



# IMUGENE

Developing Cancer Immunotherapies

ASX:IMU

## Leading Innovation in Cancer Treatment

September 2024

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**Imugene is a clinical stage cancer company developing three drug products in CAR T cell therapy and oncolytic viruses.**

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# Investment Highlights

**Market Capitalisation**

As of 2 September 2024

**A\$500M**

**Cash Position**

As of 30 June 2024

**A\$93.1M** (Pro-forma)

## 4 PLATFORM TECHNOLOGIES

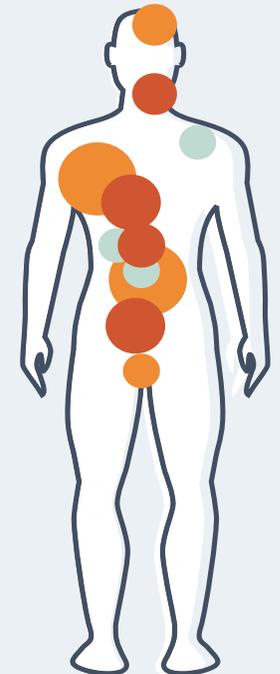
Allo CAR T Cell Therapy  
CF33 Oncolytic Virus  
onCARlytics  
B Cell Immunotherapy

**LONG-  
LIFE  
PATENT  
PORTFOLIO**



## DISEASE AREAS

Blood cancers  
Breast (TNBC)  
Lung (NSCLC)  
Gastric  
Gastroesophageal  
Colorectal (CRC)  
Melanoma  
Head and Neck  
Cholangiocarcinoma  
Pancreatic  
Bladder



## 4 CLINICAL STUDIES

> 200 cancer patients dosed

azer-cel Ph1b DLBCL (FDA IND)  
VAXINIA: Ph1 Solid Tumours (FDA IND)  
onCARlytics: Ph1 Solid Tumours (FDA IND)  
PD1-Vaxx: Ph2 neoPOLEM



