

# FIGHTING AGAINST CANCER

July 2024

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# INVESTMENT HIGHLIGHTS

Strong cash position



Expert leaders with 13 prior FDA approved cancer drugs



Numerous key catalysts expected in 2024



Long-life patent portfolio



4 cancer therapeutics in 4 clinical trials



**MARKET CAPITALISATION AS OF**  
20 JUNE 2024

A\$432M



**CASH AS OF**  
31 MARCH 2024

A\$114.1M



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# THREE NOVEL TECHNOLOGIES ADVANCING THROUGH THE CLINIC

## **Allo CAR T Cell Therapy** IMUGENE



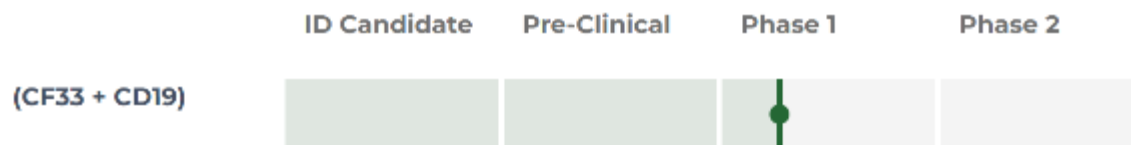
**azer-cel trial:** In patients with DLBCL blood cancer who failed autologous CAR T therapy

## **CF33 Oncolytic Virus** IMUGENE



**VAXINIA MAST trial:** in patients with metastatic or advanced solid tumours with additional focus on cholangiocarcinoma, or bile tract cancer

## **onCARlytics** IMUGENE



**onCARlytics OASIS trial:** in patients with advanced or metastatic solid tumours in combination with blinatumomab

Subject to patient enrolment, preliminary early data from all 3 programs expected in 2024

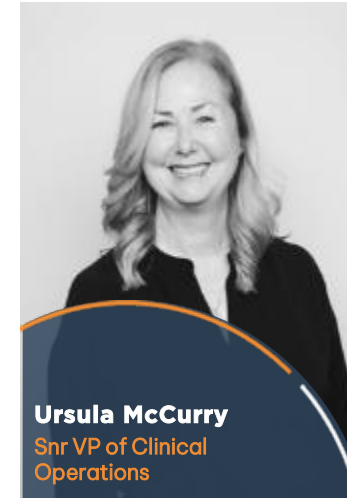
\* DLBCL (diffuse large B cell lymphoma)

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# IMUGENE CLINICAL EXECUTIVE TEAM

Over 150 years of Cancer Drug Development Experience  
13 FDA Approved Drugs to market



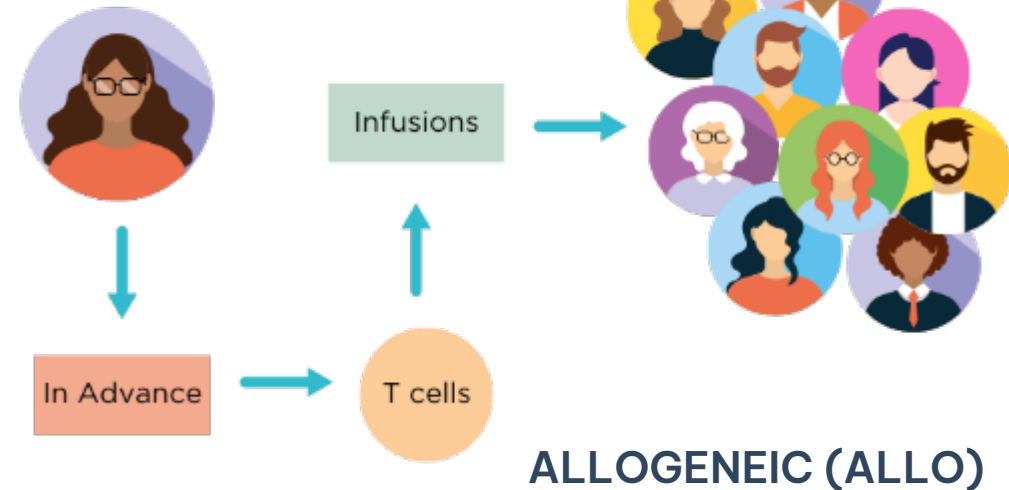
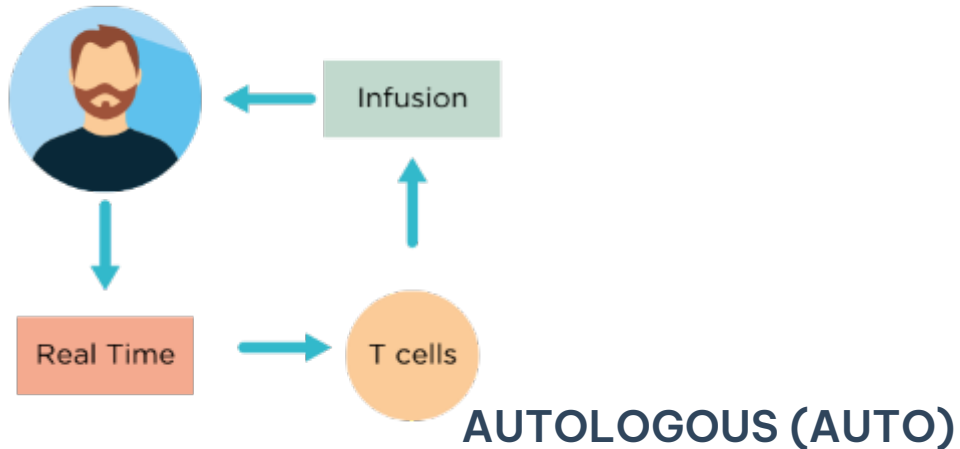
# AZER-CEL CD19 ALLOGENEIC CAR T CELL THERAPY

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# 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

# ALLOGENEIC (ALLO) CAR T THERAPY - A LIVING DRUG; OFF THE SHELF

Allo CAR T cell therapy is a type of immunotherapy that uses healthy donor T Cells that are genetically modified and engineered to be used "off the shelf" for multiple patients

1



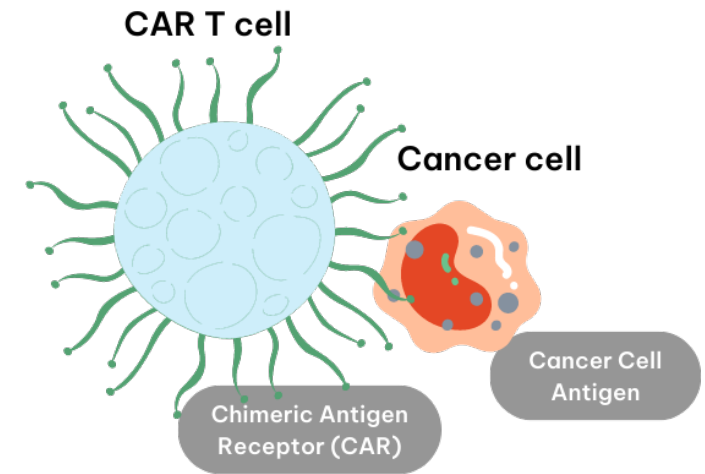
**HEALTHY** donors provide T Cells to make the CART product candidate. Donor T cells are processed for "universal match" and incorporated to chimeric antigen receptor designed to attack tumour cells.

