



# IMUGENE

Developing Cancer Immunotherapies

ASX: IMU

## DEVELOPING CANCER IMMUNOTHERAPIES

Bell Potter Emerging Leaders Conference  
May, 2024

ersonal use only

# DISCLAIMER

1. The information in this presentation does not constitute personal investment advice. The presentation is not intended to be comprehensive or provide all information required by investors to make an informed decision on any investment in Imugene Limited (Company). In preparing this presentation, the Company did not take into account the investment objectives, financial situation and particular needs of any particular investor.
2. Further advice should be obtained from a professional investment adviser before taking any action on any information dealt with in the presentation. Those acting upon any information without advice do so entirely at their own risk.
3. Whilst this presentation is based on information from sources which are considered reliable, no representation or warranty, express or implied, is made or given by or on behalf of the Company, any of its directors, or any other person about the accuracy, completeness or fairness of the information or opinions contained in this presentation. No responsibility or liability is accepted by any of them for that information or those opinions or for any errors, omissions, misstatements (negligent or otherwise) or for any communication written or otherwise, contained or referred to in this presentation.
4. Neither the Company nor any of its directors, officers, employees, advisers, associated persons or subsidiaries are liable for any direct, indirect or consequential loss or damage suffered by any person as a result of relying upon any statement in this presentation or any document supplied with this presentation, or by any future communications in connection with those documents and all of those losses and damages are expressly disclaimed.
5. Any opinions expressed reflect the Company's position at the date of this presentation and are subject to change
6. International offer restrictions – This document does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States or any other jurisdiction in which it would be unlawful. In particular, the New Shares have not been, and will not be, registered under the US Securities Act of 1933 and may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws. The distribution of this presentation in jurisdictions outside Australia may be restricted by law and any such restrictions should be observed.

# INVESTMENT HIGHLIGHTS

**MARKET CAPITALISATION AS OF**  
27 MAY 2024

A\$520M



**CASH AS OF**  
31 MARCH 2024

A\$114.1M



## 4 PLATFORM TECHNOLOGIES

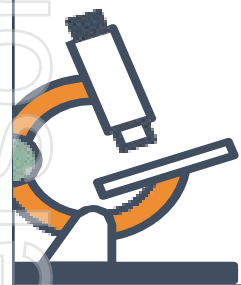
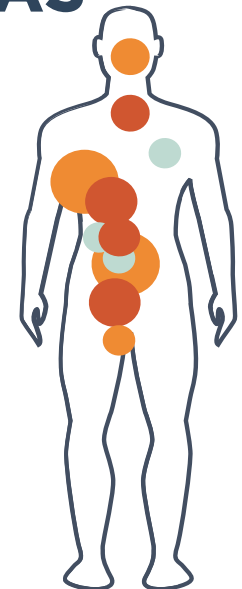
Allo CAR T Cell Therapy  
CF33 Oncolytic Virus  
onCARlytics  
B Cell Immunotherapy



Azer-Cel Research Center in  
Durham, North Carolina

## DISEASE AREAS

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



## 4 CLINICAL STUDIES

azer-cel Ph1b DLBCL (FDA IND)

VAXINIA: Ph1 Solid Tumours (FDA IND)

onCARlytics: Ph1 Solid Tumours (FDA IND)

