



# IMUGENE

Developing Cancer Immunotherapies

**ASX: IMU**

## DEVELOPING CANCER IMMUNOTHERAPIES

January, 2024

JP Morgan



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# INVESTMENT HIGHLIGHTS

## MARKET CAPITALISATION

5 January 2024

A\$860M  
US\$576M



## CASH AS OF

30 September 2023

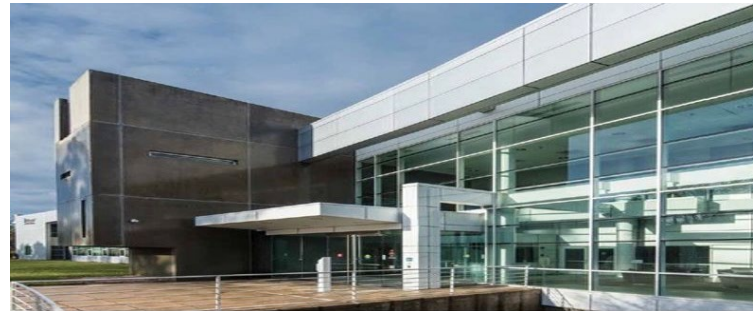
A\$163M  
US\$109M



## 4 PLATFORM TECHNOLOGIES

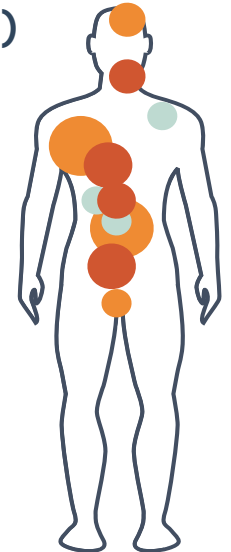
Allo CAR T Cell Therapy  
CF33 Oncolytic Virus  
onCARlytics  
B Cell Immunotherapy

## IN-HOUSE GMP CELL THERAPY MANUFACTURING FACILITIES



## DISEASE AREAS

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



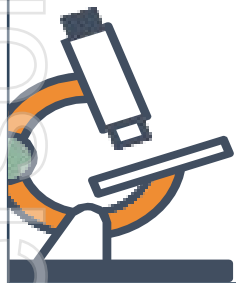
azer-cel Ph1b DLBCL (FDA IND)

VAXINIA: Ph1 Solid Tumors (FDA IND)

onCARlytics: Ph1 Solid Tumors (FDA IND)

HER-Vaxx: Ph2 HER2+ Metastatic GC (FDA IND)

PD1-Vaxx: Ph2 neoPOLEM



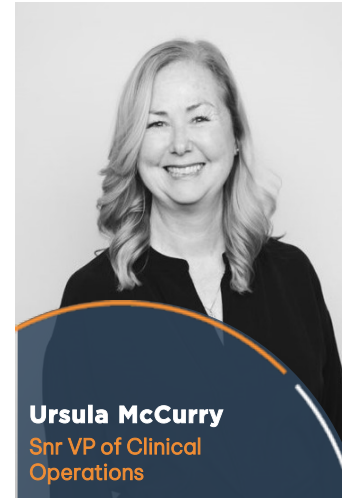
## 5 CLINICAL STUDIES

## LONG-LIFE PATENT PORTFOLIO



# IMUGENE CLINICAL EXECUTIVE TEAM

Over 150 years of combined experience in Clinical Development  
13 FDA Approved Drugs to market



# CELL THERAPY AND ONCOLYTIC VIRUS PLATFORMS DELIVER INNOVATIVE AND POTENT THERAPIES TO PATIENTS

Allogeneic  
CAR T  
Cell Therapy

**azer-cel**

CF33  
Oncolytic Virus  
(OV) Therapy

**VAXINIA**

OnCARlytics  
CF33-CD19  
OV Therapy

**onCARlytics**

B Cell  
Immunotherapy

**HER-Vaxx  
& PD1-Vaxx**

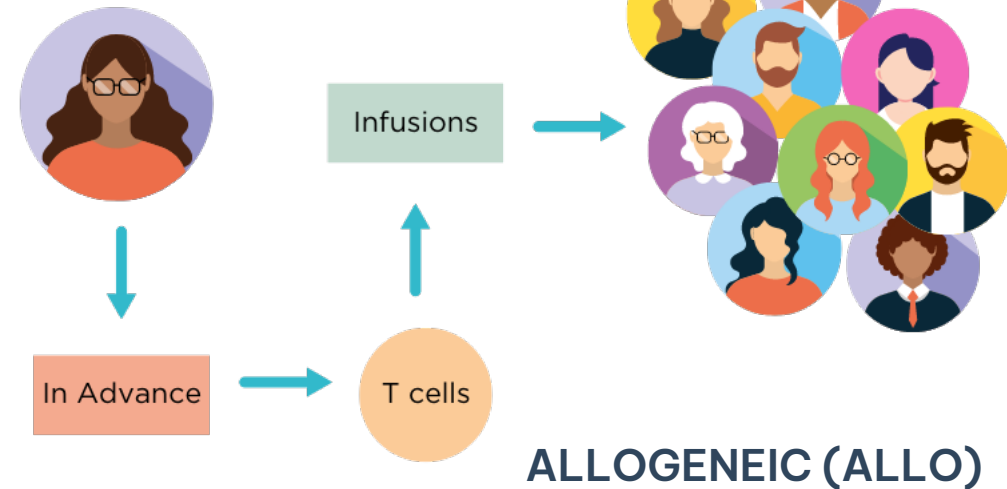
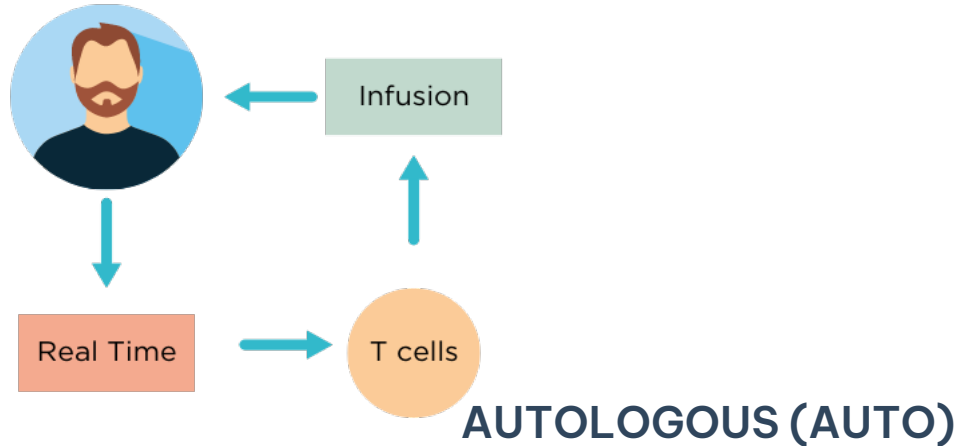
# AZER-CEL CD19 ALLOGENEIC CAR T CELL THERAPY

ersonal use only



# THE FUTURE OF CELL THERAPY IS OFF THE SHELF (ALLOGENEIC) CAR T

Patients shouldn't have to wait for treatment



- Auto CAR Ts are made from the patient's own T-cells cells. Limited patient access (highly personalized)
- Long and complex manufacturing process and wait time (requires leukapheresis\* and often extra chemotherapy treatment until cells are ready)
- High manufacturing costs
- Variable potency due to health of patients own T cells

- Allo CAR Ts are made from a universal donor. Broad patient access (multiple patients from a single batch)
- Can be mass produced, available on demand and off-the-shelf immediately (no leukapheresis\* and no bridging treatment required). **Ready when you need them.**
- More efficient and cost-effective manufacturing
- Healthy donor cells engineered for potency and persistence

\*Leukapheresis is a process where your blood passes through a machine that takes out the white blood cells and returns all the other blood cells and plasma back into the bloodstream