**Allo CAR T Cell Therapy**  
IMUGENE

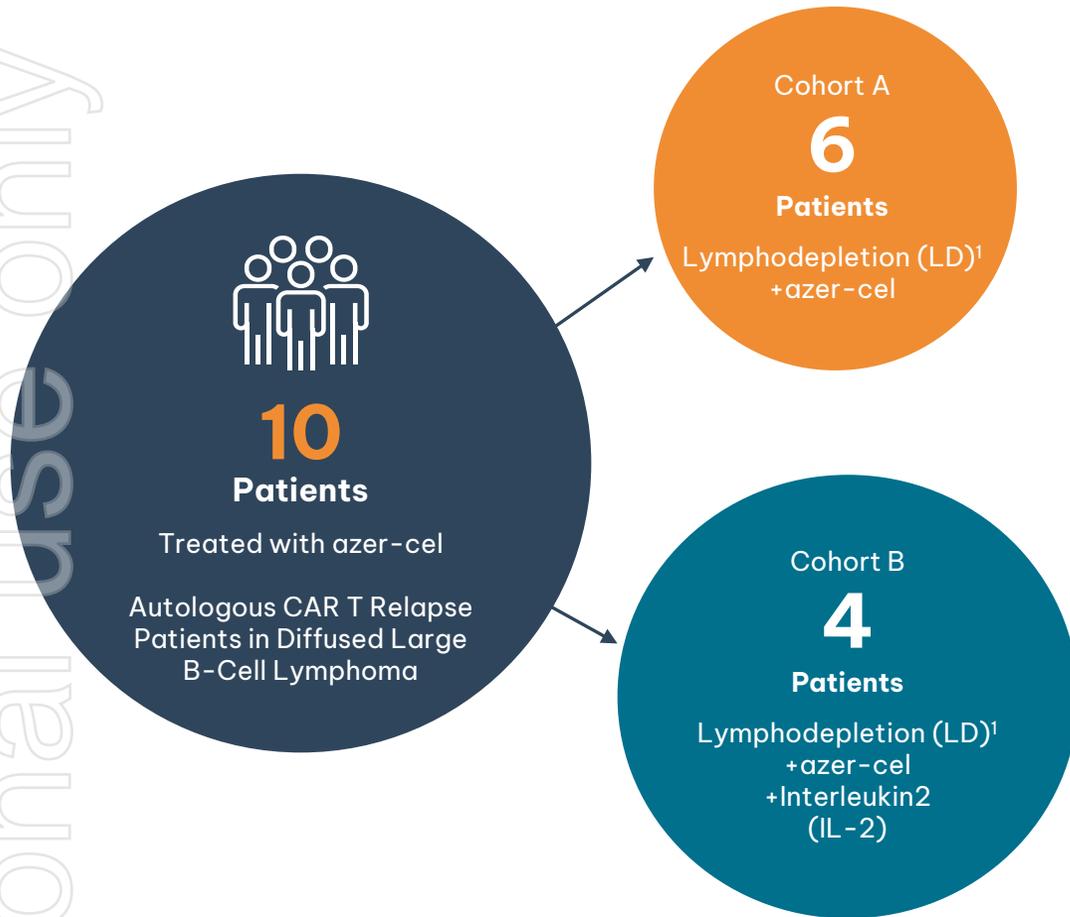
# AZER-CEL CD19 CAR T FOR BLOOD CANCER



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# 67% CR Rates Observed in Phase 1b Cohort B



<sup>1</sup>Lymphodepletion(LD)/chemotherapy: Aug Cy: Flu 30mg/m2 x 3d, Cy 750mg/m2 x 3d

	Evaluable patients: Cohort A+B (N=9)	Evaluable patients: Cohort A (N=6)	Evaluable patients: Cohort B (N=3)*
Overall Response Rate %	4 (44%)	2 (33%)	2 (67%)
Complete Response %	3 (33%)	1 (17%)	2 (67%)
Best Durability (Time of response)		<60 days	>120 days on going

\*One patient currently SD, probable pseudoprogression; assessment of response at follow up scans.

## Cohort B Results

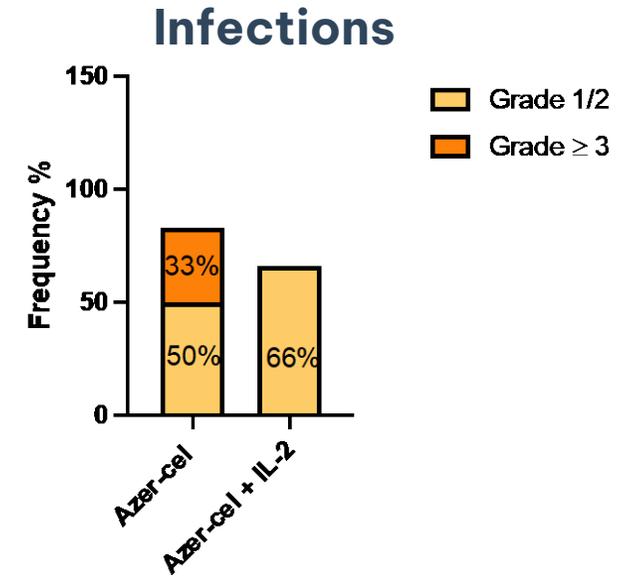
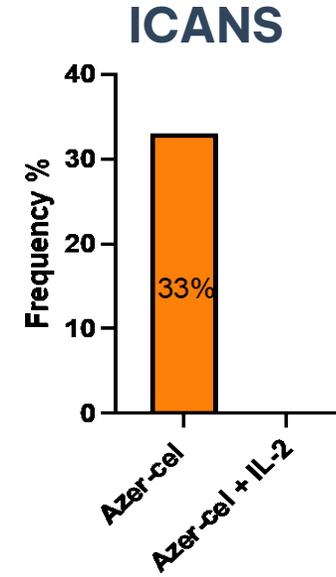
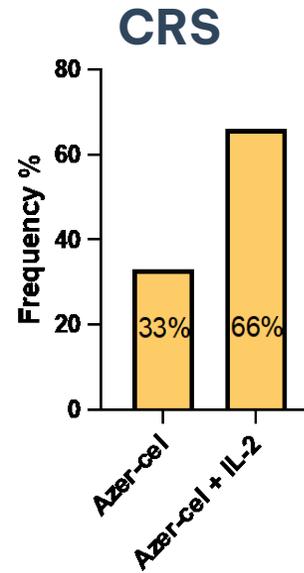
- The first 2 patients treated achieved a complete response (CR), 1 patient had stable disease (SD)\*, 1 patient yet to be evaluated
- Responses were seen in patients who failed multiple prior treatments, including autologous CAR T therapies
- Phase 1b trial continues to enroll patients into Cohort B across 15 leading cancer centres in the U.S. including, Columbia University, University of Minnesota, Emory and Moffitt Cancer Centres and plans are ongoing to open up to 5 sites in Australia.

