

# 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



# THREE NOVEL TECHNOLOGIES ADVANCING THROUGH THE CLINIC

 **Allo CAR T Cell Therapy**  
IMUGENE



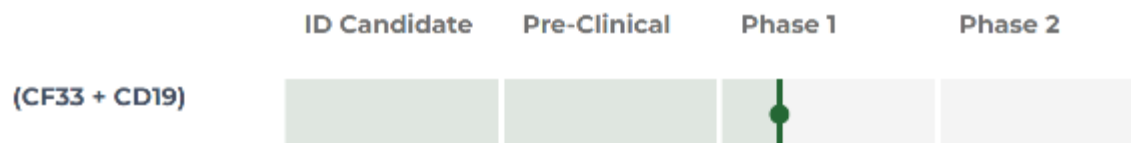
**azer-cel trial:** In patients with DLBCL blood cancer who failed autologous CAR T therapy

 **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



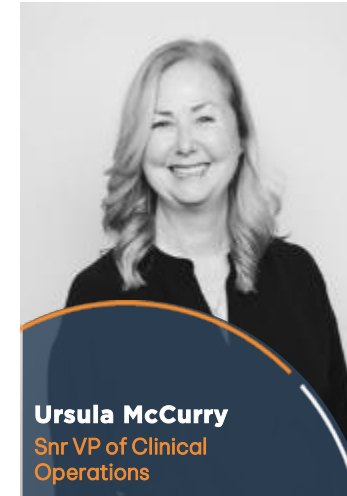
**onCARlytics OASIS trial:** in patients with advanced or metastatic solid tumours in combination with blinatumomab

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

\* DLBCL (diffuse large B cell lymphoma)

# IMUGENE CLINICAL EXECUTIVE TEAM

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

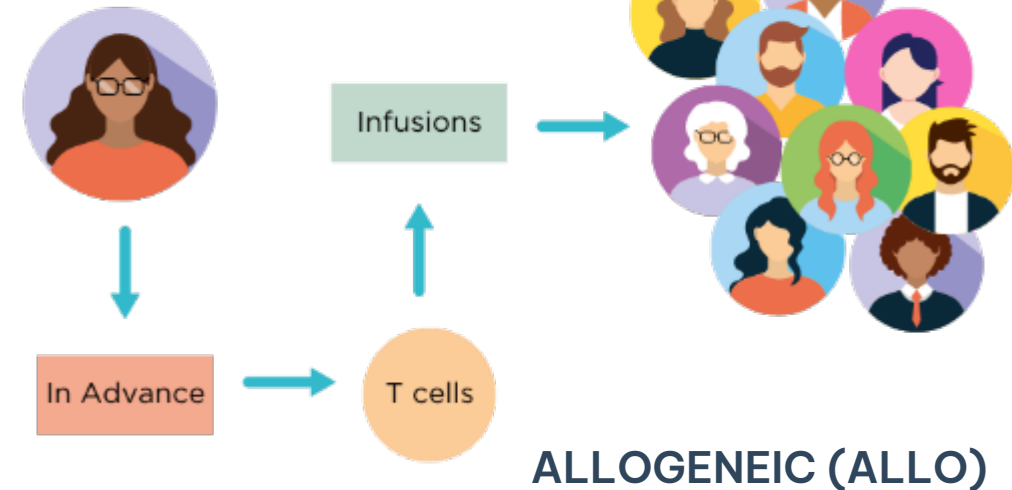
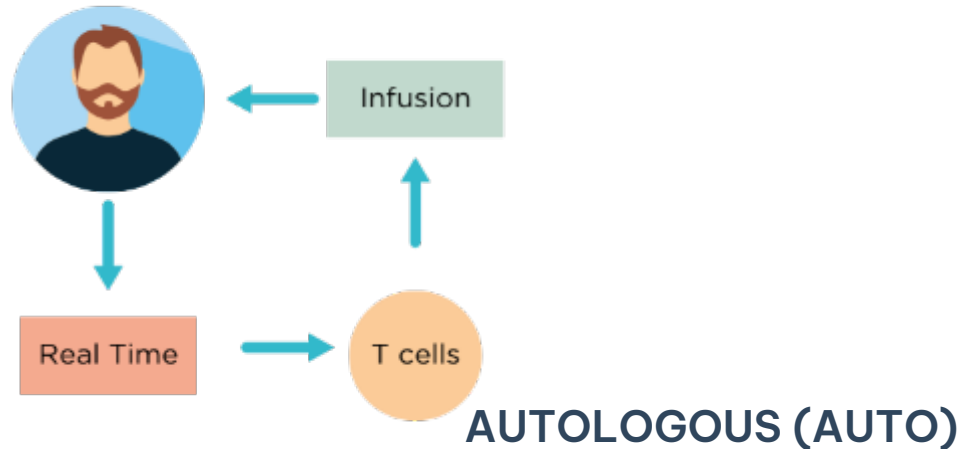