2



As an "off the shelf" product, the processed batches can be frozen and shipped to multiple hospitals and clinics. **Each batch product can produce multiple doses.** The re-programmed CD 19 T Cells are then injected into the cancer patient

3



When the CD19 T Cells see the cancer cells with CD19 on them, the T Cells attack and kill them



# AZER-CEL HAS MEANINGFUL CLINICAL ACTIVITY IN BLOOD CANCER

## 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 DRUG FOR BLOOD CANCER

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  
Demonstrating Safety

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

# AZER-CEL OFF-THE-SHELF (ALLOGENEIC) CAR T



## Safety and Efficacy in DLBCL<sup>1</sup>(Type of Blood Cancer)

- Azer-cel showed no safety concerns
- 83% overall response rate (ORR) with durable responses of 6 months



## High Unmet Need

- DLBCL is an aggressive and fast-growing type of non-Hodgkin's lymphoma (Blood Cancer)
- ~30,000 new cases per year in the U.S.<sup>2</sup>



## First-to-Market Potential

- Currently in Phase 1b trial; potential for registrational Phase 2/3 trial for FDA approval
- Azer-cel could be the first approved allogeneic CAR T therapy for patients with DLBCL who failed autologous CAR T



## Blockbuster<sup>3</sup> Drug Potential

- Global CAR T market ~USD \$3B in 2023; projected to be ~USD \$23B by 2033, growing at a compound annual growth rate of 23.35%<sup>4</sup>
- 60-65% of patients treated with autologous CD19 CAR T have their cancer return; azer-cel could be a treatment

### Azer-cel

- Allogeneic CAR T therapy
- Takes healthy donor immune cells & re-engineers them to fight cancer.

1. DLBCL (Diffuse large B-cell lymphoma) 2. <https://www.polivy-hcp.com/newly-diagnosed/rchp/about/unmet-need-in-dlbcl.html> 3. a medication that generates annual sales of over \$1 billion 4. <https://www.novaoneadvisor.com/report/car-t-cell-therapy-market> CAR T-cell Therapy Market Size, Share & Trends Analysis

# CD19 AUTOLOGOUS CAR T RELAPSE MARKET IS LARGE AND GROWING



**60-65%**

of patients currently treated with autologous CD19 CAR T will relapse<sup>1</sup>



**By 2025**

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

Estimate total Global G8 markets to be ~18k patients per year<sup>2</sup>

Azer-cel potential blockbuster sales of ~\$2.5B<sup>3</sup> per annum in DLBCL (Blood cancer) CAR T relapsed patients

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

1. Estimated from ZUMA 1 and ZUMA 7 EFS rates;
2. G8 includes US, Japan, Canada and EU5 assuming equal access to CAR T therapies; market research, CancerMPac
3. TAM: total addressable market is total number of treatable patients x price at 100% market share

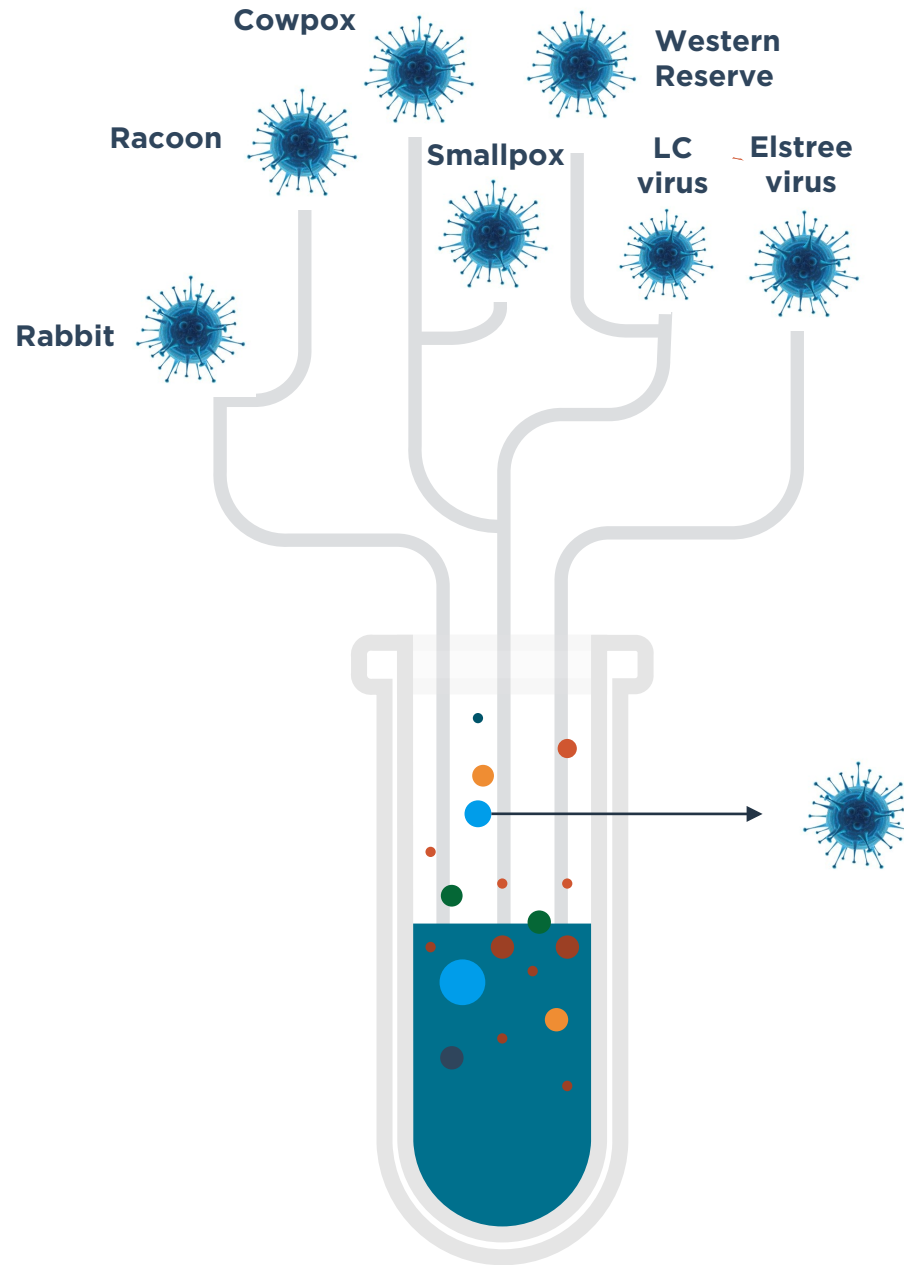


# CF33 ONCOLYTIC VIRUS

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# WHAT IS THE CF33 VIRUS & WHERE DID IT COME FROM?