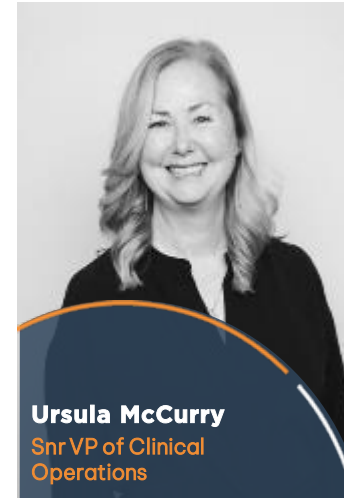
PD1-Vaxx: Ph2 neoPOLEM

## LONG-LIFE PATENT PORTFOLIO



# IMUGENE CLINICAL EXECUTIVE TEAM

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



**Genentech**  
A Member of the Roche Group

**EXELIXIS**



**IMMUNE-ONC**  
Therapeutics



**Genentech**  
A Member of the Roche Group

**AMGEN**

**EXELIXIS**

**celularity**



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

**AMUNIX**

**Genentech**  
A Member of the Roche Group

**EXELIXIS**



**Fate**  
THERAPEUTIC



**Juno**  
THERAPEUTICS

**Genentech**  
A Member of the Roche Group

**WindMIL**  
THERAPEUTICS

**Bristol Myers Squibb**

**AMGEN**

**NOVARTIS**





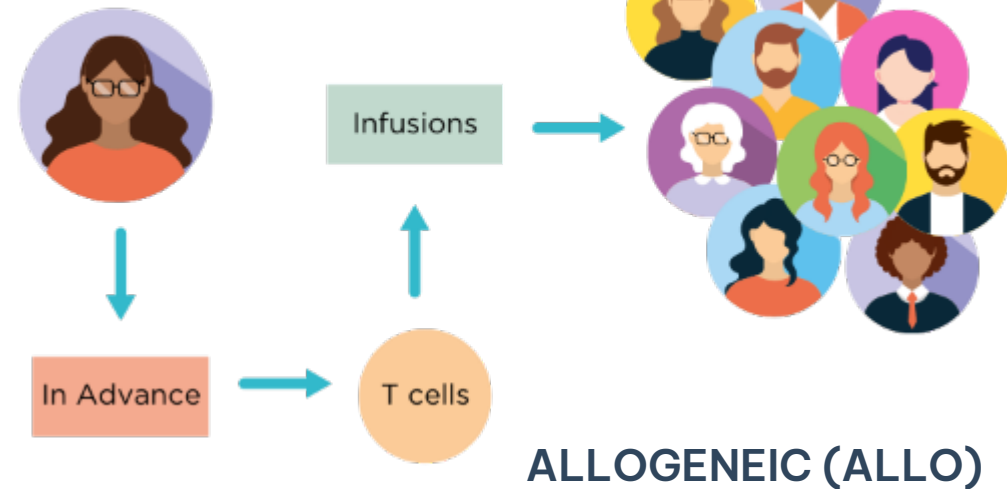
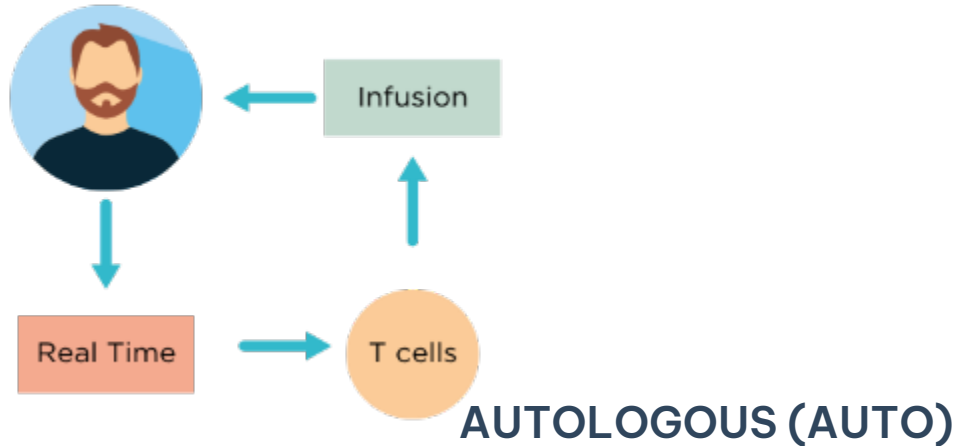
# AZER-CEL CD19 ALLOGENEIC CAR T CELL THERAPY

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



- 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<sup>1</sup>)

## 2nd line

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

## 3rd line

No standard of care – for  
auto CAR T relapse  
patients<sup>2</sup>

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

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

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

<sup>1</sup>Rituximab, Cyclophosphamide, Doxorubicin Hydrochloride (Hydroxydaunomycin), Vincristine Sulfate (Oncovin), Prednisone

<sup>2</sup>COLUMVI® received conditional accelerated marketing authorisation in 2023 for 3L+ DLBCL

# AZER-CEL CASE STUDY

63-year-old Male

Dx: DLBCL

Tumor Burden: 2029 mm<sup>2</sup>

8 Previous lines of therapy:

1. R-CHOP --> R-EPOCH (CR x 6 months)
2. Ritixumab + Cytarabine + Oxaliplatin + Dex
3. Yescarta (CR x 8 months)
4. CA-4948 (IRAK4/FLT3 inhibitor) (refractory)
5. Vemurafinib (BRAF inhib) (refractory)
6. Mosunetuzumab (CD20 bispecific)- PR x 1 month
7. Experimental therapy - (refractory)
8. Ritux + Revlimid + Polatuzumab - (refractory)

Day 0



Day 28



Outcome: Day 28 Complete Response

# AZER-CEL PHASE 1B STUDY DESIGN

Potentially leading to Phase 2 Pivotal Study in 2025

## DOSE ESCALATION

## EXPANSION

Dose Level

Conditioning Regimen (s)

Patient Population DLBCL Relapsed after CD19 Auto CAR T



# 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>



**U.S. FOOD & DRUG**  
ADMINISTRATION

Phase 2 Pivotal Study  
For market approval (BLA)

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

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

Population: Relapse after auto-CART in DLBCL patients

Positive FDA guidance on the potential registrational trial

~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 by Kincell Bio





# IMUGENE AND KINCELL BIO PARTNERSHIP

## KinCell Bio acquired Imugene's North Carolina manufacturing facility

- Imugene retains rights to azer-cel
- Imugene will receive up to \$6M USD in upfront and milestone-driven payments over 3 years
- Imugene will recognize \$32M USD in staff cost reductions, manufacturing efficiencies and overhead savings over the next 3 years
- KinCell will manufacture Imugene's azer-cel clinical trial supply