# AZER-CEL CD19 ALLOGENEIC CAR T CELL THERAPY



# 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

# 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



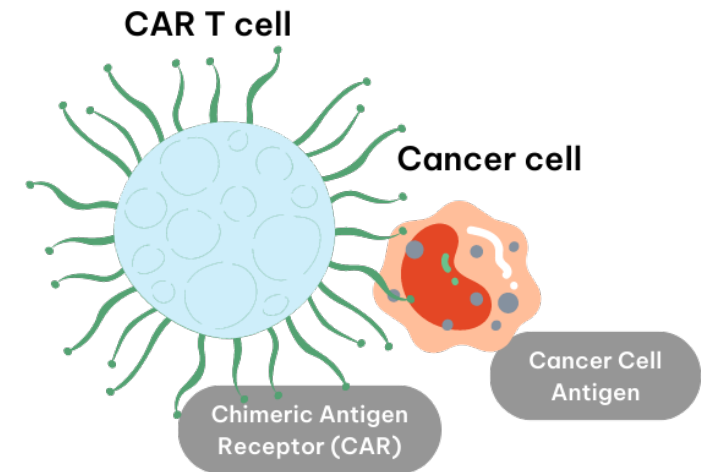
**HEALTHY** donors provide T Cells to make the CART product candidate. Donor T cells are processed for "**universal match**" and incorporated to chimeric antigen receptor designed to attack tumour cells.

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)



