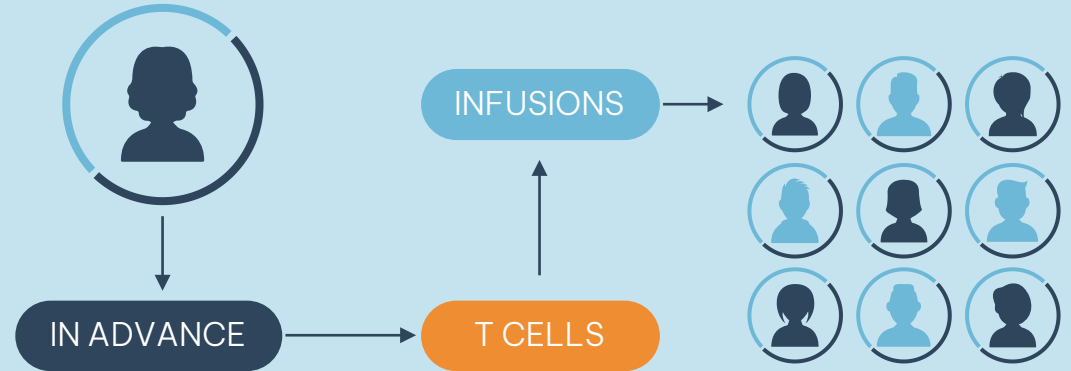
Limited patient access

Long and complex manufacturing process and wait time (requires leukapheresis and bridging is often required)

High manufacturing costs

Variable potency

## ALLOGENEIC



Broad patient access

Available on demand and off-the-shelf immediately (no leukapheresis and no bridging required)

More efficient and cost-effective manufacturing

Healthy donor cells engineered for potency and persistence

# TOTAL BODY OF EVIDENCE

Azer-cel has meaningful Clinical Activity across B Cell Malignancies

## 84 patients treated with azer-cel

61

Non-Hodgkin lymphoma (NHL)  
Patients

58% ORR<sup>1</sup>

41% CR<sup>2</sup>



23

B-Cell lymphoblastic  
leukaemia (B-ALL) Patients

61% ORR

61% CR/CRi

All Doses / All LD\* Regimens

1. ORR – Overall Response Rate

2. CR – Complete Response

\*lymphodepletion

Note: Based on Patients Evaluable for Efficacy



# AZER-CEL IS ACTIVE IN CAR T RELAPSED PATIENTS

Demonstrated high response rates and durability



Azer-cel has the potential to provide new standard of care for this high-risk population with unmet need

# CD19 AUTO CAR T RELAPSE MARKET IS LARGE AND GROWING



## ~85%

of patients continue to have CD19+ disease

In our prospective data, patients continue to have antigen positive disease



## 60-65%

of patients currently treated with auto CD19 CAR T will relapse (fail)<sup>2</sup>



## By 2025

Global CAR T relapse patient pool is expected to grow ~4x as auto CAR T drugs become the SOC in 2L+

Estimate total Global G8 markets to be ~18k patients per year<sup>3</sup>

Note: Retrospective Literature states that 12-28% of patients have antigen negative relapse (CD19-)

1. Precision Internal Clinical Data; 2. Estimated from ZUMA 1 and ZUMA 7 EFS rates; 3. G8 includes US, Japan, Canada and EU5 assuming equal access to CAR T therapies; market research, CancerMPact

# PHASE 2 TRIAL ASSUMPTIONS (POTENTIAL REGISTRATIONAL/TO MARKET)

Potential registrational study (FDA approval) to start upon completion of the Phase 1B study H2 2024

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Population: Auto CAR T failures in DLBCL patients

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Positive formal and informal FDA guidance on the potential registrational study

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~35+ sites in the U.S.: Phase 1B trial currently conducted at Dana Farber, Moffit, MDACC, COH, Karmanos, U Minnesota, Cornell, Columbia

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Drug product for Phase 1B confirmatory trial completed

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Drug material manufactured in North Carolina at our facility