Engineered next-generation virus

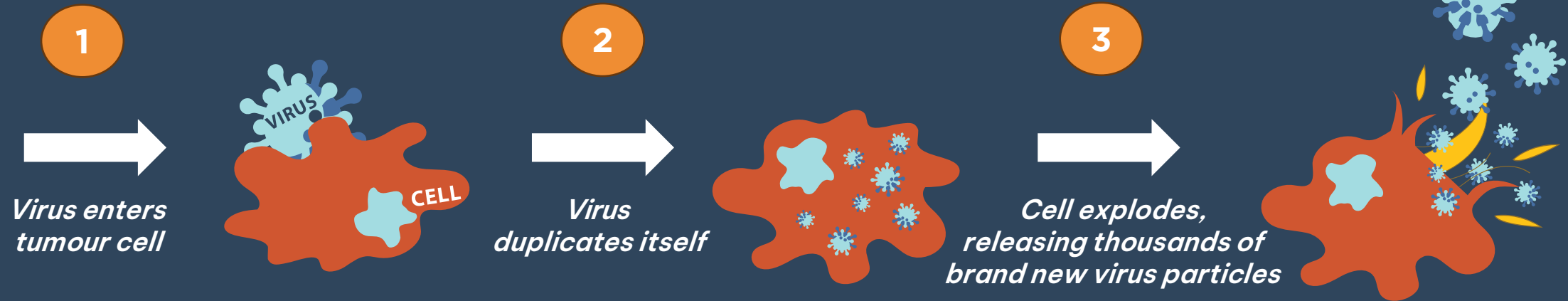


 **CF33 Oncolytic Virus**  
IMUGENE

**CF33**  
Invented by  
Professor Yuman Fong

 City of  
Hope™

# 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)

# PHASE 1 MAST TRIAL - ENCOURAGING EARLY SIGNALS



## Patients

- 40 patients have been evaluated in the trial



## Disease Control

- Nearly half of the patients (48%) have remained on treatment for >3 months
- 3 patients have remained on treatment for >200 days



## Responses

- Patient with bile tract cancer had a complete response (CR) (no signs of cancer); ongoing remission for >1.6 years . 2 patients with melanoma had partial responses (PRs) (decrease in cancer) and 17 patients achieved stable disease (SD)



## Bile Tract Trial

- Trial in bile tract cancer patients based on positive response
- Preliminary data are expected in late 2024/early 2025



## Fast Track

- US FDA Fast Track Designation for bile tract cancer, which allows for faster review

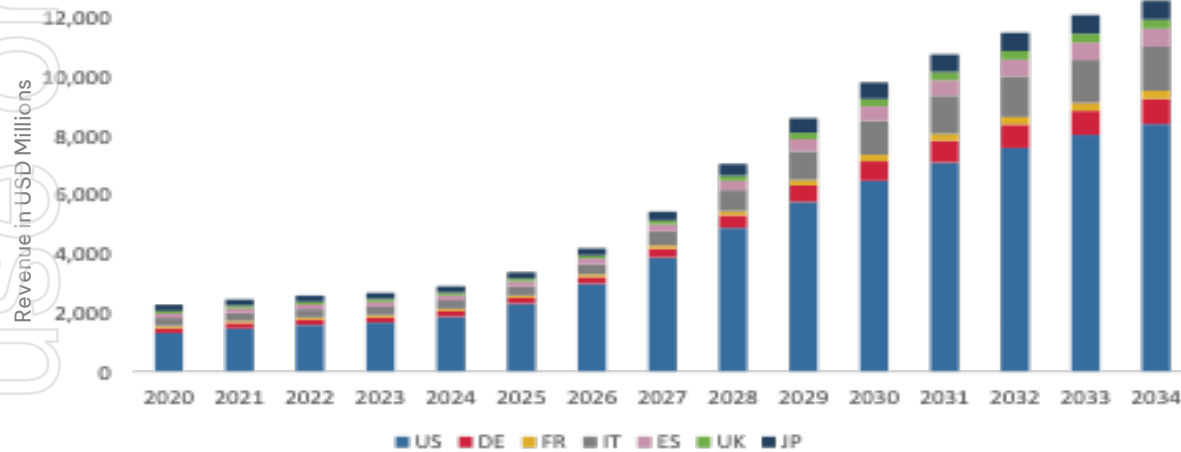


\*Preliminary enrollment update; data and number of evaluable patients subject to change with full statistical analysis



# IMUGENE IS PURSUING LARGE AND GROWING INDICATIONS

- The global solid tumor cancer treatment market size was estimated at USD 185.97 billion in 2022 and is projected to hit around USD 532.42 billion by 2032, growing at a compound annual growth rate (CAGR) of 11.09% during the forecast period 2023 to 2032.<sup>1</sup>



- Bladder cancer is a highly recurrent disease
- Total (NMI)<sup>2</sup> bladder cancer market size was USD \$2.3 B in 2020
- Expected to grow to USD \$12.5B by 2034 at a compound annual growth rate (CAGR) of 12.3%





Delveinsight Non-muscle Invasive Bladder Cancer (NMIBC) Market Insight, Epidemiology, and Market Forecast – 2034 (January 2024)

- Bile tract cancer
- Total market size was USD \$613 million in 2020
- Expected to grow to USD \$2.2B million by the end of 2034, at a compound annual growth rate (CAGR) of 9.4%

Delveinsight Biliary Tract Cancer Market Insight, Epidemiology, and Market Forecast – 2034 (February 2024)

<sup>1</sup><https://www.precedenceresearch.com/solid-tumor-cancer-treatment-market> <sup>2</sup>Non muscle invasive (NMI)

# OTHER ONCOLYTIC VIRUSES IN DEVELOPMENT

COMPANY	MARKET CAP (USD)	ASSET/TARGET CANCERS
 Replimune®	\$561.49 M	RP1, Various solid cancers
 GENELUX	\$81.414 M	Olvi-Vec, Ovarian cancer
 GCG ONCOLOGY™	\$2.09 B	cretostimogene grenadenorepvec, Bladder cancer
 CANDEL THERAPEUTICS	185.98 M	Lung, pancreatic, prostate, brain cancers

- Oncolytic viruses are validated, generating interest from other companies
- Imugene has differentiated oncolytic viruses and a unique opportunity

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# ONCARLYTICS FOR SOLID TUMORS