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

**Azer-cel**

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



## 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

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



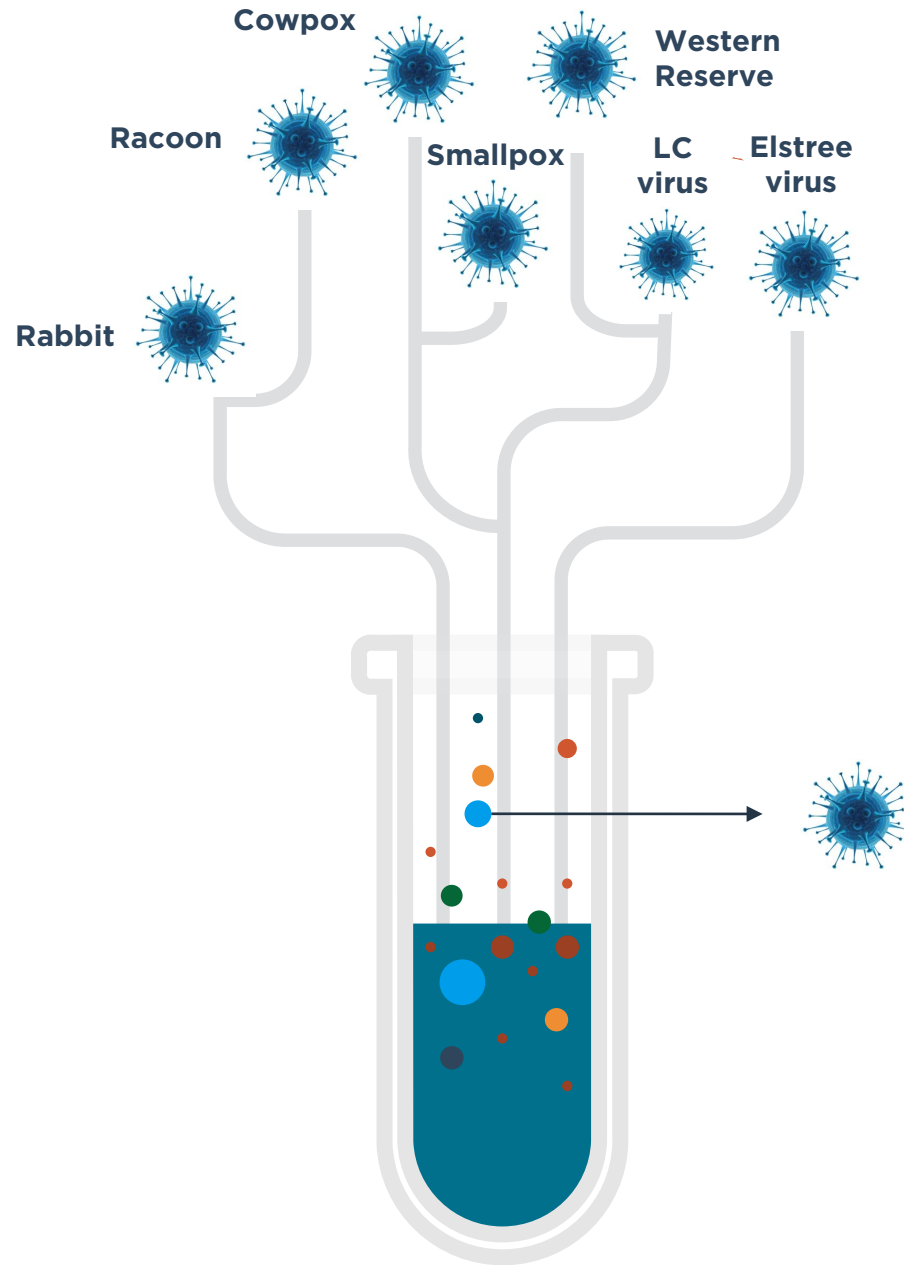
**CF33 Oncolytic Virus**  
IMUGENE

# CF33 ONCOLYTIC VIRUS



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

Engineered next-generation virus

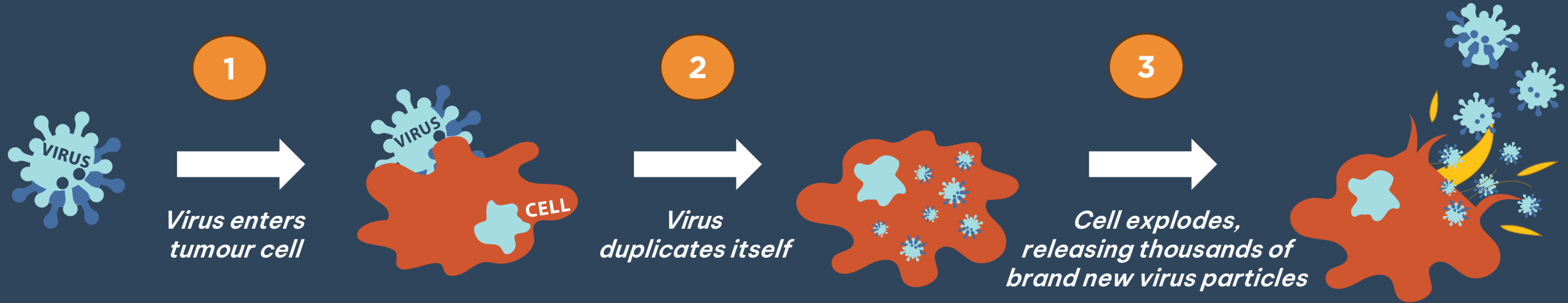


 **CF33 Oncolytic Virus**  
IMUGENE

**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

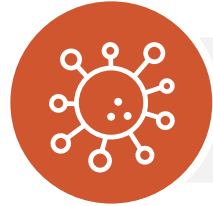
- Tvec approved in the United States for skin cancer (2015)
- Oncorine approved in China for head and neck cancer (2005)
- Delytact approved in Japan for brain cancer (2021)

# PHASE 1 MAST TRIAL - ENCOURAGING EARLY SIGNALS



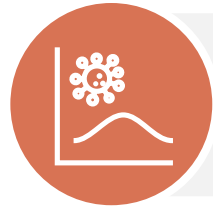
## Patients

- 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



HIGHLANDS ONCOLOGY

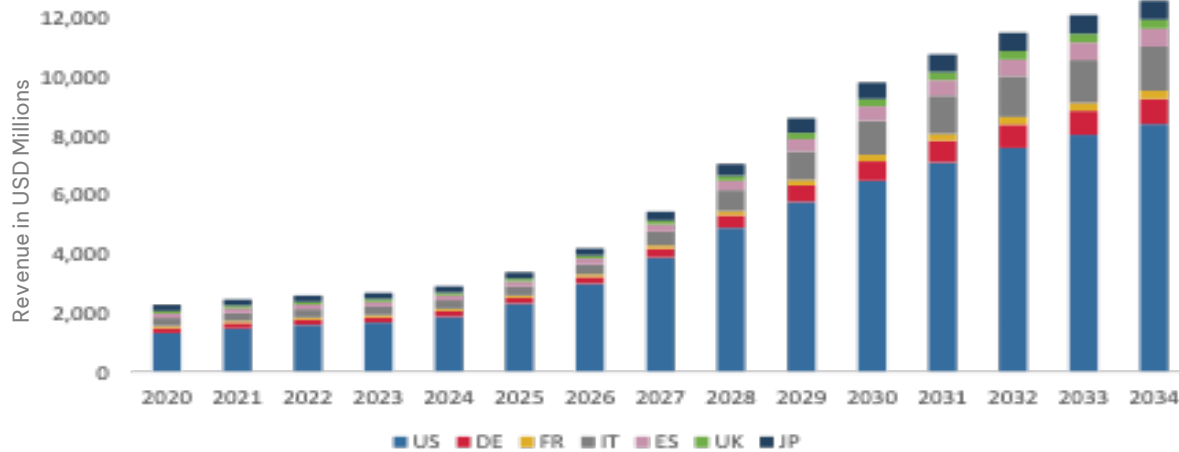


\*Preliminary enrollment update; data and number of evaluable patients subject to change with full statistical analysis



# 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%





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

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
	\$561.49 M	RP1, Various solid cancers
	\$81.414 M	Olvi-Vec, Ovarian cancer
	\$2.09 B	cretostimogene grenadenorepvec, Bladder cancer
	185.98 M	Lung, pancreatic, prostate, brain cancers