# Azer-cel has a Manageable Safety Profile

No evidence of GVHD or GR.  $\geq 3$  CRS

## Safety Profile

- Manageable CRS occurs within first week but resolves quickly
- In Cohort B, no ICANS has been observed to date
- While infections have occurred, the majority have been Grade 1 or 2



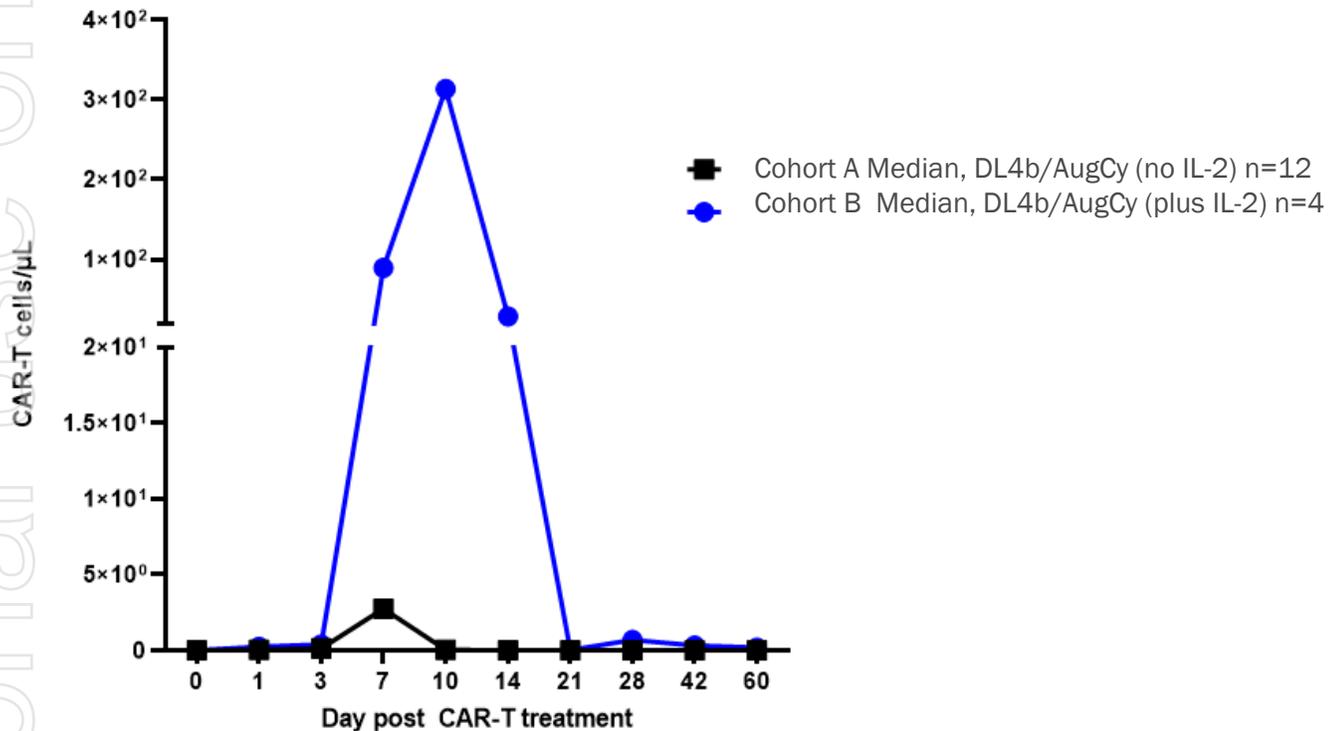
		Cohort A azer-cel N=6	Cohort B azer-cel + IL-2 N=3*
CRS	Time to Onset, Median	0.5 days (0-1)	8.5 days (3-14)
	Duration, Median	1.5 days (1-2)	1 day
ICANS	Time to Onset, Median	4.5 days (4-5)	-
	Duration, Median	3.5 days (3-4)	-