# AZER-CEL HAS MEANINGFUL CLINICAL ACTIVITY IN 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 HAS THE POTENTIAL TO BE A NEW STANDARD OF CARE

High response rates and durability

84 blood cancer patients treated with azer-cel: 61 patients with Non-Hodgkin lymphoma (NHL); 23 patients with B-Cell acute lymphoblastic leukaemia (B-ALL)

Across All Subjects

All Doses /  
All LD\* Regimens

61  
NHL Patients

18  
Patients

CAR T Relapse Pts

83% Overall  
Response Rate

61% Complete Response Rate  
55% Duration of Response  $\geq$  6-months<sup>1</sup>

\*Median duration in  $\geq$  6-month responders is 431 days

Note: Based on Patients Evaluable for Efficacy

<sup>1</sup>N=11 patients evaluable for > 6 months duration on response, 6 durable responders past 6 months or longer with 431 (> 1 year) median days on response; DoR measured from DO

\*lymphodepletion

# DIFFUSE LARGE B-CELL LYMPHOMA IS AN AGGRESSIVE TYPE OF NON-HODGKIN LYMPHOMA

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- B-cells become cancerous and grow uncontrollably
- Most common type of non-Hodgkin lymphoma (80,500 cases/year)
- Most common in people over 50
- Fast growing and needs rapid treatment
- Relapsed/refractory DLBCL has a high unmet medical need

# HOW IS DLBCL TREATED TODAY?

~30,000 New Cases in the U.S. Annually (2020 – SEER)

## 1st line

R-CHOP (Combination  
Chemotherapy\*)

~60% of patients are cured  
with R-CHOP (Combination  
Chemotherapy\*)

## 2nd line

High dose chemotherapy  
w/ stem cell transplant.  
Auto CD19 CAR T cell  
therapies: Yescarta  
(Gilead), Kymriah  
(Novartis), Breyanzi (BMS)

~6,000 patients become  
eligible  
for 2nd line; 20-25% of  
these patients are cured

## 3rd line

No standard of care – for  
auto CAR T relapse  
patients

60-65% of patients treated  
with  
auto CD19 CAR T relapse

Pool of post CAR T patients  
needing next line therapy  
expected to grow as auto  
CAR T therapies continue to  
penetrate in earlier lines of  
therapy

\*Rituximab, Cyclophosphamide, Doxorubicin Hydrochloride (Hydroxydaunomycin), Vincristine Sulfate (Oncovin), Prednisone

# CD19 AUTOLOGOUS CAR T RELAPSE MARKET IS LARGE AND GROWING



**~85%**

of patients continue to express CD19 the target of azer-cel

In our prospective data, patients continue to have antigen positive disease<sup>1</sup>



**60-65%**

of patients currently treated with autologous CD19 CAR T will relapse<sup>2</sup>



**By 2025**

Global CAR T relapse patient pool is expected to grow ~4x as autologous CAR T drugs become the SOC

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

**Azer-cel potential blockbuster sales of ~\$2.5B<sup>4</sup> per annum in DLBCL CAR T relapsed patients**

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, CancerMPac
4. TAM: total addressable market is total number of treatable patients x price at 100% market share

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

Potential registrational study (FDA approval) to start upon completion of the Phase 1B study H2 2024. Dependent on acceptable CR rate and durability of CR

Population: Relapse after auto-CART in DLBCL patients

Positive FDA guidance on the potential registrational study

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

Drug product for Phase 1B confirmatory trial completed

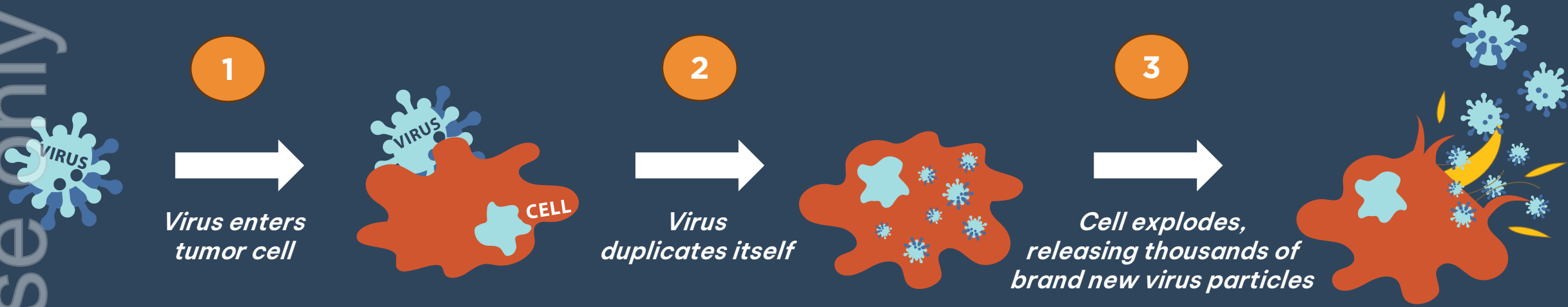
Drug material manufactured in North Carolina at our facility



# CF33 ONCOLYTIC VIRUS

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# CF33 CAN INFECT AND SELECTIVELY KILL TUMOR CELLS



## Engineering enhancements

- Infect and kill only cancer cells
- Carry payloads to increase killing

## Multiple ways to kill cancer cells

- Direct killing
- Activation of immune cells to kill cancer cells
- Priming the tumor environment to enhance immune response<sup>1</sup>

## Precedent for approval

- Tvec approved in the United States for skin cancer (2015)
- Oncorine approved in China for head and neck cancer (2005)
- Delytact approved in Japan for brain cancer (2021)