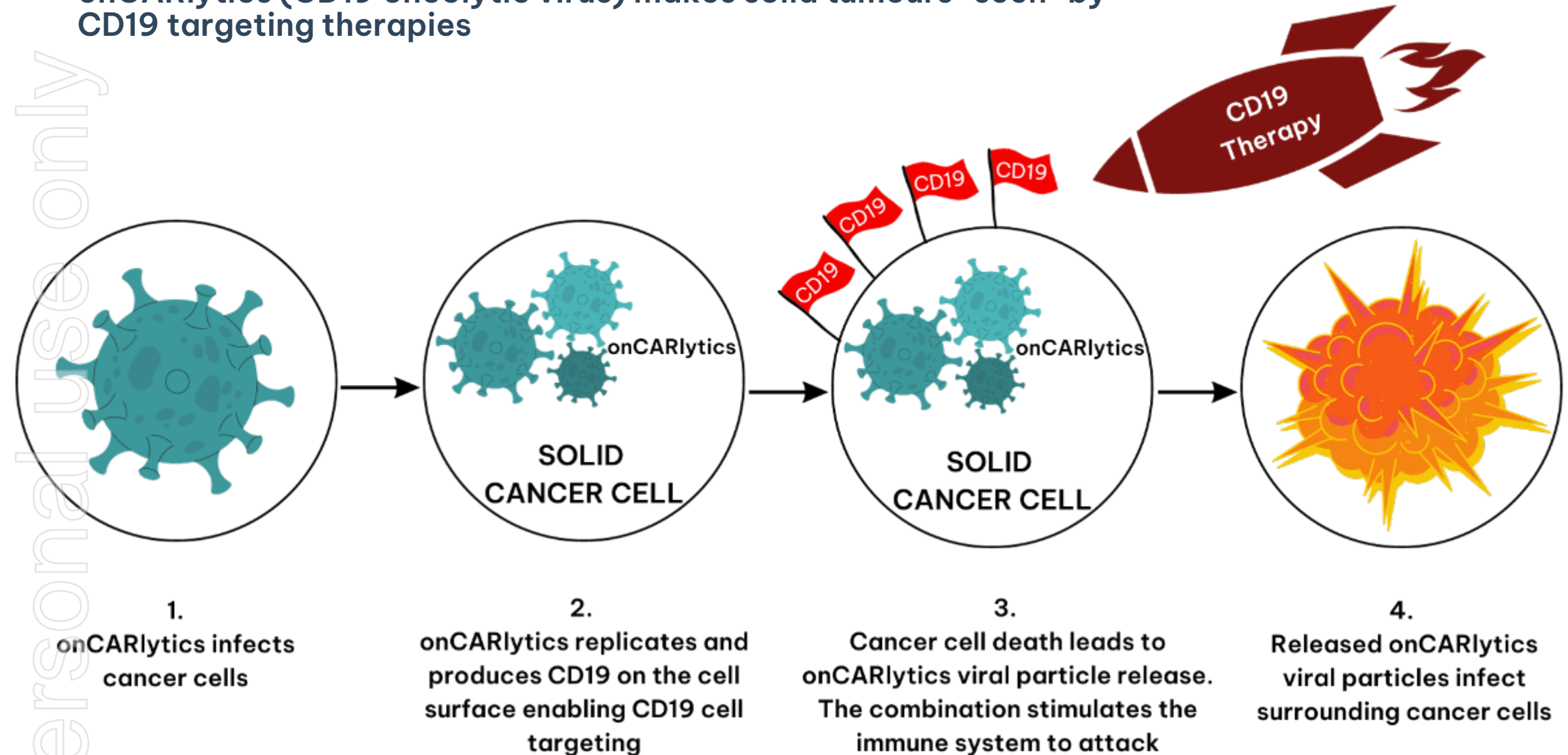
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# HOW DOES ONCARLYTICS WORK?

onCARlytics (CD19 oncolytic virus) makes solid tumours “seen” by CD19 targeting therapies

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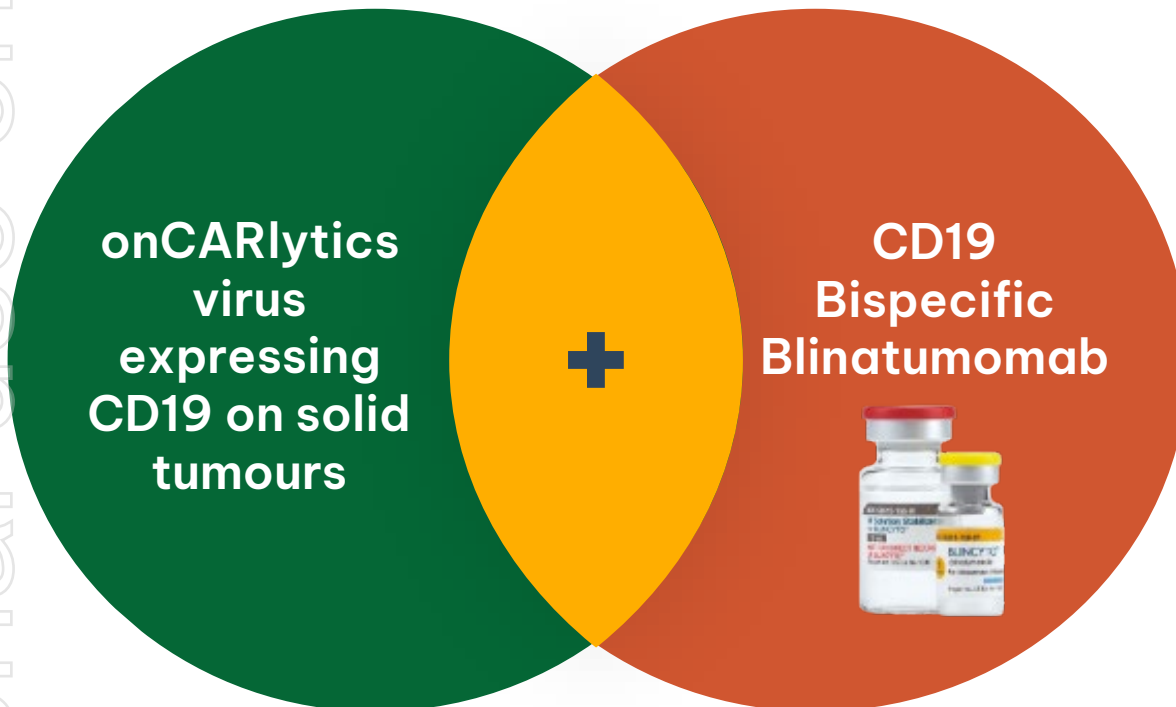