CRS: Cytokine release syndrome  
ICANS: Immune Effector Cell-Associated Neurotoxicity Syndrome

\*Data pending for 4<sup>th</sup> patient    Data extract Aug2024

# Addition of IL-2 to Dosing Regimen Enhances CAR-T Expansion and Possibly Efficacy In *Vivo*

CAR T Pharmacokinetic (PK) profile for DL4b/AugCy subjects (+/- IL-2)



## IL-2 effect on azer-cel persistence

- Limited expansion seen *in vivo* in the absence of IL-2
- Higher C-Max in patients with IL-2
- Addition of IL-2 increases CAR-T persistence out to at least 60 days
- Increased azer-cel persistence likely correlates with therapeutic response

\*One subject still within D28 assessment window

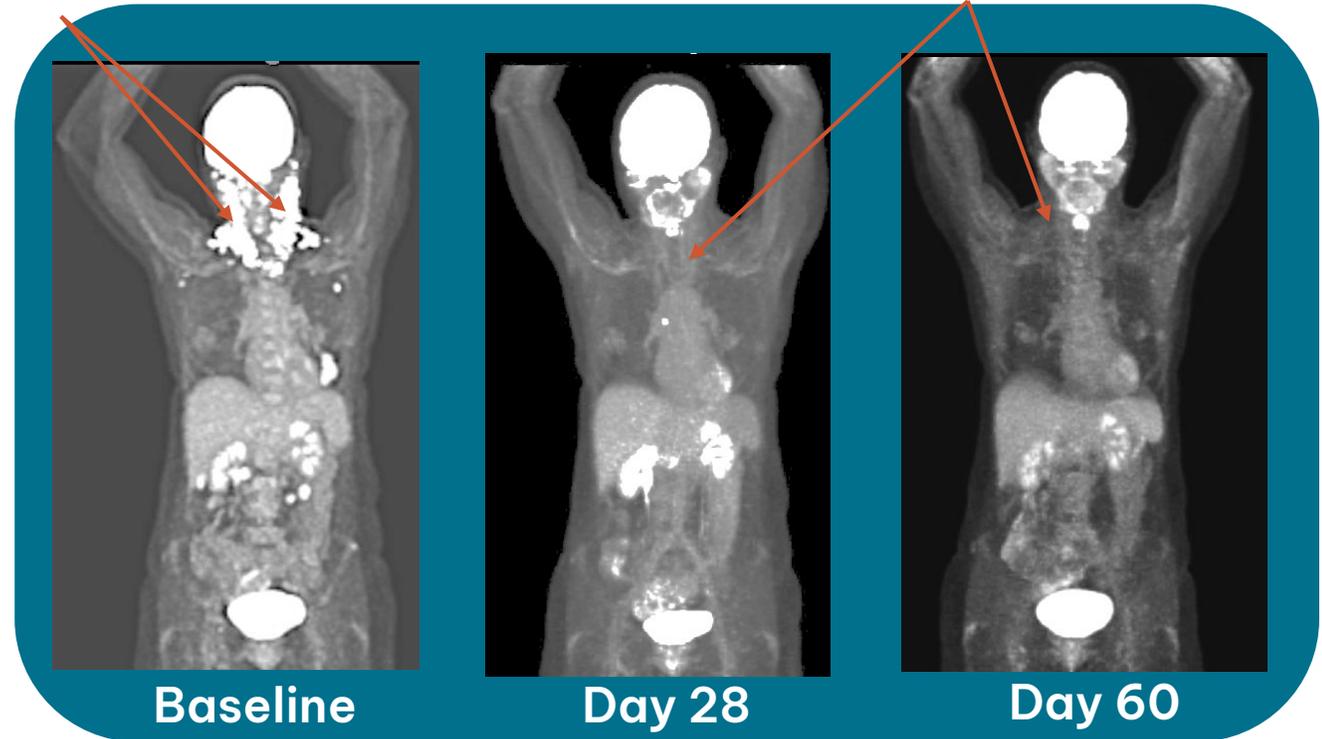
# Representative PET Scans of Complete Responses