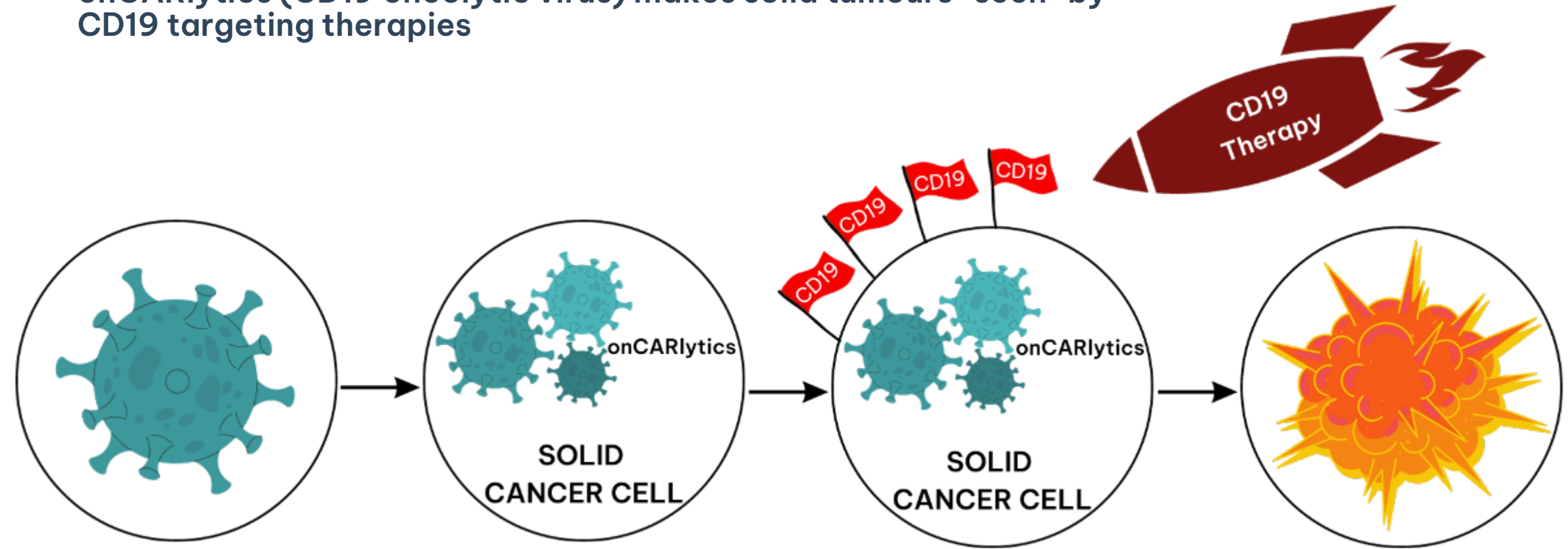
- Oncolytic viruses are validated, generating interest from other companies
- Imugene has differentiated oncolytic viruses and a unique opportunity

# ONCARLYTICS FOR SOLID TUMORS



# HOW DOES ONCARLYTICS WORK?

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



1.  
onCARlytics infects  
cancer cells

2.  
onCARlytics replicates and  
produces CD19 on the cell  
surface enabling CD19 cell  
targeting

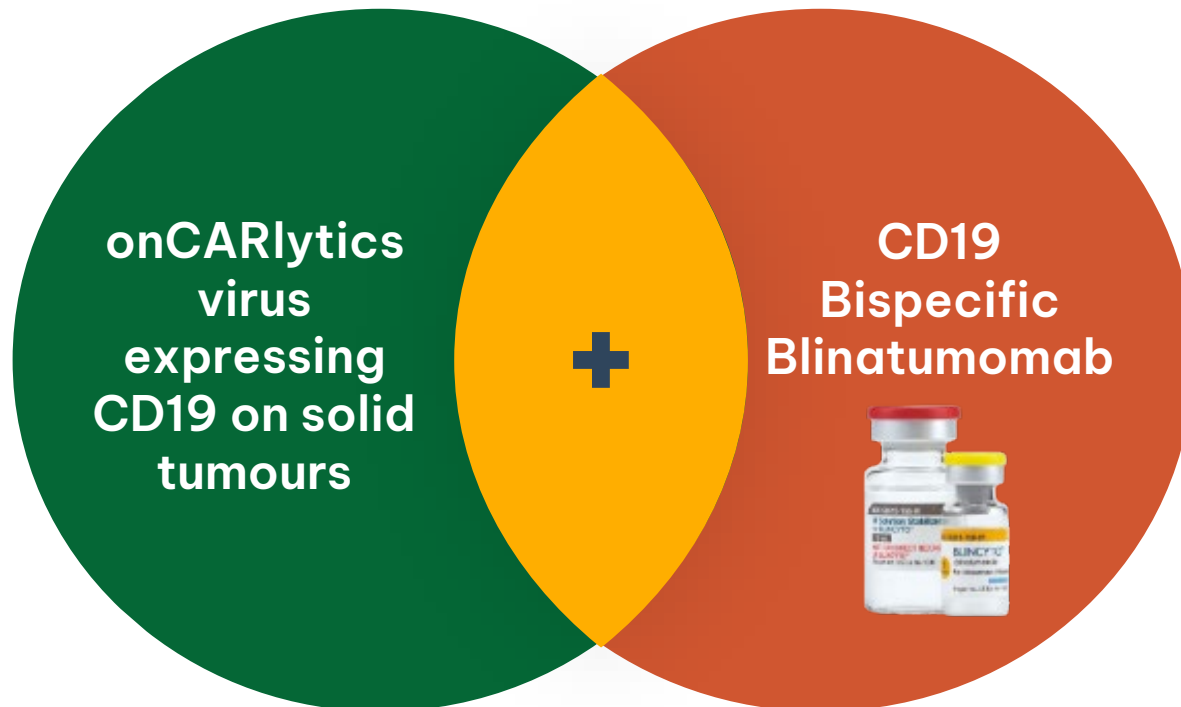
3.  
Cancer cell death leads to  
onCARlytics viral particle release.  
The combination stimulates the  
immune system to attack