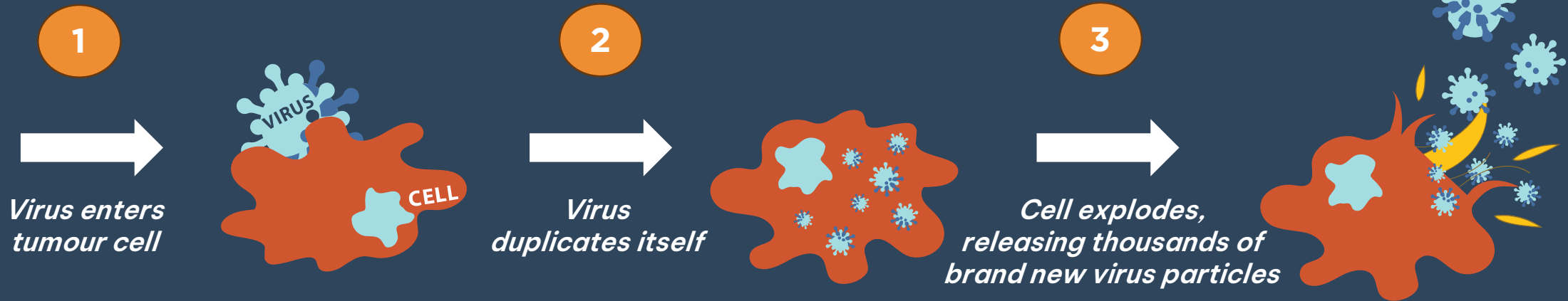


kinCell

**CF33 ONCOLYTIC  
VIRUS**

ersonal use only

# 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 tumour 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)

# OUR PHASE 1 MAST STUDY HAS ENROLLED WELL



## Dose Administration (Parallel Groups)

n=52-100 patients

IT

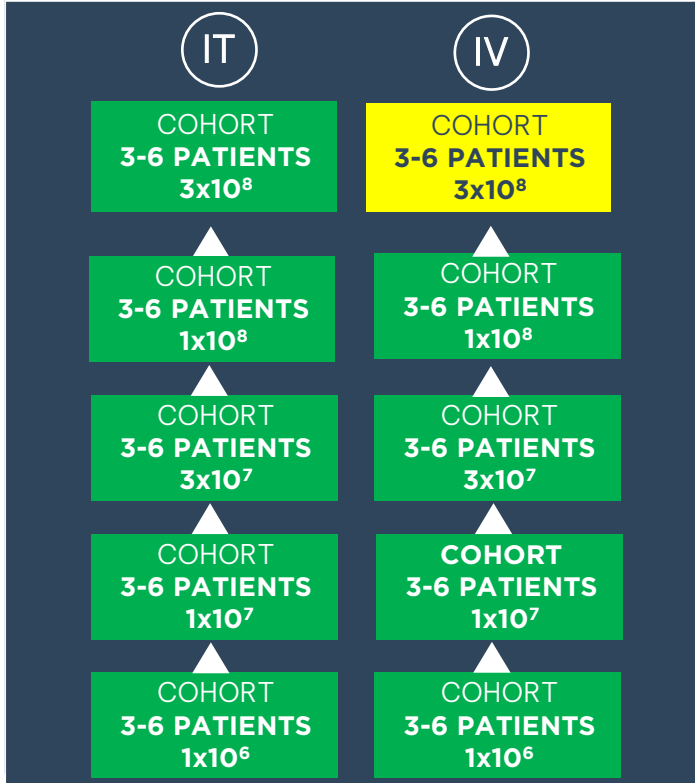
**Intratumoural (IT) Administration**  
Metastatic and Advanced Solid Tumours

IV

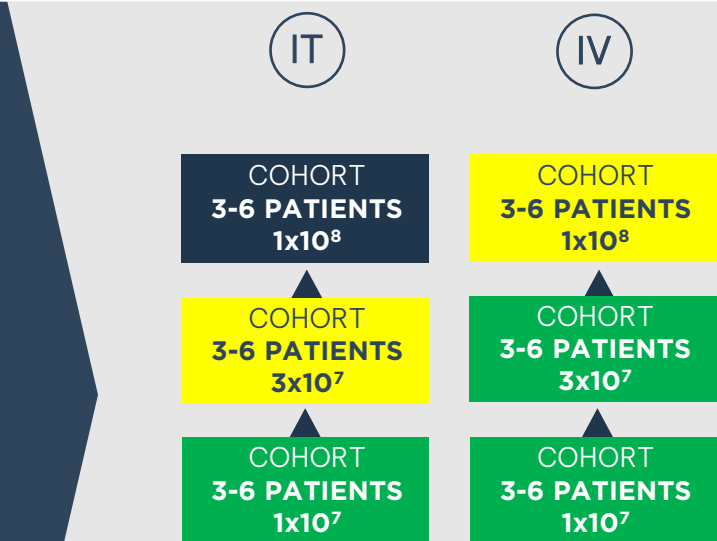
**Intravenous (IV) Administration**  
Metastatic and Advanced Solid Tumours