## Subject Treatment Summary

- 60 yo female, first diagnosed with DLBCL, stage IV in Apr 2012. Treated at University of Minnesota (UMN).
- Prior to azer-cel, **patient failed 5 prior lines of therapy**; R-CHOP x 6; Rituxan, RICE x 2 followed by BEAM + auto HCT and maintenance therapy (Rituximab + ADAM17 inhibitor); **Yescarta/Flu/Cy**; Loncastuximab / ibrutinib
- Azer-cel treatment regimen
  - Cohort B: Augmented Cy conditioning regimen (750 mg/m<sup>2</sup>/d (3d)  
Cyclophosphamide i.v. + 30 mg/m<sup>2</sup>/d (3d)  
fludarabine iv) + low dose SC IL-2
- **Notable Safety Events – No CRS/ICANS**
- Response – PR @ D28, CR @ D60 & D90

Tumour

Tumour-free



# Azer-cel Clinical Development Strategy



## Milestones:

- Preliminary early DLBCL Phase 1b data update
- Diffused Large B-Cell Lymphoma (DLBCL) Phase 1b interim data update
- Target regulatory meeting with FDA
- FPI in registration Phase 2/3 trial

# Experienced Leadership Team has brought > 17 FDA Approved Drugs to Market



**Leslie Chong**  
Chief Executive Officer  
& Managing Director

**Genentech**  
*A Member of the Roche Group*

**EXELIXIS**

**Roche**

**gsk**



**Dr. Paul Woodard, MD**  
Chief Medical Officer

**IMMUNE-ONC**  
therapeutics

**Bellicum**

**Genentech**  
*A Member of the Roche Group*

**AMGEN**

**EXELIXIS**



**Dr Bradley Glover, PhD  
MBA**  
Chief Operating Officer

**Kite**  
*A GILEAD Company*

**Genentech**  
*A Member of the Roche Group*

**Roche**

**celularity**

**illumina**



**Ursula McCurry**  
Chief Clinical  
Operations Officer

**AMUNIX**

**Genentech**  
*A Member of the Roche Group*

**EXELIXIS**

**SuperGen**



**Dr. John Byon, MD, PhD**  
Senior VP of Clinical  
Development

**Fcte**  
THERAPEUTICS

**Lyell**

**JUNO**  
THERAPEUTICS

**Genentech**  
*A Member of the Roche Group*



**Dr Monil Shah**  
Head of Business  
Development  
(consultant)

**WindMIL**  
THERAPEUTICS

**Bristol Myers Squibb**

**AMGEN**

**NOVARTIS**

**Celgene**

# Expected Upcoming Key Catalysts

## H2 2024

- **azer-cel:** Preliminary early DLBCL Phase 1b data update
- **onCARlytics:** FPI IT Combo Cohort 1
- **onCARlytics:** Early IT and/or IV Combo data
- **VAXINIA:** Second indication trial open
- **VAXINIA:** Preliminary early Bile Tract expansion trial update