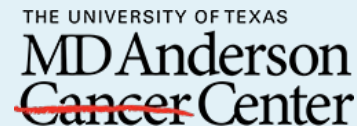


**Dana-Farber**  
Cancer Institute



Masonic Cancer Center

UNIVERSITY OF MINNESOTA



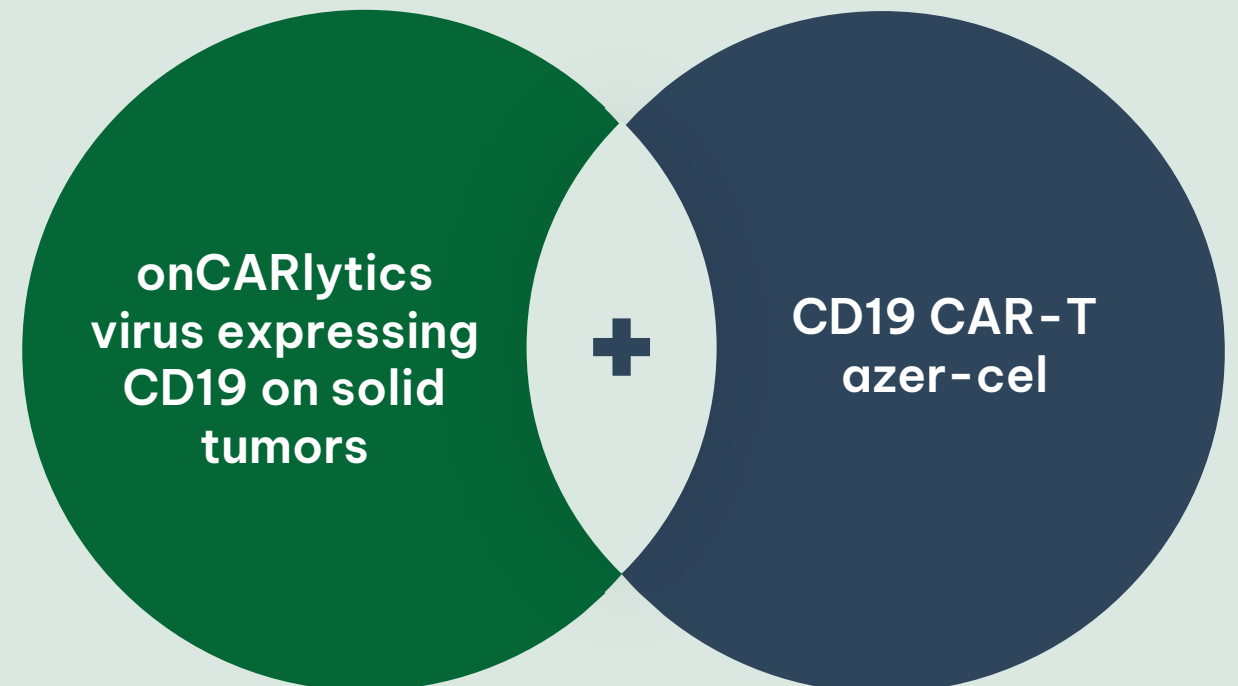
# AZER-CEL OFFERS ONCARLYTICS AN IN-HOUSE COMBINATION APPROACH FOR SOLID TUMOURS

Enables Imugene to progress its own combination solution in multiple solid tumour indications

Strengthen current development of onCARlytics by adding an in house off the shelf CD19 CAR T

Enables and boosts Imugene's footprint in the blood cancer and continued solid tumour oncology markets

## Combination treatment for solid tumours



# CMC & MANUFACTURING

Fully GMP compliant



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Manufacturing – 32,800 (17,300 manufacturing +15,500 expansion) sq ft facility in Durham, NC

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GMP compliant / 3rd party audits completed with no findings

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Turn-key solution ready for final registrational trial drug product supply

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Robust and validated process for 84 patients dosed to date (optimized along the way)

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Drug product for Phase 1B confirmatory trial completed

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Experts transitioning to Imugene for continuity of drug manufacturing

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# AZER-CEL VALUE INFLECTION POINTS EXPECTED IN THE NEXT 12-18 MONTHS

## Key Events

- Q3, 2023 FDA Process 1.2 Drug Lot Release (validating Phase 2 registrational study drug)
- Q3, 2023 FDA IND transferred to Imugene
- Q4, 2023 First Patient in for Phase 1b Expansion
- Q2, 2024 Patient recruitment status and completion of enrolment of Phase 1b
- Q4, 2024 Phase 1b readout and FDA feedback on registrational study
- Q4, 2024 Status on Site approval activity
- Q1, 2025 First Patient Dosed on registrational Study

2023

2024

2025

Q3, 2023  
FDA drug lot  
release

Q4, 2023  
FPI on Ph1b  
Expansion

Q2, 2024  
Phase 1b  
completed  
enrollment

Q4, 2024  
FDA feedback on  
registrational study

Q1, 2025  
First Patient In  
for registrational  
Study

Q3, 2023  
FDA IND  
Transferred to  
Imugen

Q1, 2024  
Enrollment Status  
in Phase 1b

Q3, 2024  
Phase 1b readout

Q4, 2024  
First Site  
Activated

# WHY IMUGENE?



Diverse asset portfolio with multiple shots on goal across four novel platforms



Experienced Management team\*



Ongoing clinical trials in diverse solid tumours and blood cancers with multiple value inflection points



Robust cash runway with funding through key milestones

\*Addition of Dr. Paul Woodard, Dr. John Byon and Dr. Brad Glover

# MULTIPLE VALUE REALISATION PATHWAYS



Company  
acquisition



Partner with  
big pharma



License  
technologies  
separately



Develop /  
Commercialise  
independently





**IMUGENE**

Developing Cancer Immunotherapies

ASX:IMU

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[imugene.com](http://imugene.com)