# ONCARLYTICS (CF33-CD19)

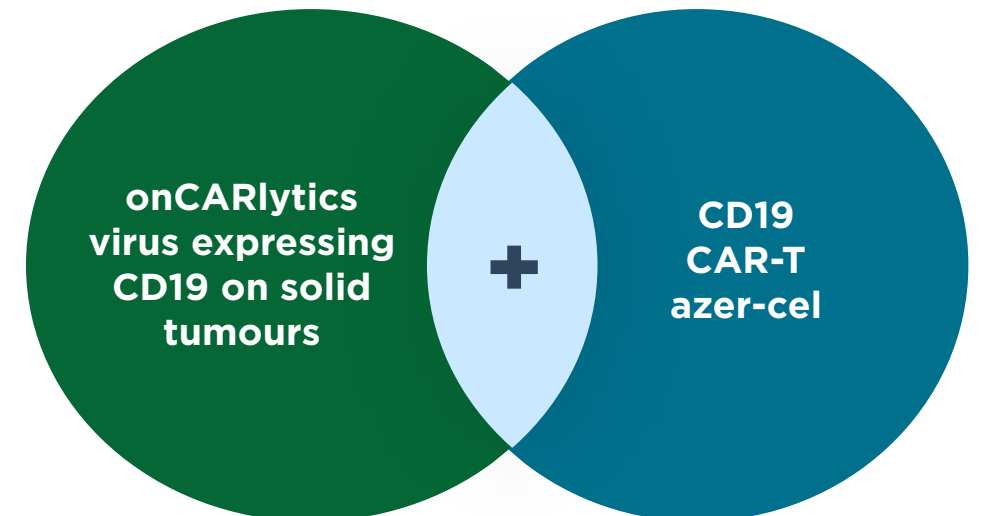
Combination treatment for solid tumours

## Current Clinical Trial



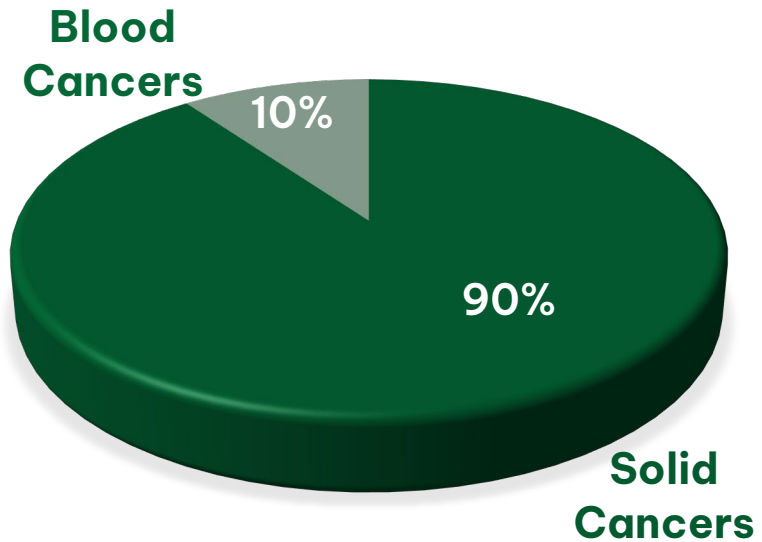
- Phase 1 trial in solid tumour patients
- Combination cohort open for enrolment
- FPI IV combination in June, 2024

- Preclinically, azer-cel in combination with onCARlytics demonstrated sustained, robust activity against multiple tumour types
- Showed 100% killing of Triple Negative Breast Cancer and Gastric Cancer at 72 hours



# VARIETY OF APPROVED THERAPIES AVAILABLE FOR COMBINATION WITH ONCARLYTICS













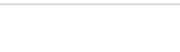
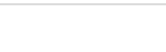


onCARlytics can become the preferred partner for CD19 therapies in solid tumours (~90% of cancer market)











- Global blood cancer CAR T market ~USD \$3B in 2023; projected to be ~USD \$23B by 2033, growing at a compound annual growth rate of 23.35%<sup>1</sup>
- The global solid tumor cancer treatment market size estimated at USD 185.97 billion in 2022 and is projected to grow around USD 532.42 billion by 2032

<sup>1</sup><https://www.precedenceresearch.com/solid-tumor-cancer-treatment-market>

## Combination Opportunities

COMPANY	FIRST FDA APPROVAL	TARGET	APPROVED CANCERS
 <b>KYMRIAH<sup>®</sup></b> (tisagenlecleucel)  <b>NOVARTIS</b>	2017	CD19 Auto CAR T	B-ALL, DLBCL
 <b>YESCARTA<sup>®</sup></b> (axicabtagene ciloleucel)  <b>Kite</b> A GILEAD Company	2017	CD19 Auto CAR T	DLBCL, R/R FL
 <b>TECARTUS<sup>®</sup></b> (brexucabtagene autoleucel)  <b>Kite</b> A GILEAD Company	2020	CD19 Auto CAR T	R/R MCL
 <b>Breyanzi<sup>®</sup></b> (lisocabtagene maraleucel)  <b>Bristol Myers Squibb<sup>®</sup></b>	2021	CD19 Auto CAR T	DLBCL
 <b>MONJUVI<sup>®</sup></b> (tolastamab-cxix)  <b>morphosys</b>	2020	CD19 Monoclonal Antibodies (MAbs)	DLBCL
 <b>Uplizna<sup>®</sup></b> (inebilizumab-cdon)  <b>HORIZON</b>	2020	CD19 MAbs	NMOSD
 <b>BLINCYTO<sup>®</sup></b> (binatumomab)  <b>AMGEN</b>	2014	CD19-CD3 Bispecific MAbs	ALL
 <b>Zynlonta<sup>®</sup></b> (loncastatamab-hera)  <b>ADC</b>	2021	CD19 Antibody- drug conjugate (ADC)	B-Cell Lymphoma

# COMPANIES DEVELOPING CAR T THERAPEUTICS

COMPANY	MARKET CAP (USD)	DRUGS/TARGETS
 NOVARTIS	\$234.50 B	Kymriah <sup>®</sup> , first CAR T-cell therapy
 Bristol Myers Squibb <sup>®</sup>	\$82.45 B	Breyanzi <sup>®</sup> , Abecma <sup>®</sup>
 GILEAD Creating Possible	\$84.88 B	Yescarta <sup>®</sup> and Tecartus <sup>®</sup> (acquired from Kite for \$11.9B)
 Autolus	\$900.53 M	AUTO 06NG in development
 LEGEND BIOTECH	\$8.24 B	LCAR-B38M in development
 BIONTECH	18.71 B	BNT211 in development
 Allogene THERAPEUTICS	\$460.53 M	Multiple therapies in development
 ImmunityBio	\$4.27 B	Bladder, ovarian, lung, HPV, lung, and other solid cancers

- CAR T therapies drive significant shareholder value
- CAR Ts are validated in blood cancers; a huge opportunity exists in solid tumors
- Imugene's azer-cel CAR T is a differentiated CAR T and represents a unique and large opportunity

# RECENTLY ACHIEVED AND EXPECTED 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
  - ☑ IT Mono Bile Tract Expansion Open

- **ONCARLYTICS:**

- ☑ FPI in Monotherapy IV arm
  - ☑ Combination arm opened
  - ☑ FPI in Combination IV arm Cohort 2