## 2025-Beyond

- **azer-cel:** DLBCL Phase 1b interim data update
- **azer-cel:** Target regulatory meeting with FDA
- **azer-cel:** FPI in registration Phase 2/3 study
- **azer-cel:** Expansion into additional blood cancers (Phase 1b Expansion Cohort)
- **onCARlytics:** Data update and trial expansion
- **onCARlytics:** Optimal Biological Dose (OBD) Established
- **onCARlytics + azer-cel** FDA IND and FPI in solid tumours
- **onCARlytics:** Phase 2 FPI
- **VAXINIA:** Optimal Biological Dose Established for IT and/or IV monotherapy
- **VAXINIA:** Phase 2 Study Open
- **VAXINIA:** Phase 2 FPI
- **VAXINIA:** IP & IA Phase 1 FPIs

### Key

**FPI:** First Patient In

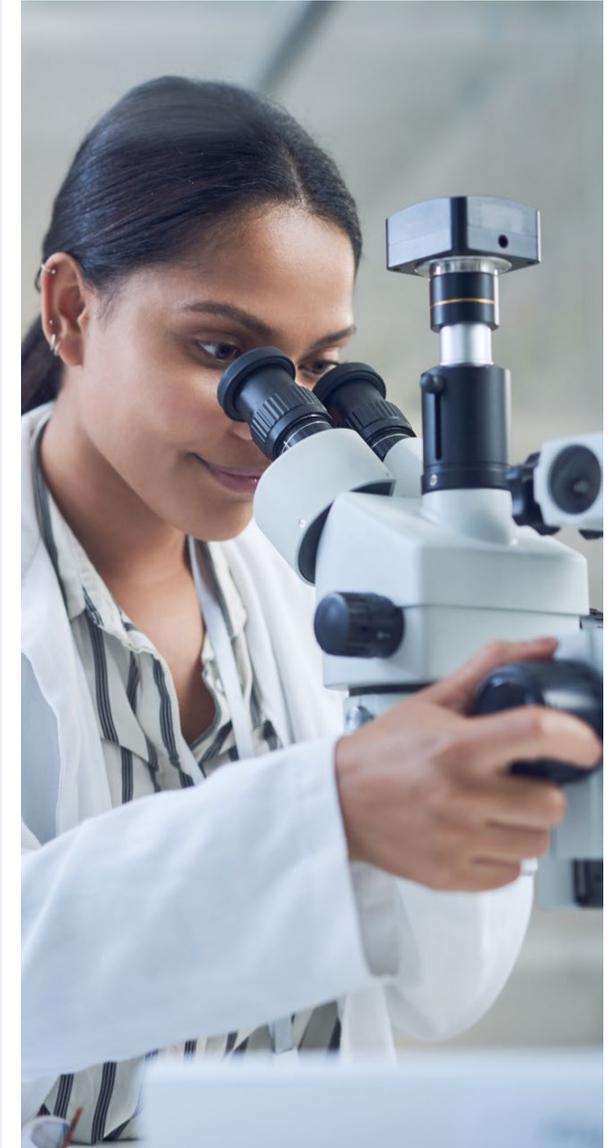
**Combo:** Combination Therapy

**Mono:** Monotherapy

**DLBCL:** Diffuse Large B-Cell Lymphoma (Blood Cancer)

**IA:** Intra-arterial, **IP:** Intraperitoneal

**IT:** Intratumoural, **IV:** Intravenous



# Investment Highlights



Robust platform technologies supporting 4 clinical trials with >200 patients treated to date in US and Australia, all under FDA INDs

Novel platforms in immuno-oncology, cell therapy (CAR Ts) and cancer viruses



Strong cash position of \$93 million as at June 2024



Clinical data readouts over next 12 months



Deeply experienced cancer drug development management team



Robust and broad patent portfolio



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Developing Cancer Immunotherapies

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