TME: tumor microenvironment  
1: Ribas et al., Cell 170:1109, 2017

# OUR PHASE 1 MAST STUDY HAS ENROLLED WELL



## Dose Administration (Parallel Groups)

n=52-100 patients

IT

### IT Administration

Metastatic and Advanced Solid Tumors

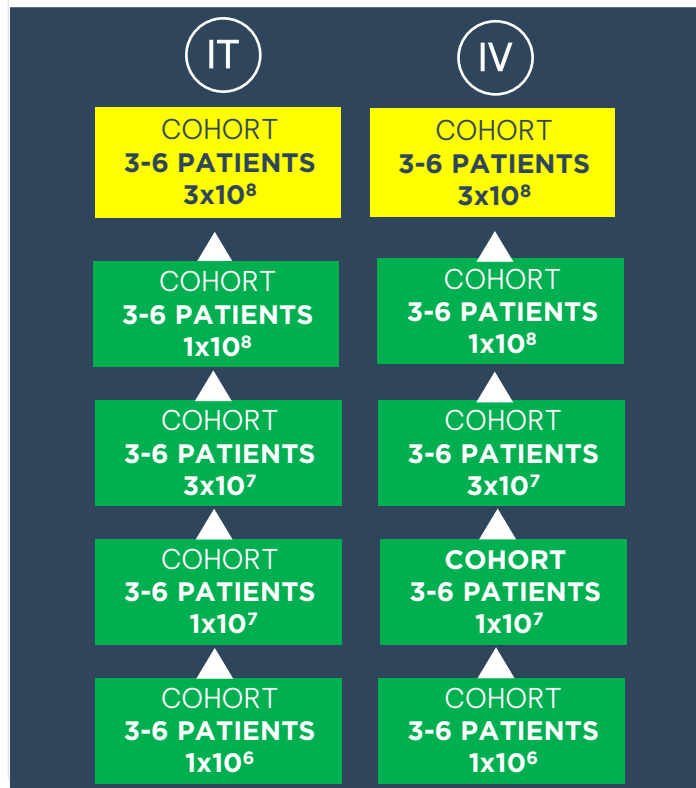
IV

### IV Administration

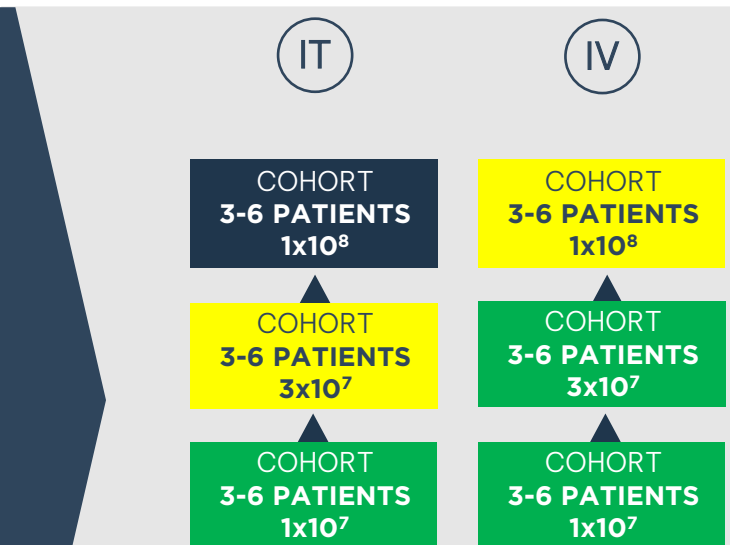
Metastatic and Advanced Solid Tumors

Site Location: USA, AUS

## VAXINIA Monotherapy Dose Escalation



## VAXINIA + Pembrolizumab Combination Dose Escalation



## Cohort Expansion

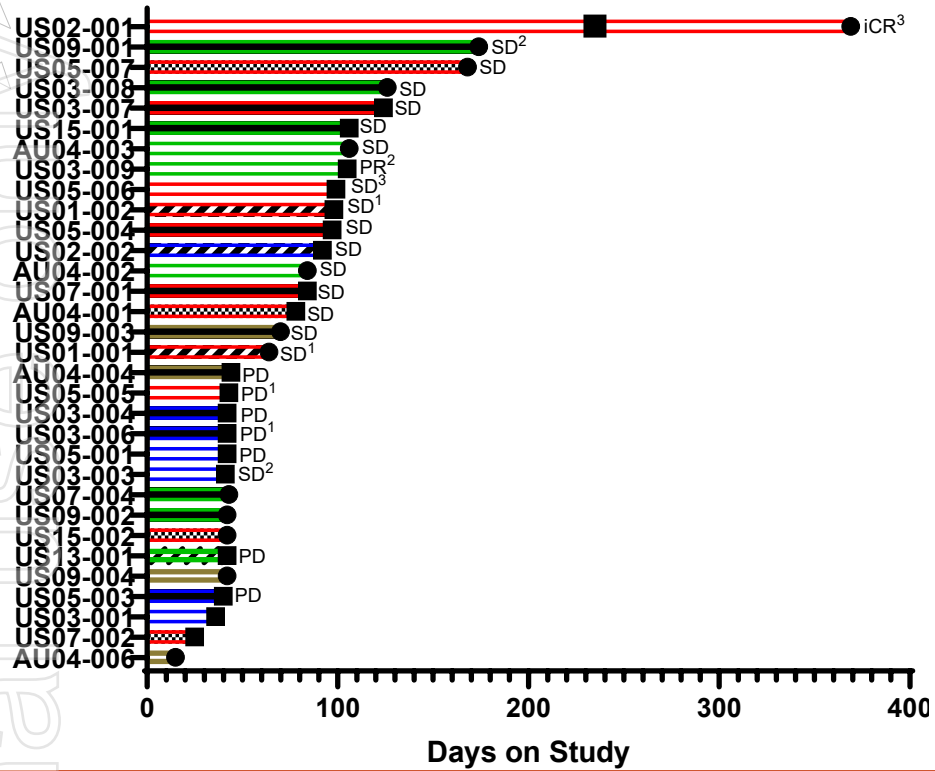
Expansion Cohorts (N=20)

Tumor Types of Interest:

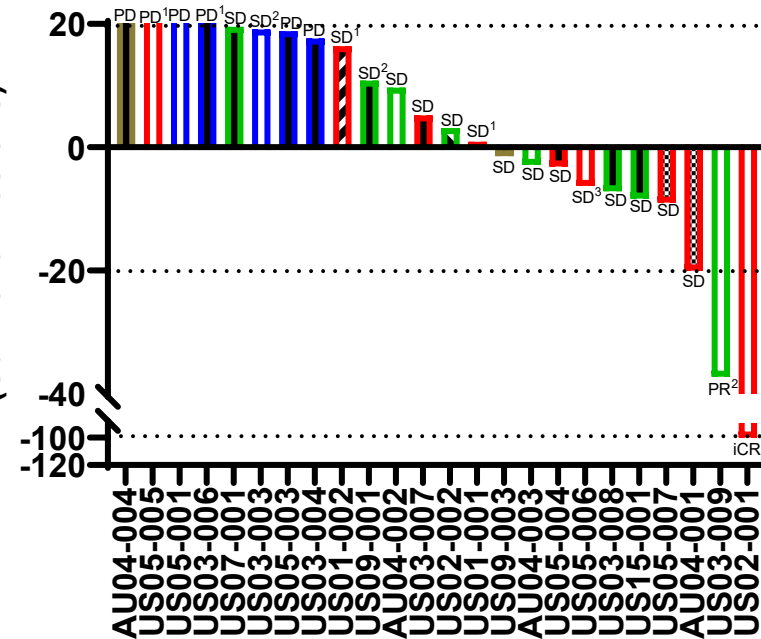
i.e. Cholangiocarcinoma (IT will occur first)



# CF33 MAST STUDY SHOW DURABLE RESPONSES IN HEAVILY PRE-TREATED POPULATION



Best Change in Tumor Response (Sum of all lesions)



● On Study  
■ Off Treatment

■ IV Admin. Without Pembrolizumab  
□ IT Admin. Without Pembrolizumab  
▨ IV Admin. With Pembrolizumab  
▩ IT Admin. With Pembrolizumab

Best viral replication detected by SPECT:  
<sup>1</sup>Mild  
<sup>2</sup>Moderate  
<sup>3</sup>Intense

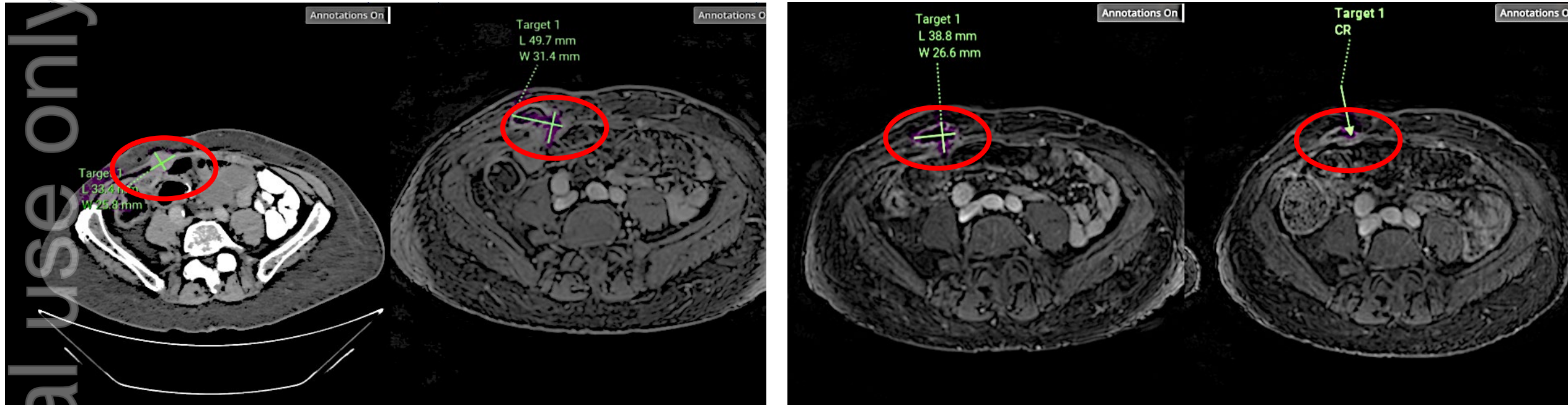
△ Biliary tract malignancies

Dose cohort:  
 PFU:  $1 \times 10^6$   
 PFU:  $1 \times 10^7$   
 PFU:  $3 \times 10^7$   
 PFU:  $1 \times 10^8$