4.  
Released onCARlytics  
viral particles infect  
surrounding cancer cells

# ONCARLYTICS (CF33-CD19)

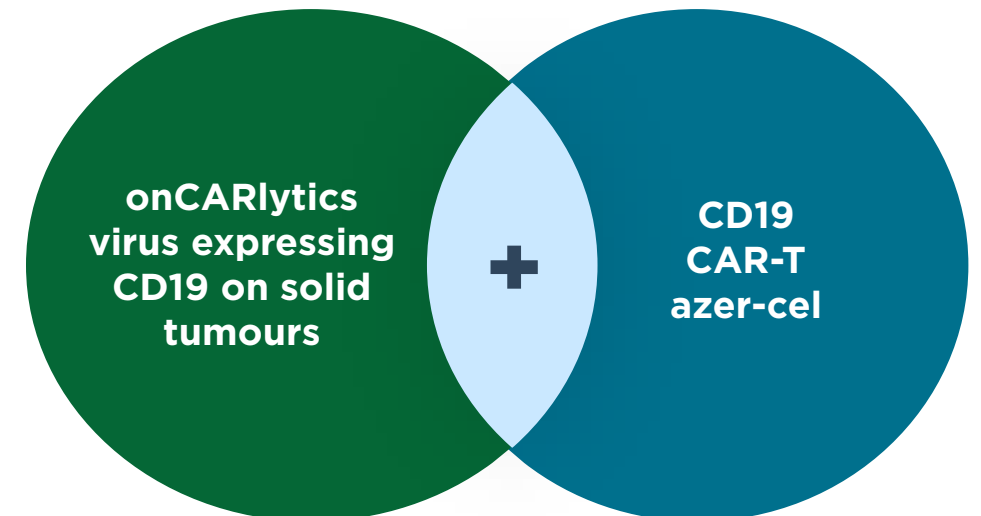
Combination treatment for solid tumours

## Current Clinical Trial



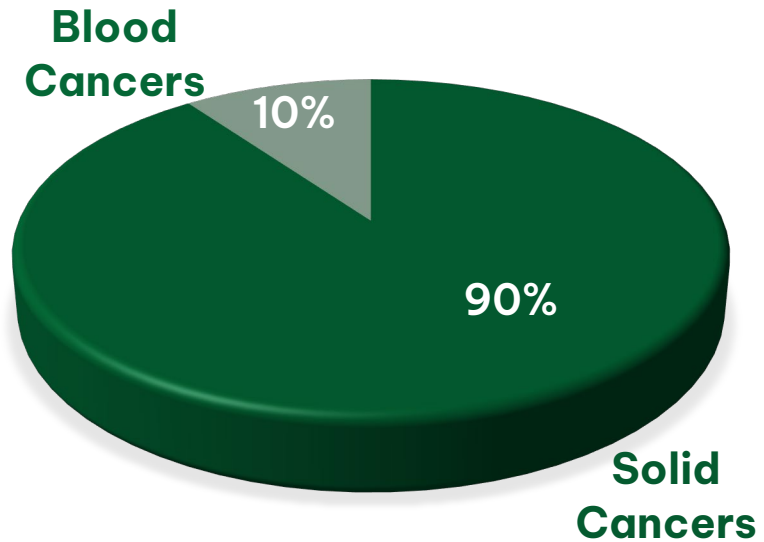
- Phase 1 trial in solid tumour patients
- Combination cohort open for enrolment
- FPI IV combination in June, 2024

- 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
	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

# 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 <sup>®</sup>	\$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:**
  - ☑ Kinell 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,

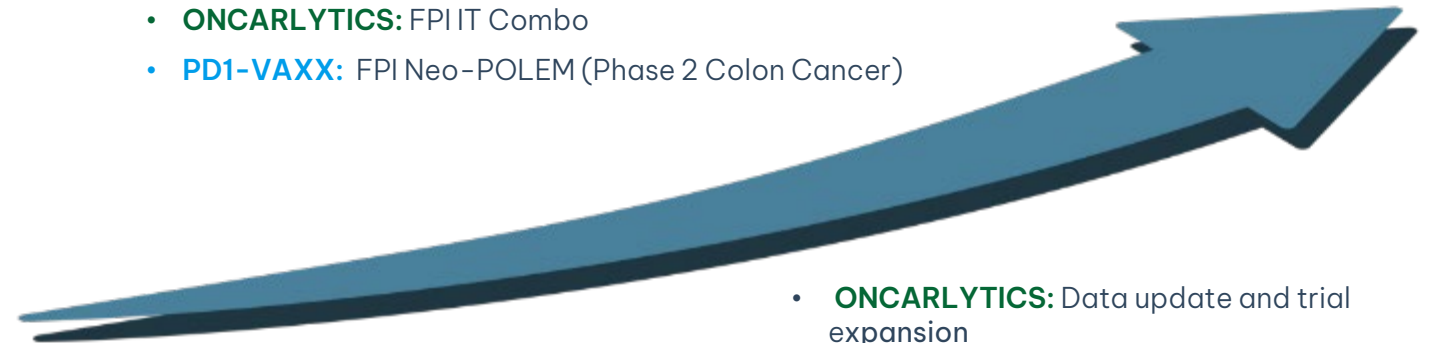
**IA:** Intra-arterial, **IP:** Intraperitoneal,