**Site Location:** USA, AUS

## VAXINIA Monotherapy Dose Escalation



## VAXINIA + Pembrolizumab Combination Dose Escalation



## Cohort Expansion

**Expansion Cohorts**  
(N=10)

**Tumour Types of Interest:**  
i.e. **Cholangiocarcinoma**  
(IT will occur first)

# PHASE 1 MAST (METASTATIC ADVANCED SOLID TUMOURS) TRIAL - ENCOURAGING EARLY SIGNALS



- 47 heavily pre-treated patients have been dosed to date (24 April 2024\*), of which 40 patients have been evaluated, meaning they received at least their first scan at day 42
- Nearly half of the evaluable patients (**48%**) have remained on treatment for more than 3 months, representing significant disease control; 3 monotherapy patients have remained on treatment for over 200 days
- During dose escalation, 1 patient with bile tract cancer who failed 3 prior treatments achieved a **complete response (CR)**, which has continued for almost 1.5 years (532 days); 2 patients with melanoma achieved **partial responses (PRs)**, and 17 patients achieved stable disease (SD) while in the trial
- Bile tract cancer expansion trial opened and is expected to enroll approximately 10 patients; preliminary early data is expected in the second half 2024
- The company received US FDA Fast Track Designation for bile tract cancer in November 2023, which allows for faster review

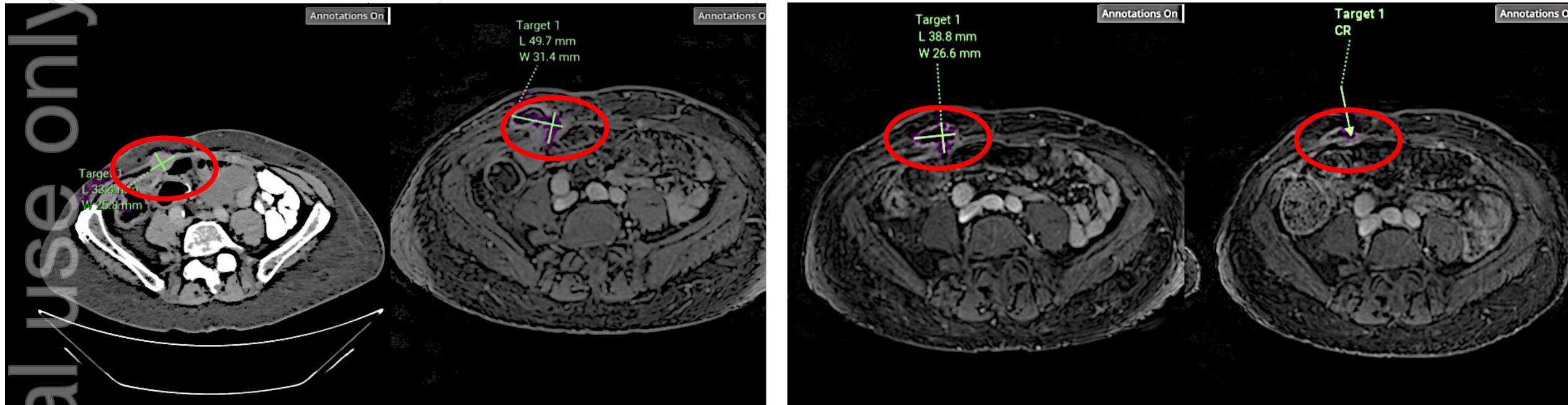


\*Preliminary enrollment update; data and number of evaluable patients subject to change with full statistical analysis



# TURNING COLD TUMOURS HOT

Complete Remission after Pseudoprogression (immune activity) in a Monotherapy patient with a cold tumour (bile tract cancer)