- 32 heavily pretreated patients enrolled to date (24 evaluable to date)<sup>1</sup>
- Most patients had control of their disease
- At higher doses patients achieved significant and durable reduction in their tumor burden

# TURNING COLD TUMORS HOT

Complete Remission after Pseudoprogession (immune activity) in a Monotherapy patient with a cold tumor (bile duct cancer)



**Baseline scan**  
Start of the Study

**Second scan**  
Pseudoprogession  
(Tumour looks to have grown due to immune activity)

**Third scan**  
Decreased size

**Fourth scan**  
Complete Remission

This patient had received 3 prior lines of chemotherapy and was PD-L1 negative with no response prior to CF33

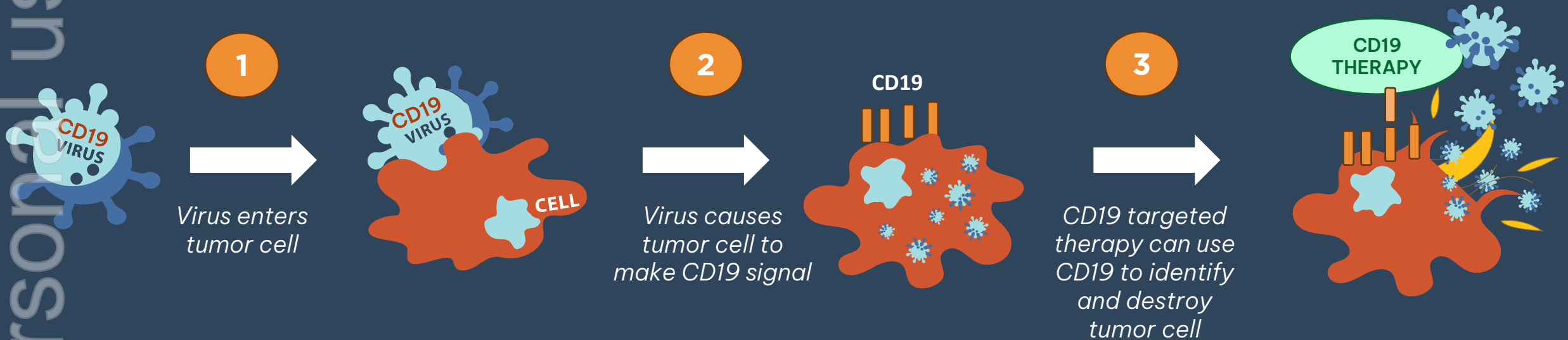
# ONCARLYTICS FOR SOLID TUMORS



# VARIETY OF APPROVED CD19 DRUGS ONLY FOR BLOOD CANCERS

- Many blood cancers such as leukemia and lymphoma have a common protein, called CD19, on the surface of their cells
- When you modify a patient's T Cells to "see" the CD19 signal, the T cell becomes laser focused on only targeting CD19, and ignores the patient's healthy cells

- Solid cancers like breast, lung, gastric, colon, etc. don't have a common target such as CD19, on their cell surface
- The holy grail in CAR T therapy is to find a CAR T which works in solid tumors (90% of cancer market)
- Imugene's onCARlytics technology seeks to overcome this challenge in solid cancers

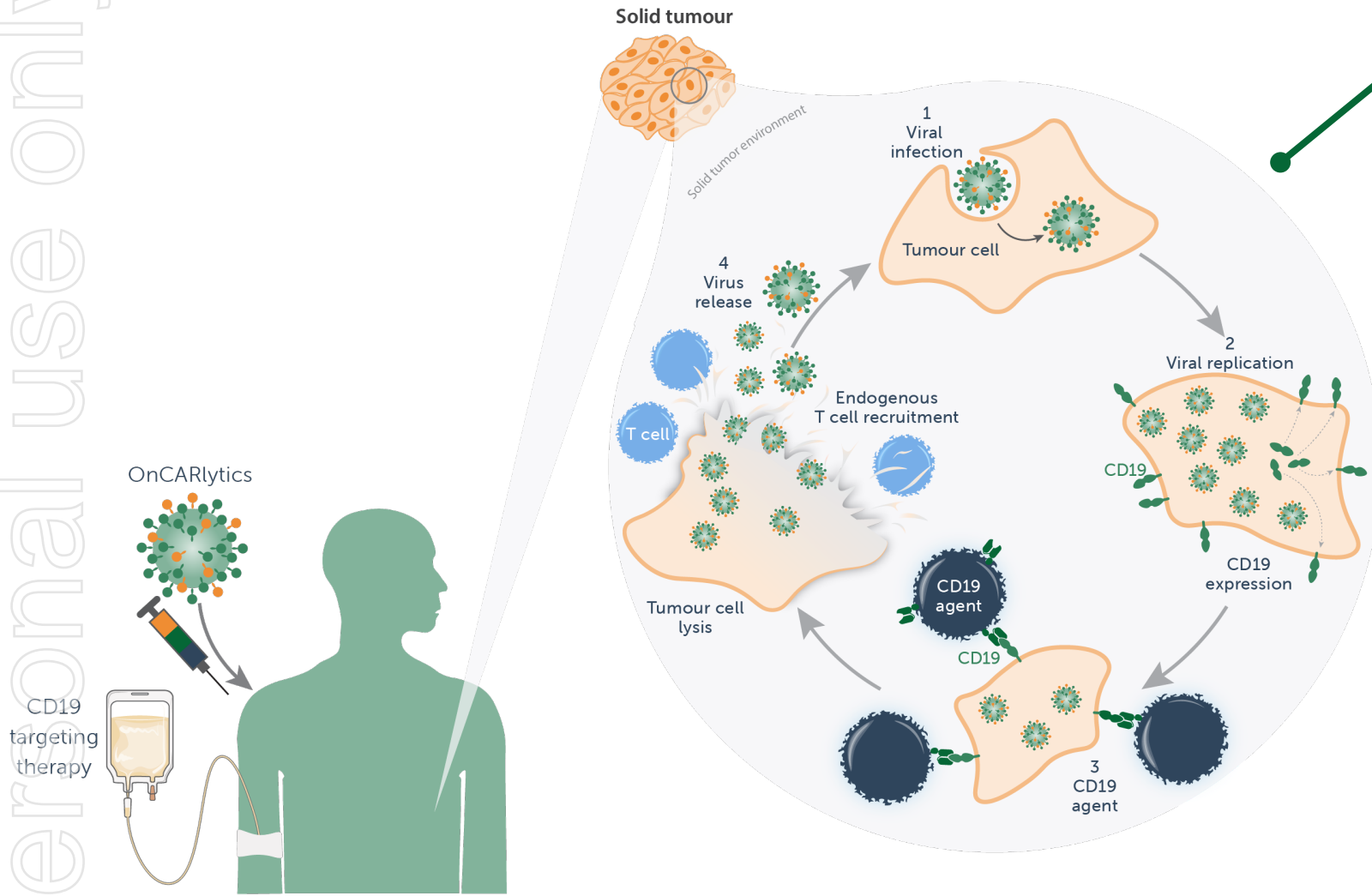


# MECHANISM OF ACTION: HOW DOES IT WORK?

*onCARlytics makes solid tumors “seen” by CD19 targeting therapies*

1. OnCARlytics infects Tumor cells
2. Virus replication and production of CF33-CD19 on the cell surface enabling CD19 cell targeting
3. Tumor cell lysis leads to viral particle release and the combination promotes endogenous immune cell recruitment to Tumors
4. Released viral particles re-initiate virus infection of surrounding Tumor cells.