**Key:**

**FPI**, First Patient In, **Combo**: Combination Therapy

**Mono**: Monotherapy,

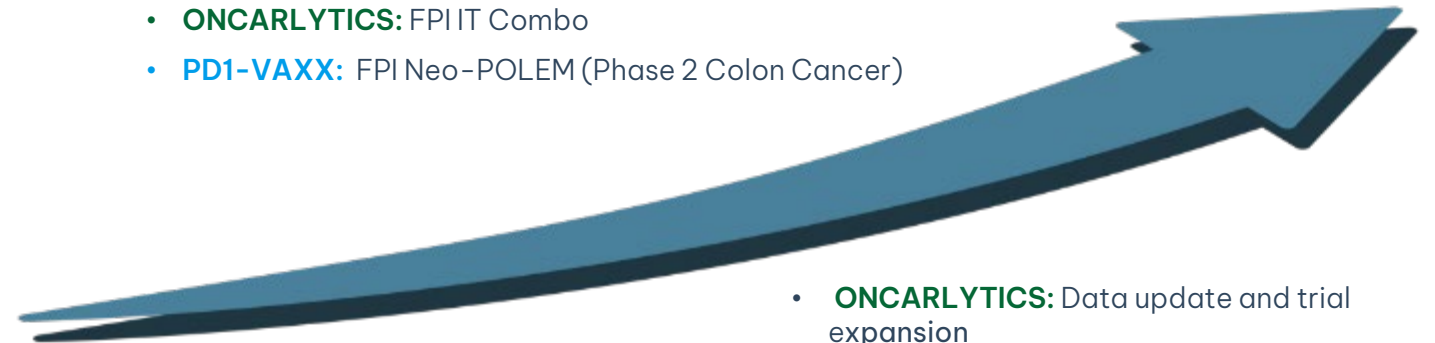
**IA**: Intra-arterial, **IP**: Intraperitoneal,

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



### H2 2024

- **VAXINIA**: IT Expansion Open other indication
- **AZER-CEL**: Prelim early Phase 1b data update
- **ONCARLYTICS**: FPI IT Combo
- **PD1-VAXX**: FPI Neo-POLEM (Phase 2 Colon Cancer)



### 2025

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

# IMUGENE COMMERCIALISATION STRATEGY

## MULTIPLE VALUE REALISATION PATHWAYS



**COMPANY  
ACQUISITION**



**PARTNER WITH BIG  
PHARMA**



**LICENSE  
TECHNOLOGIES  
SEPARATELY**



**DEVELOP /  
COMMERCIALISE  
INDEPENDENTLY**

- The global model for biotech commercialisation is to out-license the technology to Big Pharma in Phase 1b/2 trials
- Conducting Phase 3 trials, obtaining FDA approval for the product not within the remit of biotech
- Out-licensing is highly dependent upon demonstrating safety in Phase 1 and convincing signals of efficacy in Phase 1b/2
- Licensing deals are generally structured with an up-front cash payment, payments upon reaching certain development milestones such as entering Phase 3 trials, payment on FDA approval of the drug, and royalties on net sales when the drug is on the market



# INVESTMENT HIGHLIGHTS

Strong cash position



Expert leaders with 13 prior FDA approved cancer drugs



Numerous key catalysts expected in 2024



Long-life patent portfolio



4 cancer therapeutics in 4 clinical trials



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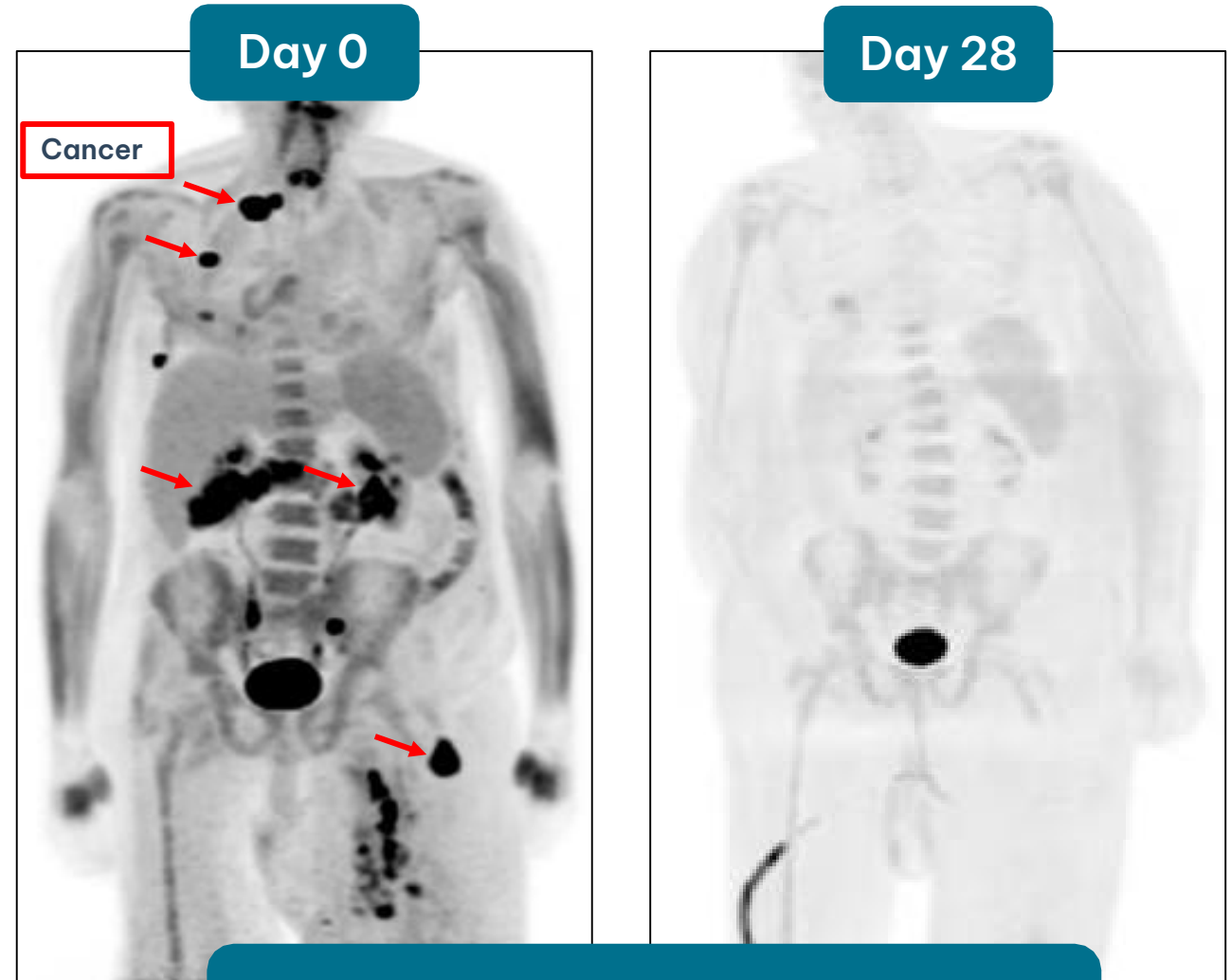
# APPENDICIES