**Baseline scan**  
Start of the Trial

**Second scan**  
Pseudoprogression  
(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

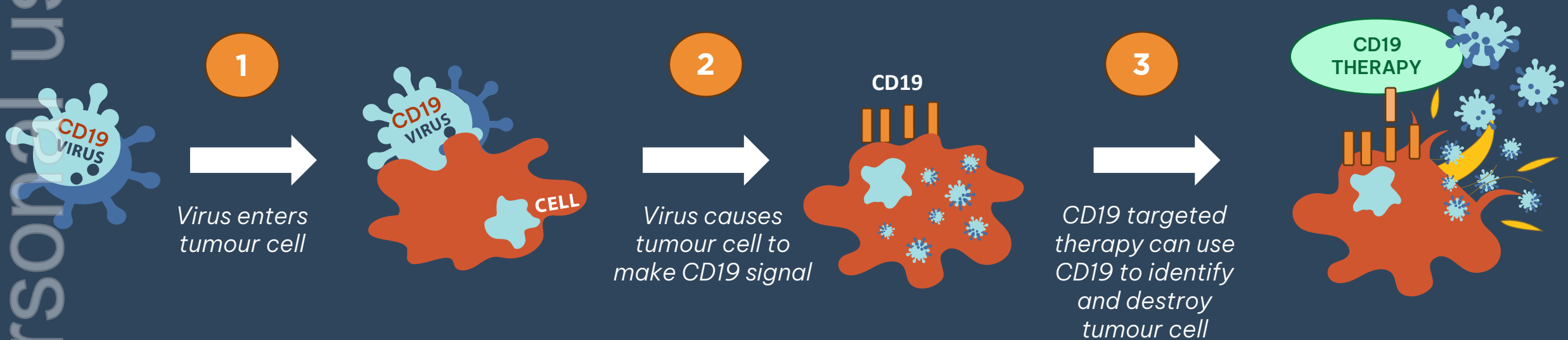
ersonal use only



# 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 tumours (90% of cancer market)
- Imugene's onCARlytics technology seeks to overcome this challenge in solid cancers