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# PHASE 1 OASIS STUDY

## Combination treatment for solid tumors

onCARlytics virus expressing CD19 on solid tumors



CD19 Bispecific Blinatumomab



- The Phase 1 study is designed to treat with onCARlytics (CF33-CD19) alone, or in combination with Blinatumomab (bispecific antibody targeting CD19) and either dosed intravenously (IV) or intratumorally (IT) in metastatic advanced patients across multiple solid tumors
- First patient enrolled (ovarian cancer) at City of Hope in October 2023
- Phase 1 planned for ~10 sites in the U.S.
- Many CD19 approved drugs which could become preferred partners to combine with onCARlytics (~90% of cancer)

# VARIETY OF APPROVED THERAPIES AVAILABLE FOR COMBINATION WITH ONCARLYTICS

onCARlytics can become the preferred partner for CD19 therapies in solid tumors (~90% of cancer market)

## Combination Opportunities

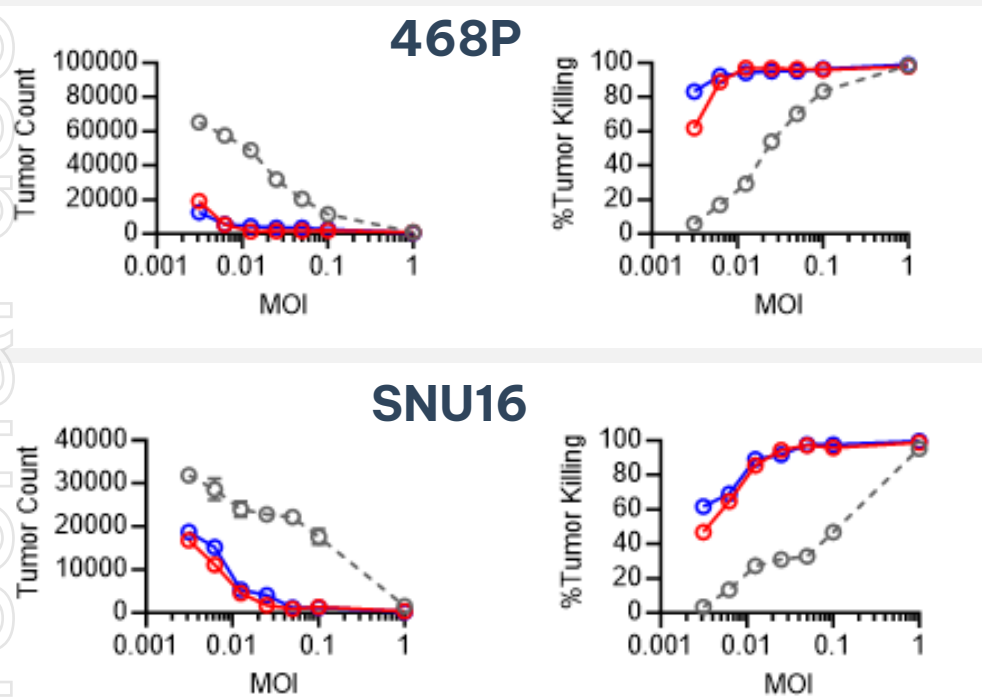
- Azer-cel (allo CD19 CAR T)
- Autologous CD19 CARTs
- Bispecific antibodies targeting CD19
- Antibody-drug Conjugates (ADC)
- Monoclonal Antibodies (MABs)

COMPANY	FIRST FDA APPROVAL	TARGET	APPROVED CANCERS
KYMRIAH <sup>®</sup> (tisagenlecleucel)  NOVARTIS	2017	CD19 Auto CAR T	B-ALL, DLBCL
YESCARTA <sup>®</sup> (axicabtagene ciloleucel)  Kite A GILEAD Company	2017	CD19 Auto CAR T	DLBCL, R/R FL
TECARTUS <sup>®</sup> (brexucabtagene autoleucel)  Kite A GILEAD Company	2020	CD19 Auto CAR T	R/R MCL
Breyanzi <sup>®</sup> (lisocabtagene maraleucel)  Bristol Myers Squibb <sup>®</sup>	2021	CD19 Auto CAR T	DLBCL
MONJUVI <sup>®</sup> (tafasitamab-cxix) 200mg for injection, for intravenous use  morphosys	2020	CD19 Monoclonal Antibodies (MABs)	DLBCL
Uplizna <sup>®</sup> (inebilizumab-cdon)  HORIZON	2020	CD19 MABs	NMOSD
BLINCYTO <sup>®</sup> (blinatumomab) for injection, 25 mg single dose vial  AMGEN	2014	CD19-CD3 Bispecific MABs	ALL
Zynlonta <sup>®</sup> (loncastuximab tesine-lpyl) for injection, for intravenous use • 150mg  ADC THERAPEUTICS	2021	CD19 Antibody-drug conjugate (ADC)	B-Cell Lymphoma

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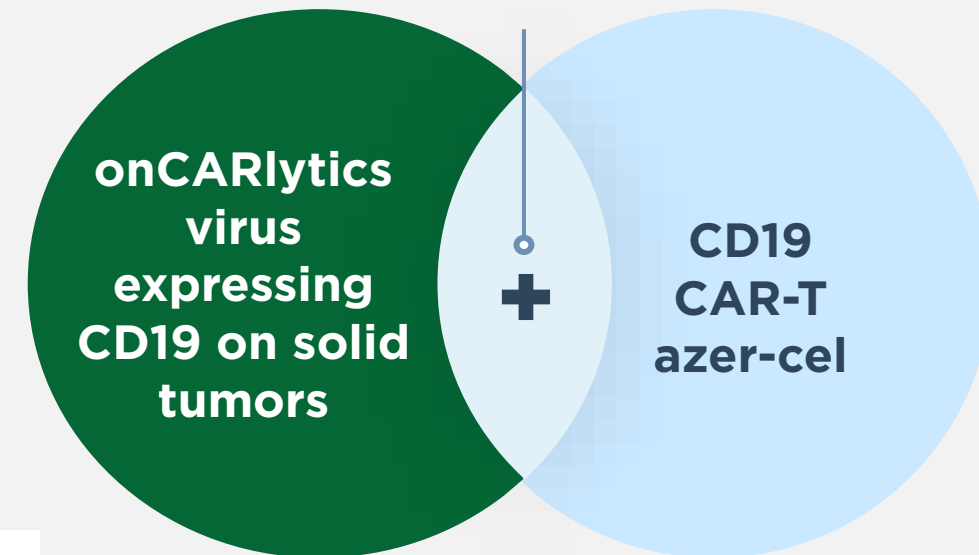
# AZER-CEL OFFERS ONCARLYTICS AN IN-HOUSE COMBINATION APPROACH FOR SOLID TUMOURS

- Azer-cel in combination with onCARlytics demonstrated sustained, robust activity against multiple tumor types
- 100% killing of Triple Negative Breast Cancer (468P) and Gastric (SNU16) Cancer lines was observed compared to controls at 72 hours