**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

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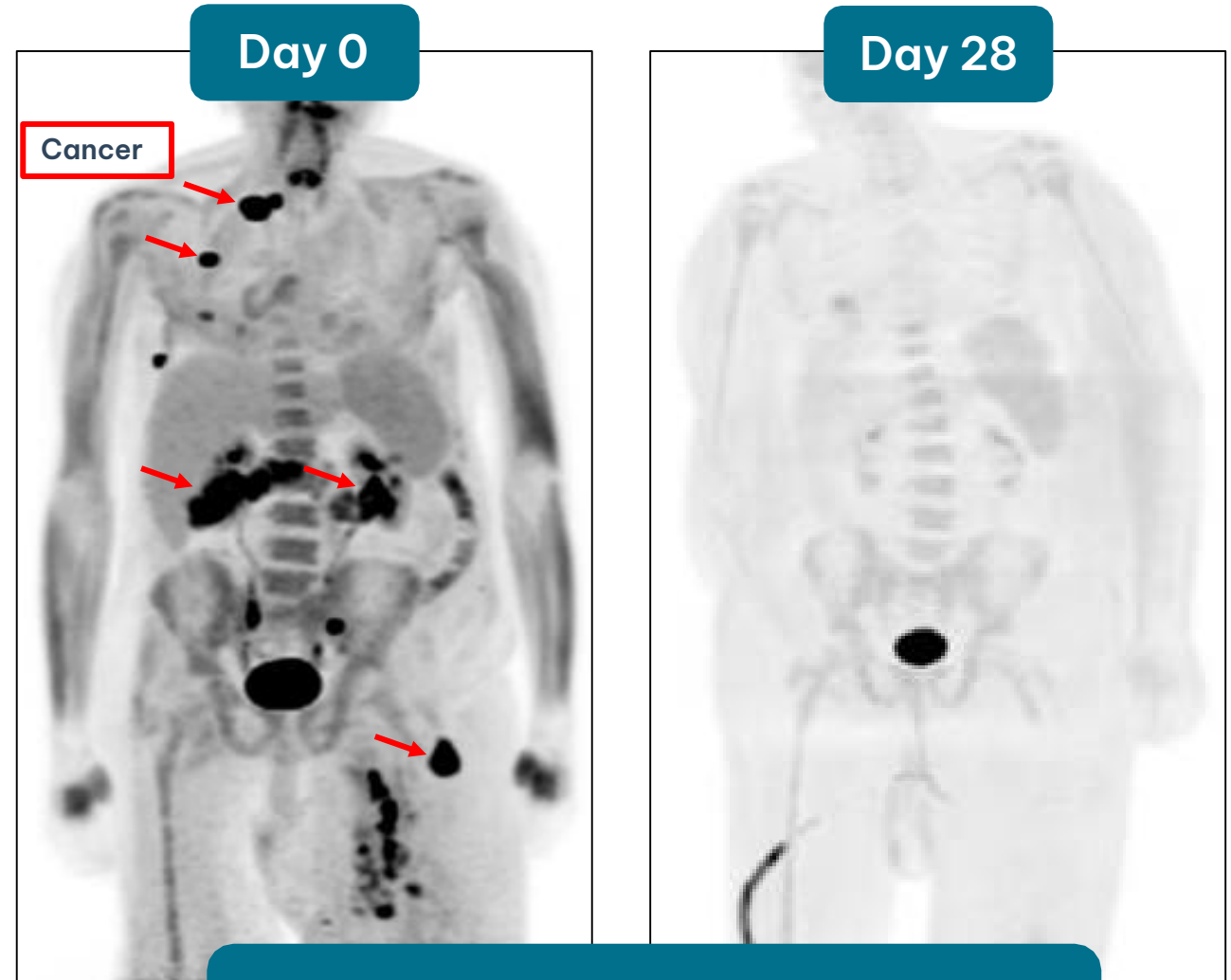


# APPENDICIES

# 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



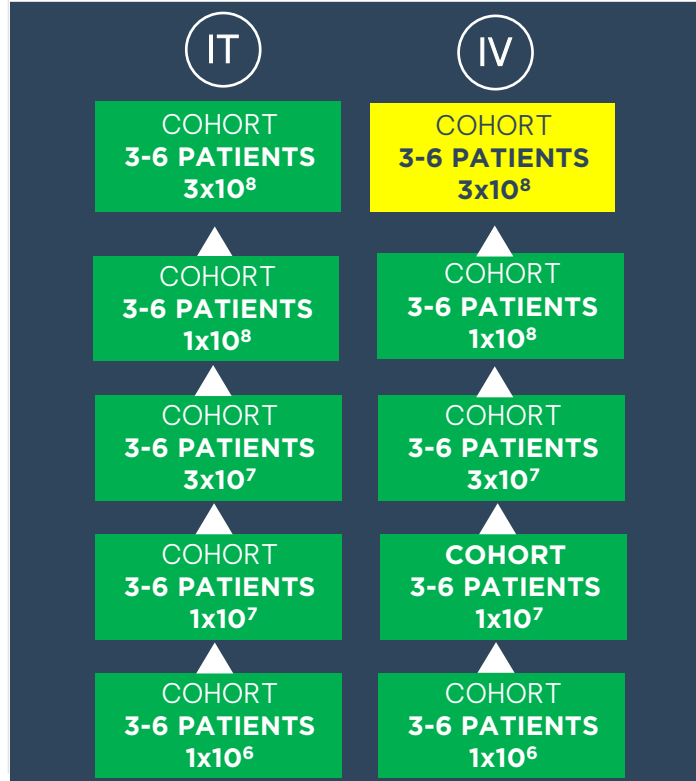
**Intratumoural (IT) Administration**  
Metastatic and Advanced Solid Tumours