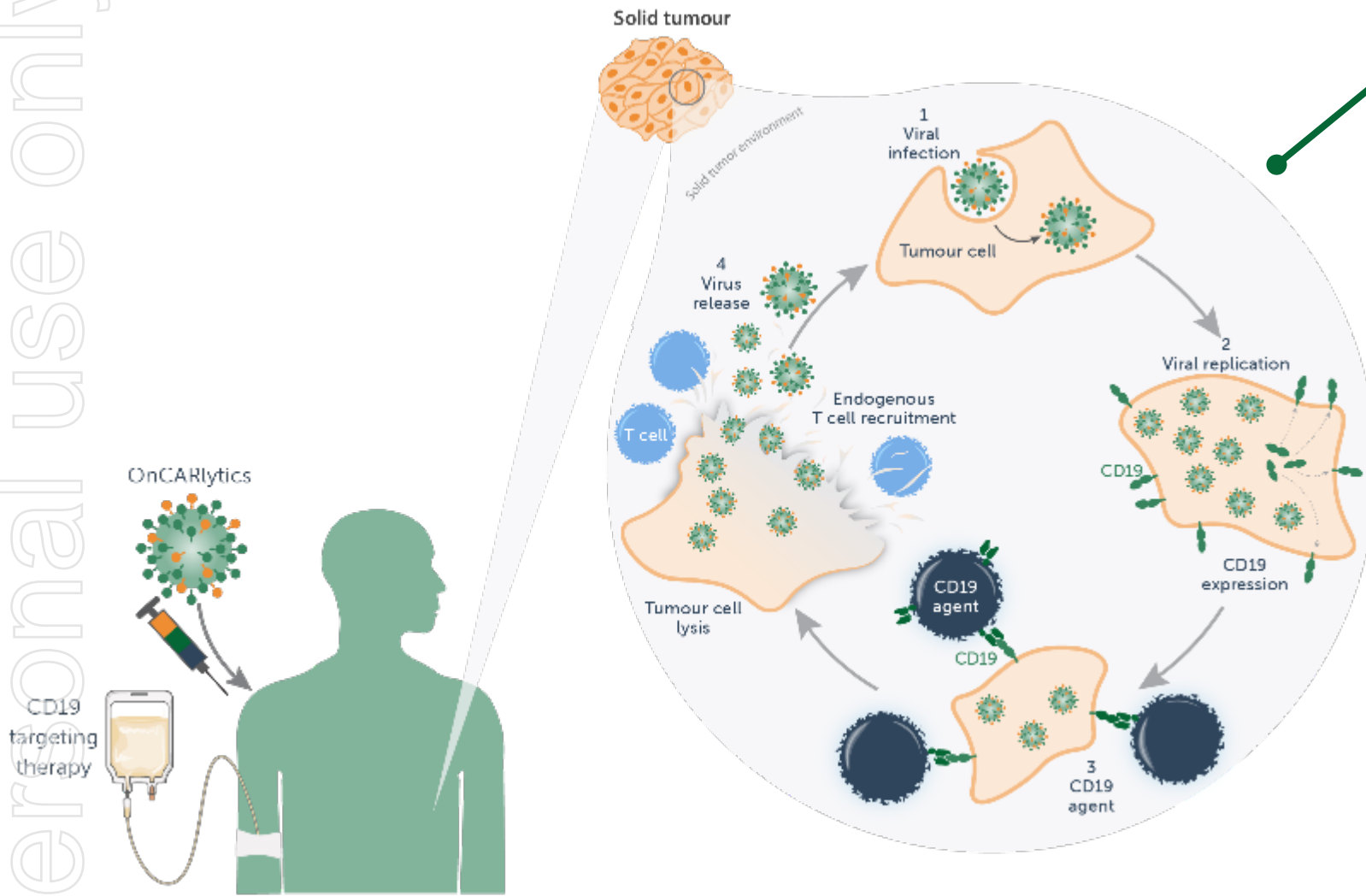


# MECHANISM OF ACTION: HOW DOES IT WORK?

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

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

ersonal use only

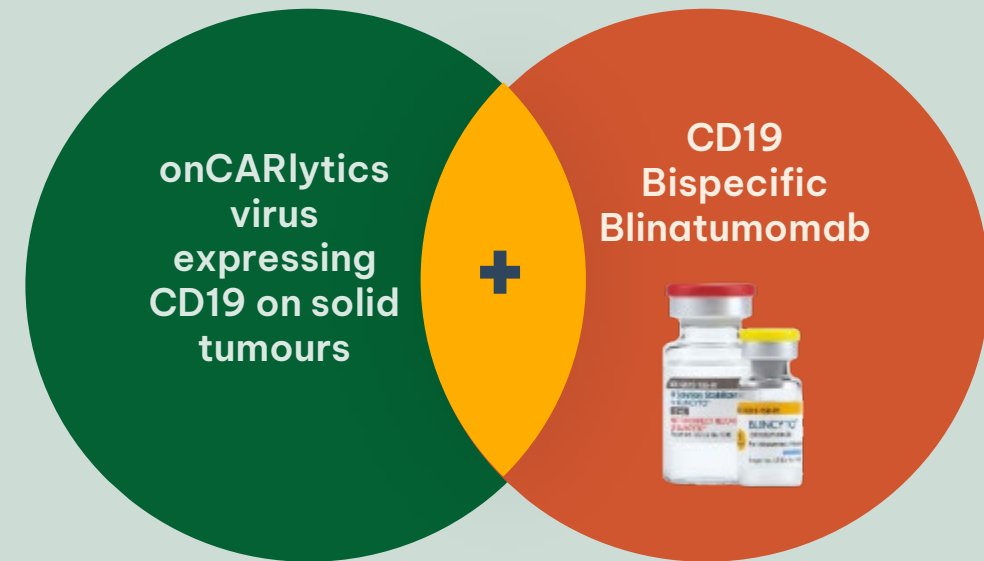




# PHASE 1 OASIS TRIAL

- Phase 1 trial designed to treat with onCARlytics (CF33-CD19) alone, or in combination with Blinatumomab (bispecific antibody targeting CD19) and either dosed IV or IT in metastatic advanced patients across multiple solid tumours
- First IT and IV patient dosed (ovarian cancer) at City of Hope in October 2023 and February 2024 respectively
- Many CD19 approved drugs, which could become preferred partners to combine with onCARlytics (~90% of cancer)
- The Cohort Review Committee (CRC) observed no safety issues in the onCARlytics monotherapy lead-in trial
- Combination with OnCARlytics and Blinatumomab now open
- Phase 1 planned for ~10 sites in the U.S. in ~40-45 patients with advanced solid tumours
- Preliminary early combination data are expected in the 4Q 2024

## Combination treatment for solid tumours





# VARIETY OF APPROVED THERAPIES AVAILABLE FOR COMBINATION WITH ONCARLYTICS

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

## Combination Opportunities

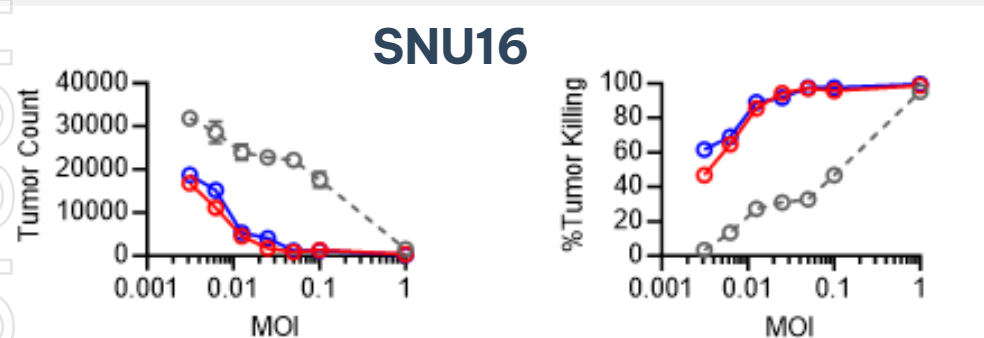
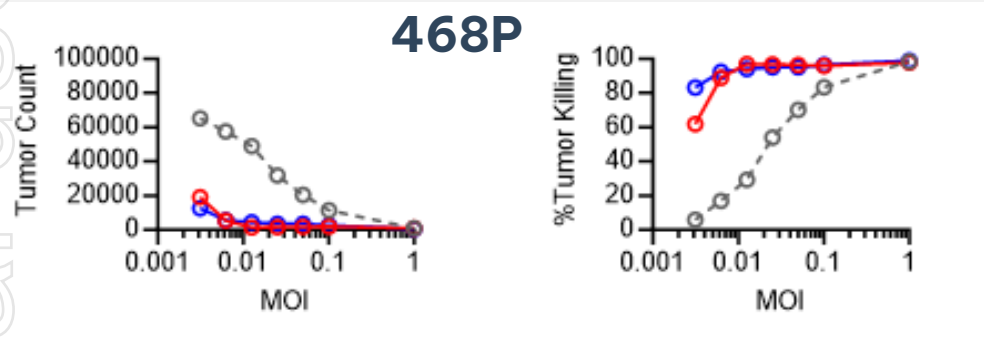
- Azer-cel (allo CD19 CAR T)
- Autologous CD19 CARTs
- Bispecific antibodies targeting CD19
- Antibody-drug Conjugates (ADC)
- Monoclonal Antibodies (MABs)