-○- MOCK  
-○- Autologous CD19  
-○- Azer-cel

## Combination treatment for solid tumors





# B-CELL IMMUNOTHERAPIES

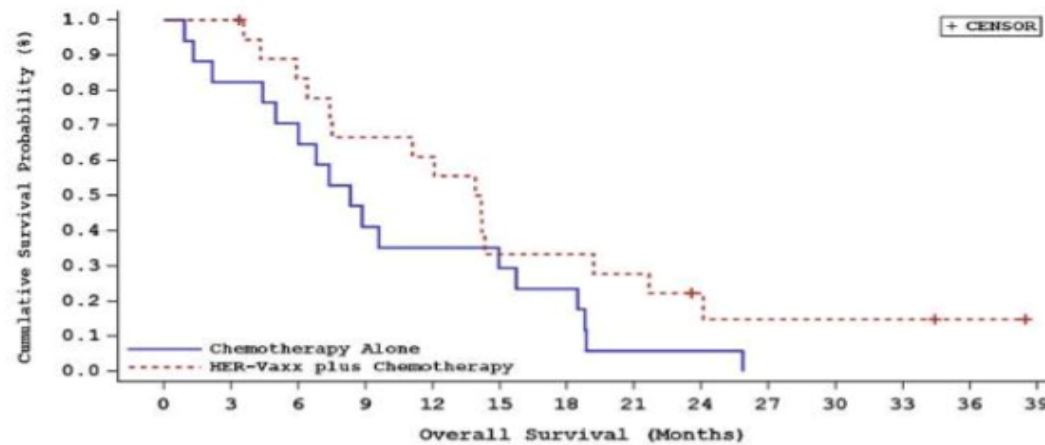
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# HER-VAXX HERIZON STUDY SHOWS CONTINUED OVERALL SURVIVAL BENEFIT WITH AN ADDITIONAL FOLLOW UP

## Overall Survival Benefit with additional 6 months follow up

34



Treatment: Number of Patients at Risk

Treatment	0	3	6	9	12	15	18	21	24	27	30	33	36	39
Chemotherapy Alone	17	14	12	7	6	5	4	1	1	0	0	0	0	0
HER-Vaxx plus Chemotherapy	19	19	15	12	11	6	6	5	3	2	2	2	1	0

Six patients/arm received post-treatment therapy including 5 patients who received trastuzumab (3 in the HER-Vaxx arm and 2 in chemotherapy arm).

	HER-Vaxx + Chemotherapy	Chemotherapy
Sample Size	19	17
Events	15	17
Median OS (2-sided 80% CI)	<b>14.0 months</b> <b>(11.1, 14.3)</b>	8.3 months (6.0, 9.59)
HR	<b>0.558</b>	
2-sided 80%CI	<b>(0.349, 0.895)</b>	
Log-rank Test (1-sided p-value)	<b>0.054*</b>	
Median PFS (2-sided 80% CI)	6.93 (5.6, 9.9)	6.01 (2.2, 8.3)

\*Significant, 1-sided p < 0.10

Data cut 01Jun22 Data Extract Date: 26DEC2022

# HER-VAXX RE-FOCUS PHASE 2 (NEXTHERIZON)

Focus on a Chemotherapy Combination in Gastric Cancer that progressed after Trastuzumab



## TRIAL



## PATIENTS



## STUDY

- Phase 2
- Open label
- USA, Australia, Taiwan
- Treat until progression/toxicity

- 2L+
- Advanced or metastatic GJ/GEJ
- Arm 1: HER-2/neu overexpressing at diagnosis
- Progressed on prior trastuzumab, T-DXd or other anti-HER-2 ADC

- Non-Randomised
- Arm 1: HER-Vaxx + ramucirumab paclitaxel

mGC/GEJ cancer  
HER-2/neu overexpressing at diagnosis  
Progressed on or after trastuzumab,  
T-DXd or other anti-HER-2 ADC  
previously received PD-1/PD-L1 treatment

Arm 1: HER-Vaxx + Chemotherapy  
N=15

**PRIMARY ENDPOINTS:**  
ORR  
Safety

**SECONDARY ENDPOINTS:**  
OS  
PFS  
DoR

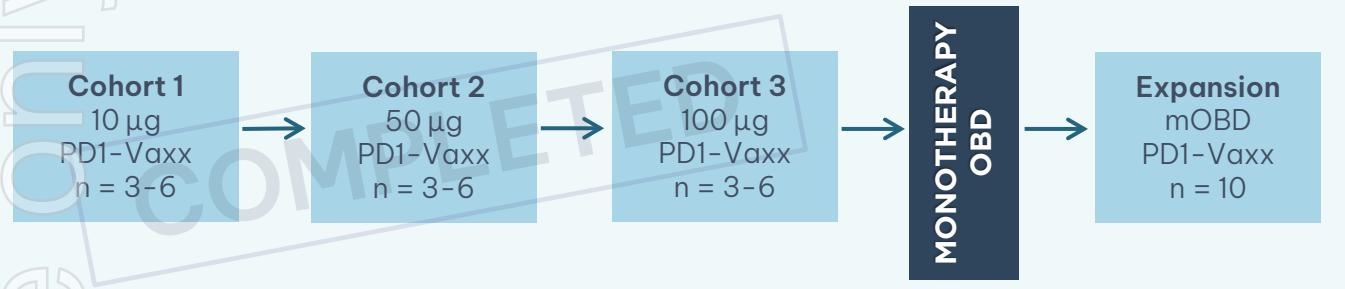
**EXPLORATORY ENDPOINT:**  
Biomarker/Immune Response

Potential  
registrational trial  
focused on unmet need

# IMPRINTER: PD1-VAXX NSCLC PHASE 1 STUDY DESIGN

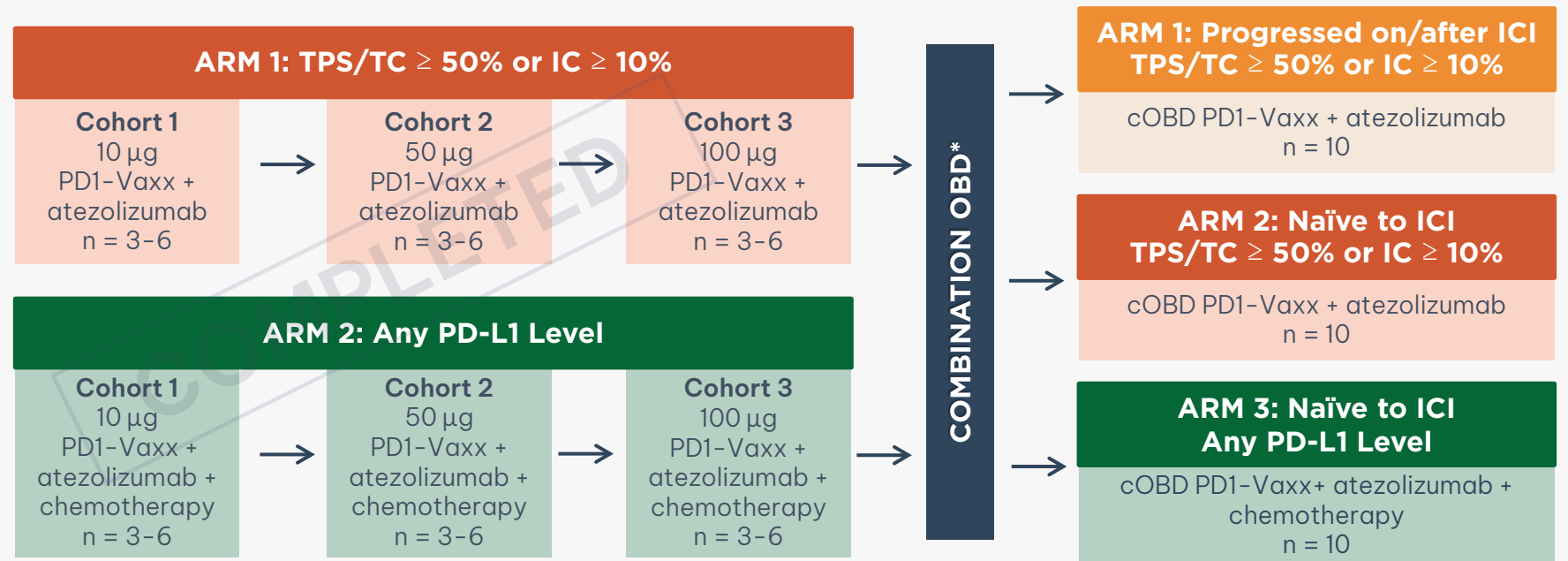
## Phase 1: PD1-Vaxx Monotherapy Dose Escalation & Expansion