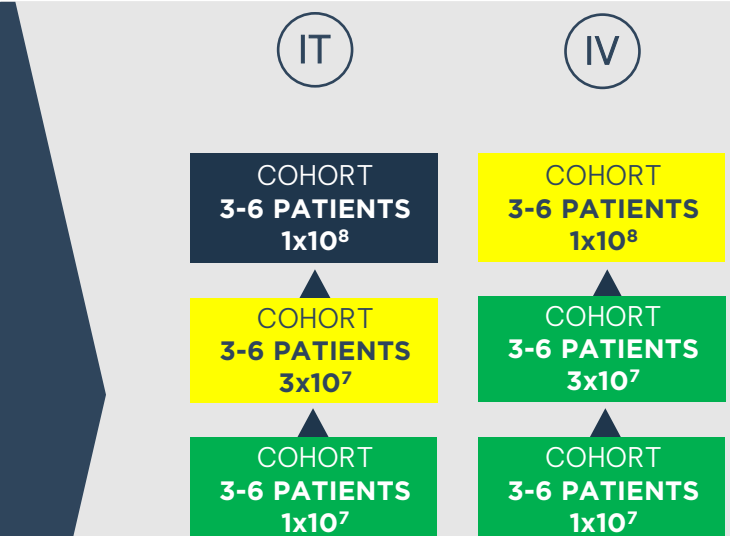
**Intravenous (IV) Administration**  
Metastatic and Advanced Solid Tumours