COMPANY	FIRST FDA APPROVAL	TARGET	APPROVED CANCERS
	2017	CD19 Auto CAR T	B-ALL, DLBCL
	2017	CD19 Auto CAR T	DLBCL, R/R FL
	2020	CD19 Auto CAR T	R/R MCL
	2021	CD19 Auto CAR T	DLBCL
	2020	CD19 Monoclonal Antibodies (MABs)	DLBCL
	2020	CD19 MABs	NMOSD
	2014	CD19-CD3 Bispecific MABs	ALL
	2021	CD19 Antibody- drug conjugate (ADC)	B-Cell Lymphoma

ersonal use only

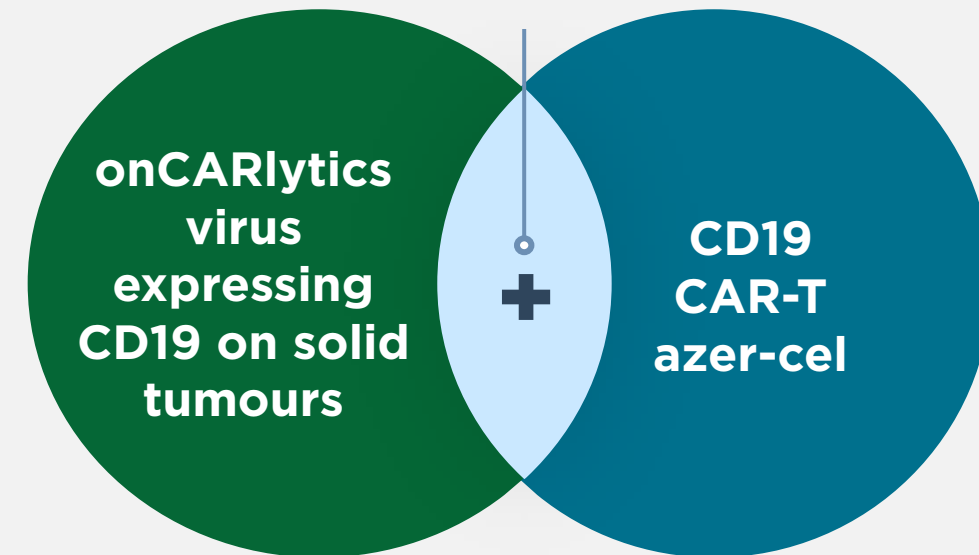
# AZER-CEL OFFERS ONCARLYTICS AN IN-HOUSE COMBINATION APPROACH FOR SOLID TUMOURS

- Azer-cel in combination with onCARlytics demonstrated sustained, robust activity against multiple tumour 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 tumours



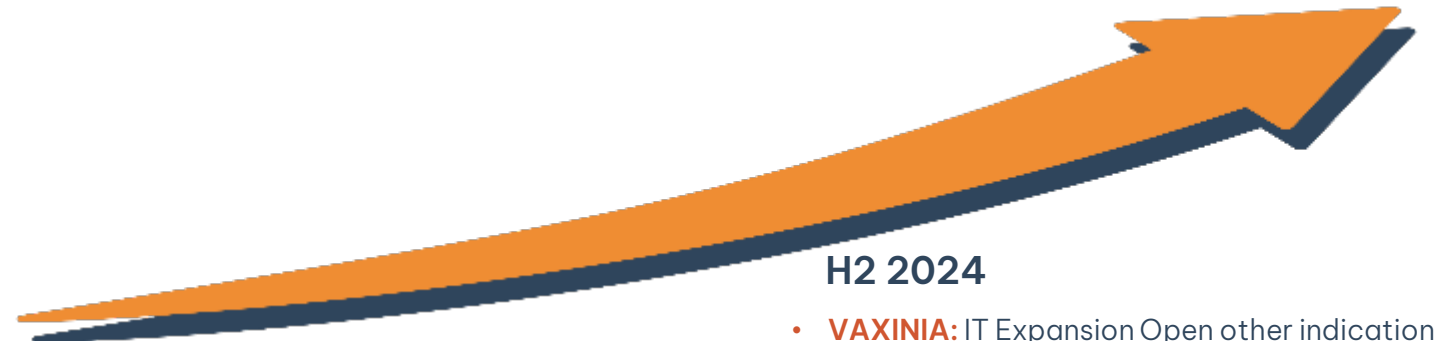
# RECENTLY ACHIEVED AND UPCOMING KEY CATALYSTS