2L+ NSCLC Progressed on/after ICI



- CR (3 years +), PRs and SD have been noted
- With encouraging data in NSCLC, Imugene has initiated a study in a disease area of higher unmet need: MSI-H colon cancer

## Phase 1b: PD1-Vaxx NSCLC Combination Dose Escalation & Expansion



mOBD = monotherapy optimal biological dose

cOBD = combination optimal biological dose

\*cOBD will be determined per arm

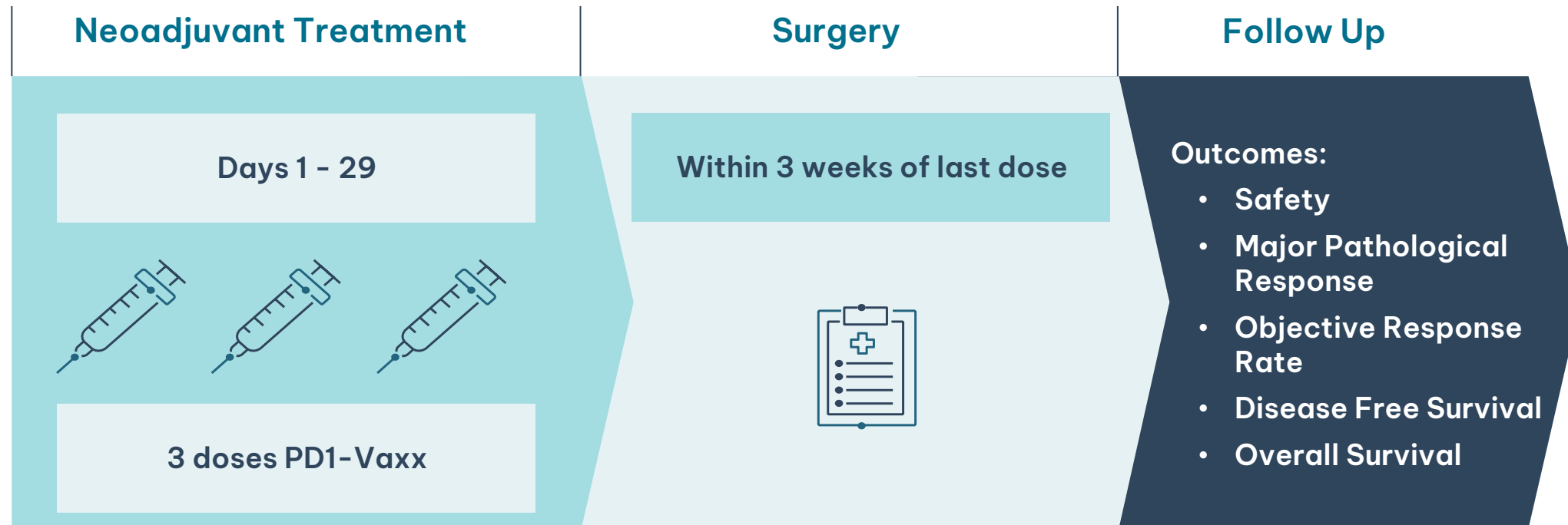
# PD1-VAXX PH2 NEOPOLEM NEOADJUVANT (PRE-SURGERY) IST IN MSI-HIGH COLORECTAL CANCER (CRC)

Site Locations:  
AUS & UK

Patient: n= 44

Inoperable,  
MSI-High  
CRC

Sites in feasibility:  
- 6 in AUS  
- 4 in UK



First Patient Enrolled Planned: 1H 2024

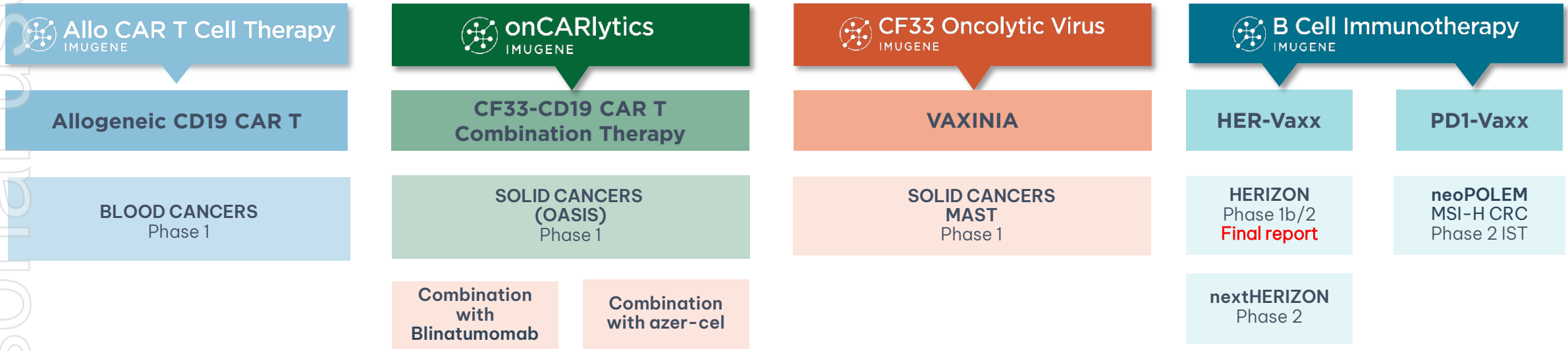
Objectives: Tumor response, safety, immunogenicity

# FOUR UNIQUE TECHNOLOGY PLATFORMS PRIORITIZING OPPORTUNITIES IN BLOOD & SOLID CANCERS

Therapeutic approaches with combination potential with existing standards of care



Platform  
Clinical Trials  
Ersot



Prioritized to near term data read outs

\*IST: Investigator Sponsored Trial

# KEY CATALYSTS FOR THE NEXT 12-24 MONTHS

## Q1 2024

- **ONCARLYTICS:** IT & IV Combination FPI
- **PD1-VAXX:** FPI neoPOLEM (Phase 2 MSI-H CRC)

## Q2 2024

- **AZER-CEL:** Phase 1b update
- **ONCARLYTICS:** FPI IT Combo Cohort 2
- **VAXINIA:** IT Mono Bile Duct Expansion Open

## Q3 2024

- **AZER-CEL:** Phase 1b update
- **ONCARLYTICS:** IV Combo Cohort 2 Open
- **VAXINIA:** IT Combo Expansion Cohort Open

## Q4 2024

- **AZER-CEL:** Target regulatory meeting with FDA
- **ONCARLYTICS:** IT & IV Combo Expansion
- **AZER-CEL:** DLBCL Phase 2 Pivotal Study Start-up

## 2025

- **AZER-CEL:** DLBCL Phase 2 Pivotal Study FPI
- **ONCARLYTICS + AZER-CEL:** Study Start Up
- **IND filing**  
**ONCARLYTICS + AZER-CEL** in solid tumors
- **AZER-CEL:** expansion into additional CD19+ cancers (Phase 1 Expansion Cohort)
- **VAXINIA:** Phase 2 FPI
- **VAXINIA:** Phase 2 Interim Data Read out
- **VAXINIA:** IP & IA Phase 1 FPIs
- **ONCARLYTICS:** Expansion

Key:

**FPI,** First Patient In, **MSI-H:** Microsatellite Instability High, **Combo:** Combination Therapy **Mono:** Monotherapy, **DLBCL:** Diffuse Large B-Cell Lymphoma, **IA:** Intra-arterial, **IP:** Intraperitoneal, **IT:** Intratumoral, **IV:** Intravenous