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# AZER-CEL PRIOR PHASE 1 CASE STUDY

## Complete Response

- 63-year-old male with DLBCL (Blood Cancer)
- Complete response (CR), or the disappearance of all signs of cancer, with azer-cel treatment
- Response seen at day 28
- Prior to azer-cel, patient had failed 8 prior cancer treatments



Outcome: Day 28 Complete Response

# PHASE 1 VAXINIA

## Metastatic Advanced Solid Tumour (MAST) Trial



### Dose Administration (Parallel Groups)

n=52-100 patients

IT

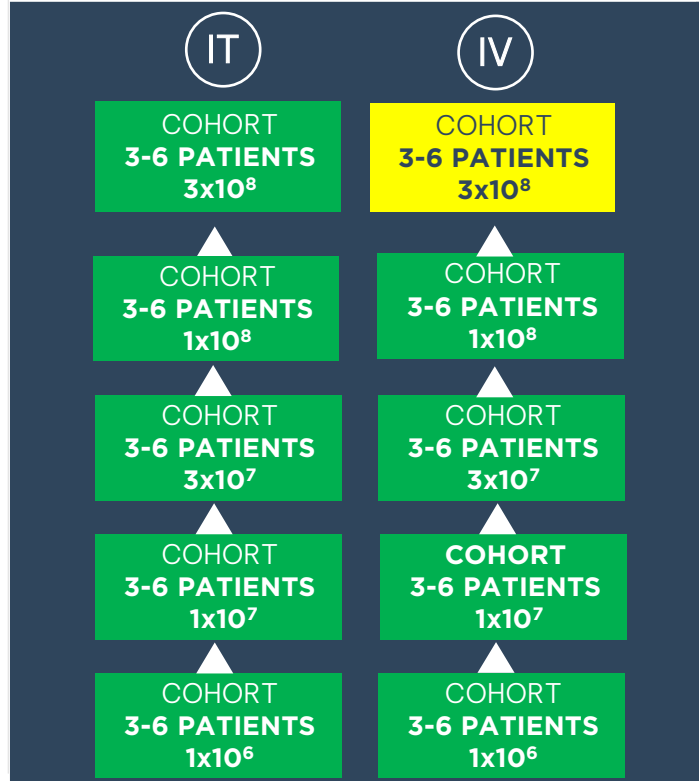
**Intratumoural (IT) Administration**  
Metastatic and Advanced Solid Tumours

IV

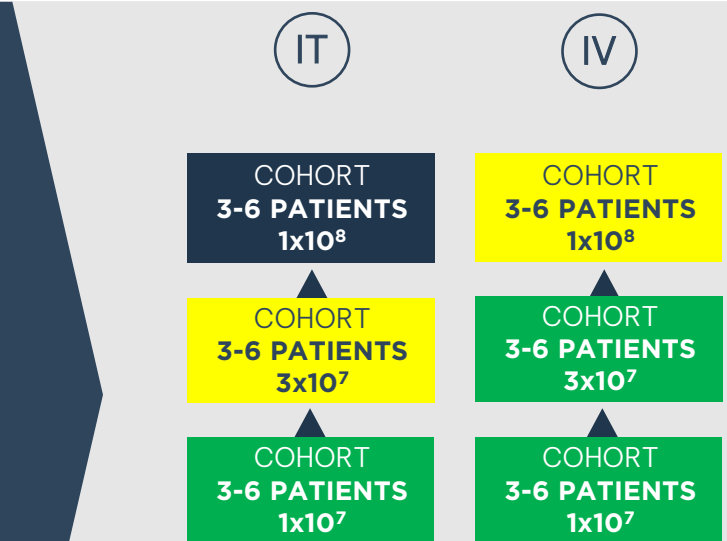
**Intravenous (IV) Administration**  
Metastatic and Advanced Solid Tumours