## RECENTLY ACHIEVED

- **AZER-CEL:**
  - Kincell Bio acquired manufacturing
- **VAXINIA:**
  - MAST trial positive early signals
  - MAST FPI in higher dose cohorts
  - Patent granted in China
  - Bile tract cancer trial opened
- **ONCARLYTICS:**
  - FPI in IV arm
  - Combination arm opened

### 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**: Intratumoural, **IV**: Intravenous

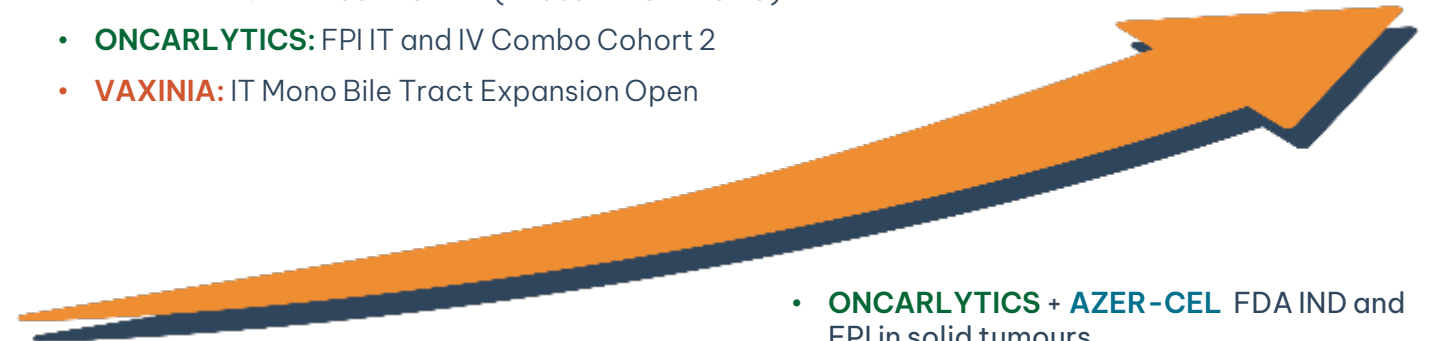


## H2 2024

- **VAXINIA**: IT Expansion Open other indication
- **AZER-CEL**: Prelim early DLBCL Phase 1b data update
- **ONCARLYTICS**: Early IT and/or IV Combo data

## H1 2024

- **PD1-VAXX**: FPI Neo-POLEM (Phase 2 MSI-H CRC)
- **ONCARLYTICS**: FPI IT and IV Combo Cohort 2
- **VAXINIA**: IT Mono Bile Tract Expansion Open



## 2025

- **ONCARLYTICS + AZER-CEL** FDA IND and FPI in solid tumours
- **ONCARLYTICS**: Data update and trial expansion
- **VAXINIA**: Phase 2 FPI
- **VAXINIA**: Phase 2 Interim Data Read out
- **VAXINIA**: IP & IA Phase 1 FPIs
- **PD1-VAXX**: NeoPOLEM (Phase 2 MSI-H CRC) update
- **AZER-CEL**: DLBCL Phase 1b data updates
- **AZER-CEL**: Target regulatory meeting with FDA
- **AZER-CEL**: Expansion into additional blood cancers (Phase 1 Expansion Cohort)

# INVESTMENT HIGHLIGHTS

**MARKET CAPITALISATION AS OF**  
27 MAY 2024

A\$520M



**CASH AS OF**  
31 MARCH 2024

A\$114.1M



## 4 PLATFORM TECHNOLOGIES

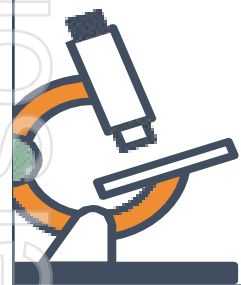
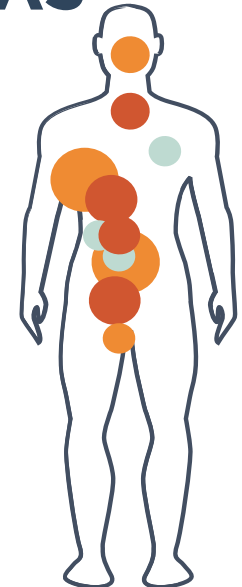
Allo CAR T Cell Therapy  
CF33 Oncolytic Virus  
onCARlytics  
B Cell Immunotherapy



Azer-Cel Research Center in  
Durham, North Carolina

## DISEASE AREAS

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



## 4 CLINICAL STUDIES

azer-cel Ph1b DLBCL (FDA IND)

VAXINIA: Ph1 Solid Tumours (FDA IND)

onCARlytics: Ph1 Solid Tumours (FDA IND)

PD1-Vaxx: Ph2 neoPOLEM

## LONG-LIFE PATENT PORTFOLIO





**IMUGENE**

Developing Cancer Immunotherapies

ASX:IMU

[shareholderenquiries@imugene.com](mailto:shareholderenquiries@imugene.com)  
[imugene.com](http://imugene.com)

ersonal use only