# FINANCIAL SUMMARY

## PUBLIC MARKET OVERVIEW (January 5, 2024)

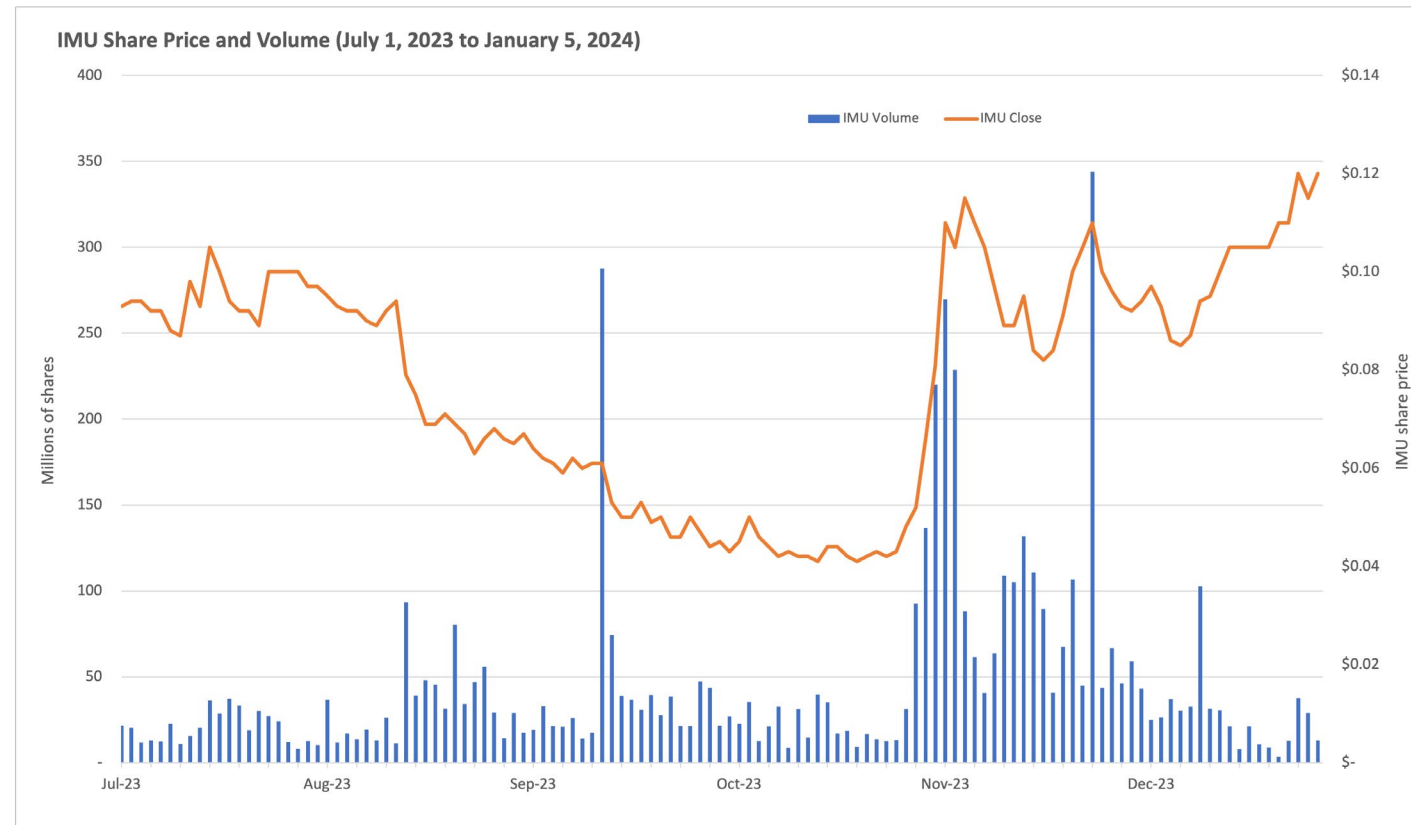
Share Price	A\$0.12
52 week range	A\$0.039 - A\$0.175
Market Capitalisation <sup>1</sup>	A\$860.3M
Cash equivalents (30 Sept '23)	A\$163.4M
Enterprise Value	A\$696.9M

## TOP 10 SHAREHOLDERS (November 30, 2023)

Mr Paul Hopper	4.47%
Mann Family	4.03%
The Vanguard Group, Inc	3.60%
Dr Nicholas Smith	1.65%
UBS Group AG	1.49%
Private clients of AustralianSuper	1.31%
Private Portfolio Managers PPM	1.23%
BlackRock Inc	1.16%
Ms Leslie Chong	1.12%
State Street Corporation	0.85%

Note:  
<sup>1</sup> Market capitalisation calculations based on ordinary shares (7.169 bn) only and excludes the dilutive impact of options outstanding (1.256 bn)

## SHARE PRICE PERFORMANCE





# WHY IMUGENE?

## Value Proposition for Investors



Advanced Portfolio with multiple shots on goal. Leader in developing allogeneic CAR T cell therapy



Experienced management team with over 150 years of combined experience in drug development & approvals



Ongoing clinical trials in blood cancer and diverse solid tumors with multiple value inflection points



Robust cash runway; prudent use of funds to protect and conserve cash resources with reprioritized programs

ersonal use only

# INVESTMENT HIGHLIGHTS

## MARKET CAPITALISATION

5 January 2024

A\$860M  
US\$576M



## CASH AS OF

30 September 2023

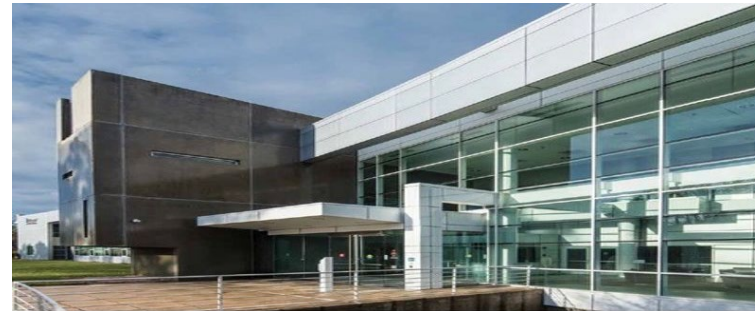
A\$163M  
US\$109M



## 4 PLATFORM TECHNOLOGIES

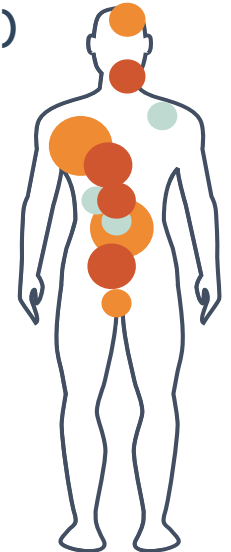
Allo CAR T Cell Therapy  
CF33 Oncolytic Virus  
onCARlytics  
B Cell Immunotherapy

## IN-HOUSE GMP CELL THERAPY MANUFACTURING FACILITIES



## DISEASE AREAS

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



azer-cel Ph1b DLBCL (FDA IND)

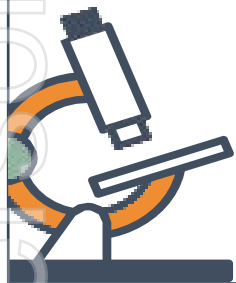
VAXINIA: Ph1 Solid Tumors (FDA IND)

onCARlytics: Ph1 Solid Tumors (FDA IND)

HER-Vaxx: Ph2 HER2+ Metastatic GC (FDA IND)

PD1-Vaxx: Ph2 neoPOLEM

## LONG-LIFE PATENT PORTFOLIO



## 5 CLINICAL STUDIES



**IMUGENE**

Developing Cancer Immunotherapies

ASX:IMU

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