**Site Location:** USA, AUS

### VAXINIA Monotherapy Dose Escalation



### VAXINIA + Pembrolizumab Combination Dose Escalation



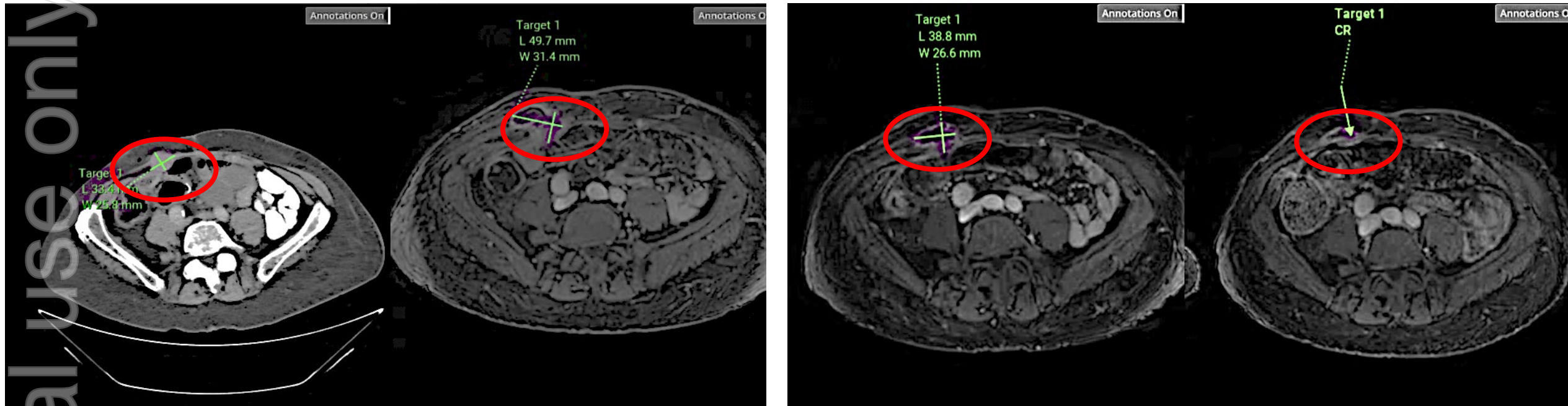
### Cohort Expansion

**Expansion Cohorts (N=10)**

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

# 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



# PHASE 1 ONCARLYTICS (CF33 + CD19)

## OASIS TRIAL

### Dose Administration (Parallel Groups)

IT

#### Intratumoural (IT) Administration

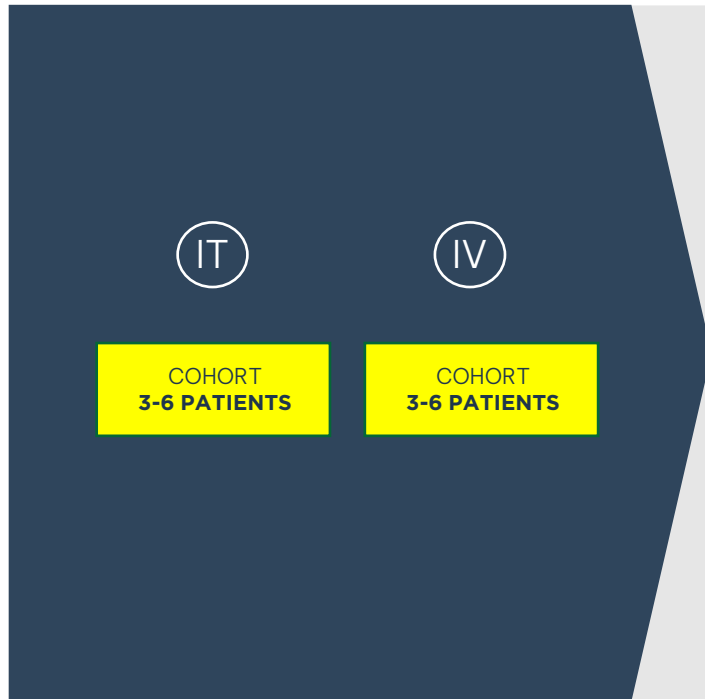
Metastatic and  
Advanced Solid  
Tumours

IV

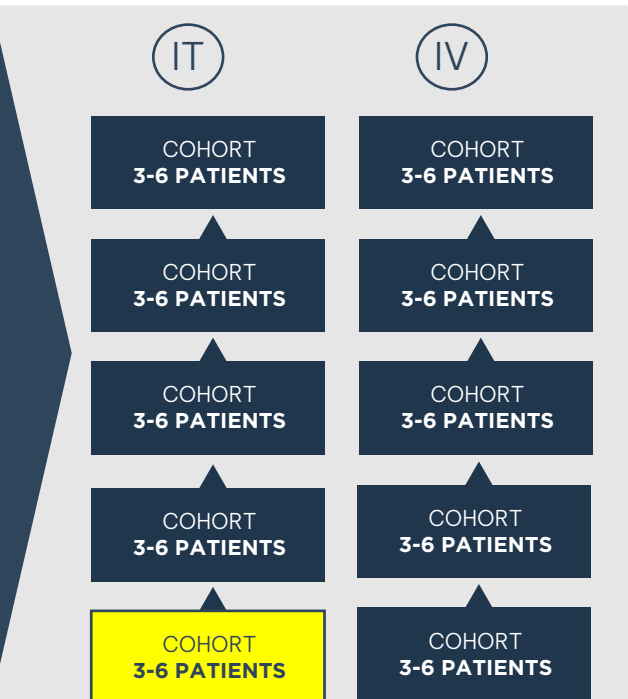
#### Intravenous (IV) Administration

Metastatic and  
Advanced Solid  
Tumours

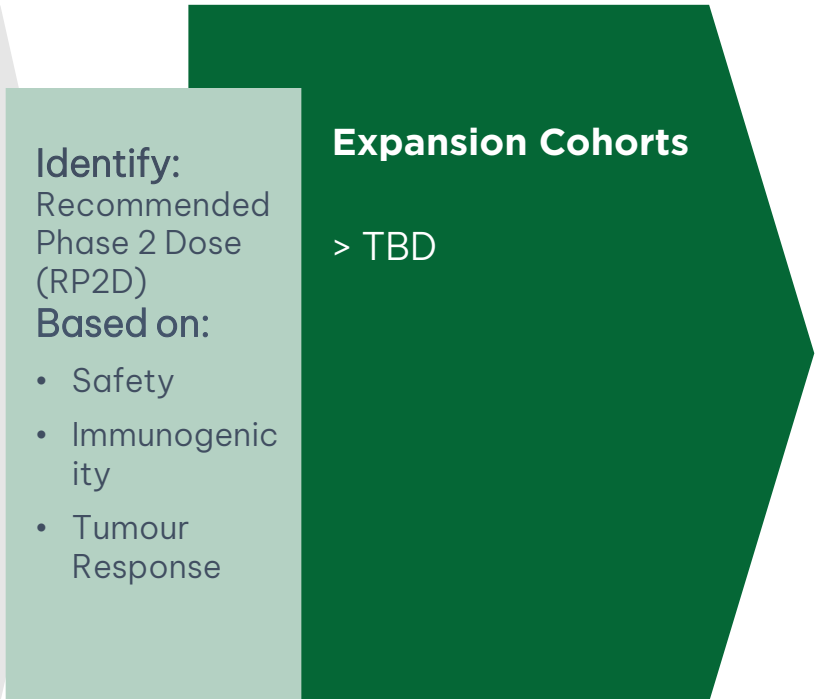
### CF33+CD19 Monotherapy Safety Run In



### CF33+CD19 + Blinatumomab Combination Dose Escalation



### Cohort Expansion



# RECENT DEALS IN CELL THERAPY SUPPORT EXPANDING MARKET

Date	Deal Type	Deal Summary (Licensor, Licensee)	Technology	Indication	Stage	Financials
May 2022	Collaboration and license agreement	Cellular Biomedicine, Janssen	CAR T therapies (CD19/CD20 bispecific and CD20)	B cell malignancies	Phase I	\$245mm upfront cash payment + milestones and royalties
Nov 2022	Acquisition	AstraZeneca, Neogene Therapeutics	TCR T cell therapies	Solid tumors	Phase I	\$200mm upfront cash for equity + \$120mm milestones
Sep 2022	Collaboration and license agreement	Arsenal Bio, Genentech	Screening and T cell engineering tools	Solid Tumours	Preclinical	\$70mm upfront cash payment + milestones and royalties
Aug 2022	Strategic global collaboration	Poseida Therapeutics, Roche	Allogeneic CAR T cell therapies	B cell malignancies	Preclinical	\$110mm upfront cash payment + milestones and royalties <i>Potentially worth \$6B+</i>
Jan 2022	Strategic collaboration	Century Therapeutics, Bristol Myers Squibb	iPSC-derived allogeneic NK and T cell therapies	Hematologic malignancies and solid tumors	Preclinical	\$150mm upfront cash (\$50mm for equity) + milestones and royalties <i>Potentially worth \$3B+</i>
Sep 2021	Strategic collaboration	Adaptimmune, Genentech	iPSC-derived allogeneic T cell therapies	Oncology indications	Preclinical	\$150mm upfront cash payment + milestones and royalties <i>Potentially worth \$3B+</i>
Jan 2021	Discovery collaboration	Arsenal Bio, Bristol Myers Squibb	Anti-CA215 CAR-T cell therapy	Solid tumors	Preclinical	\$70mm upfront cash payment + milestones and royalties



**IMUGENE**

Developing Cancer Immunotherapies

ASX:IMU

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