**Site Location:** USA, AUS

### VAXINIA Monotherapy Dose Escalation



### VAXINIA + Pembrolizumab Combination Dose Escalation



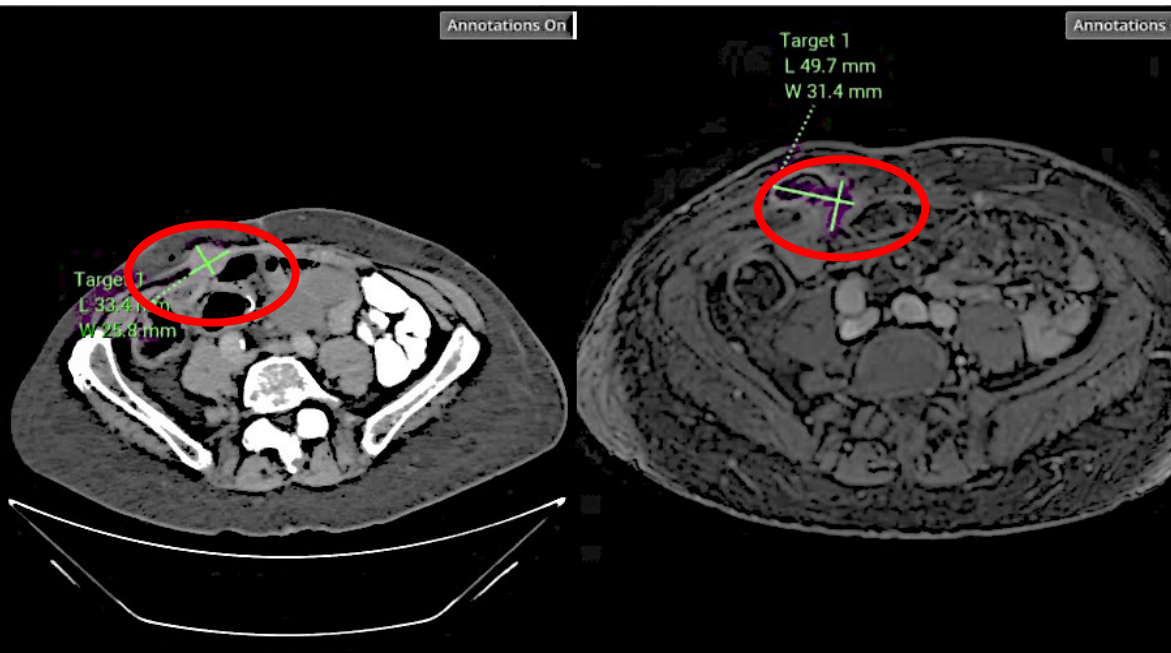
### Cohort Expansion

**Expansion Cohorts (N=10)**

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

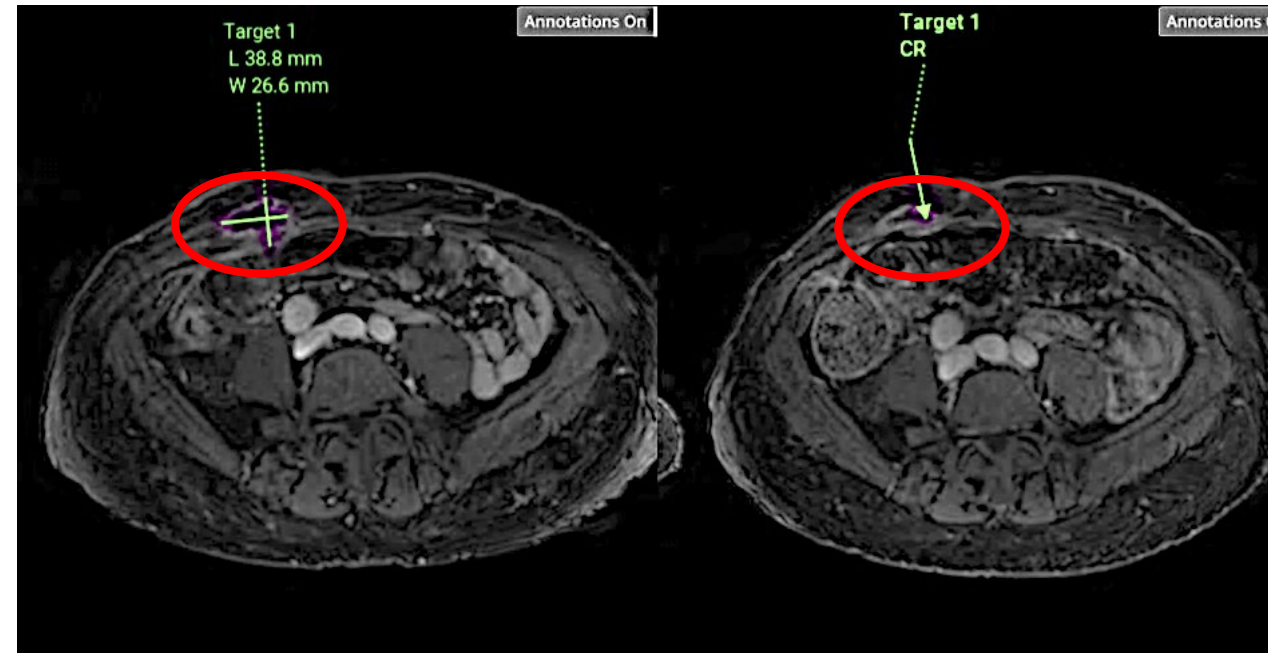
# TURNING COLD TUMOURS HOT

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)

### CF33+CD19 Monotherapy Safety Run In

### CF33+CD19 + Blinatumomab Combination Dose Escalation

### Cohort Expansion

IT

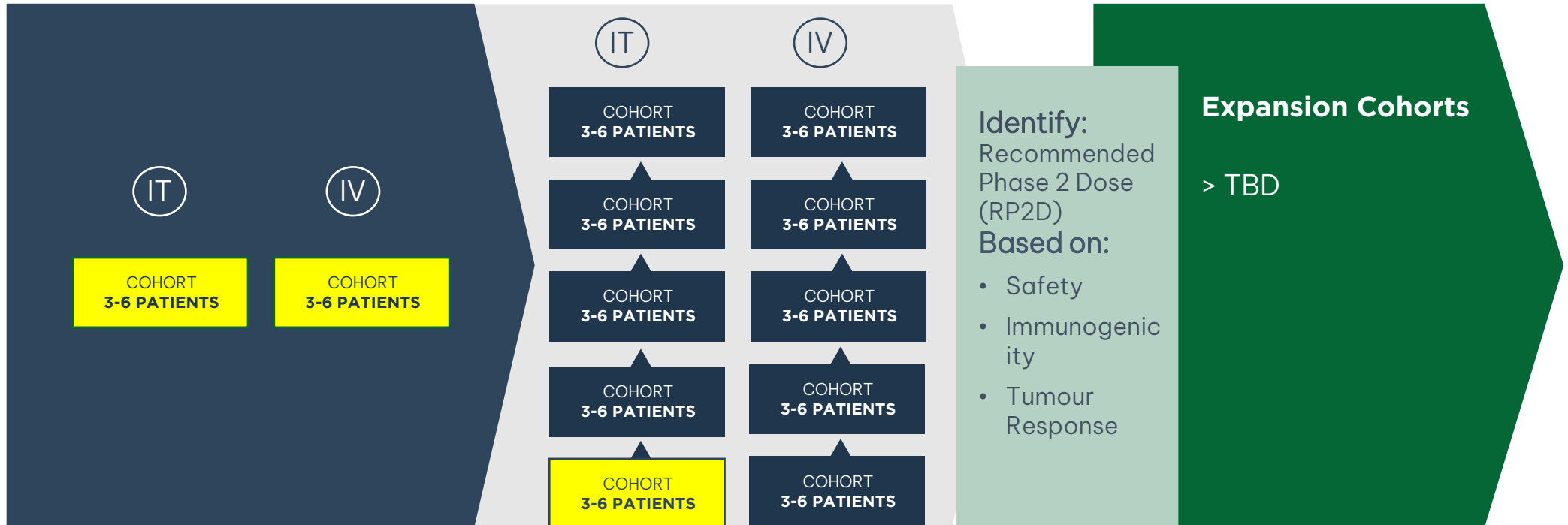
### Intratumoural (IT) Administration

Metastatic and Advanced Solid Tumours

IV

### Intravenous (IV) Administration

Metastatic and Advanced Solid Tumours



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

