



IMUGENE

Developing Cancer Immunotherapies

ASX: IMU

DEVELOPING CANCER IMMUNOTHERAPIES

Bell Potter Emerging Leaders Conference
May, 2024



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INVESTMENT HIGHLIGHTS

MARKET CAPITALISATION AS OF
27 MAY 2024

A\$520M



CASH AS OF
31 MARCH 2024

A\$114.1M



4 PLATFORM TECHNOLOGIES

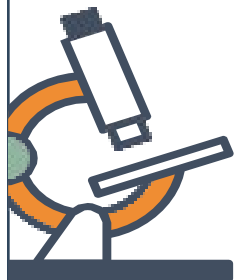
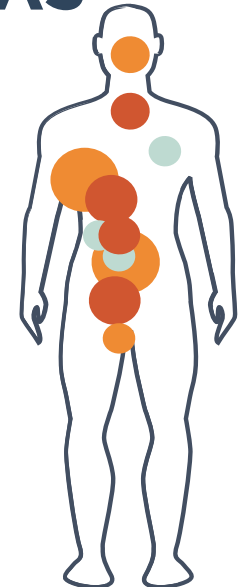
Allo CAR T Cell Therapy
CF33 Oncolytic Virus
onCARlytics
B Cell Immunotherapy



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)

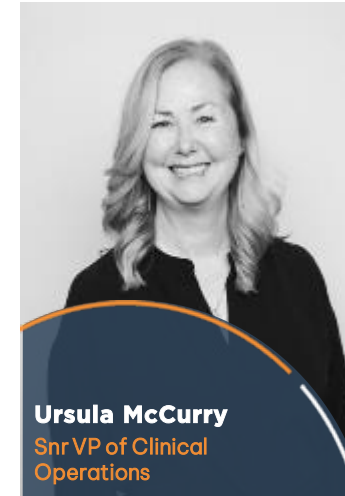
PD1-Vaxx: Ph2 neoPOLEM

LONG-LIFE PATENT PORTFOLIO



IMUGENE CLINICAL EXECUTIVE TEAM

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

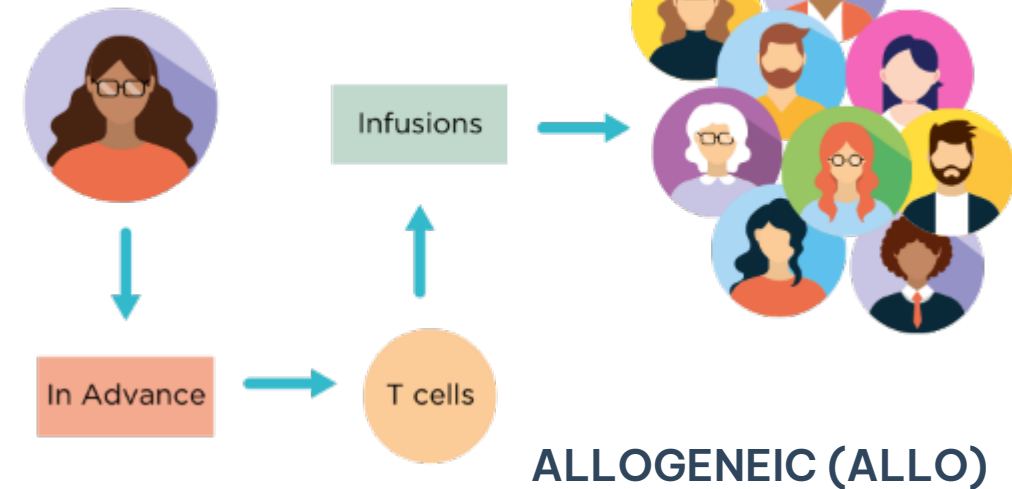
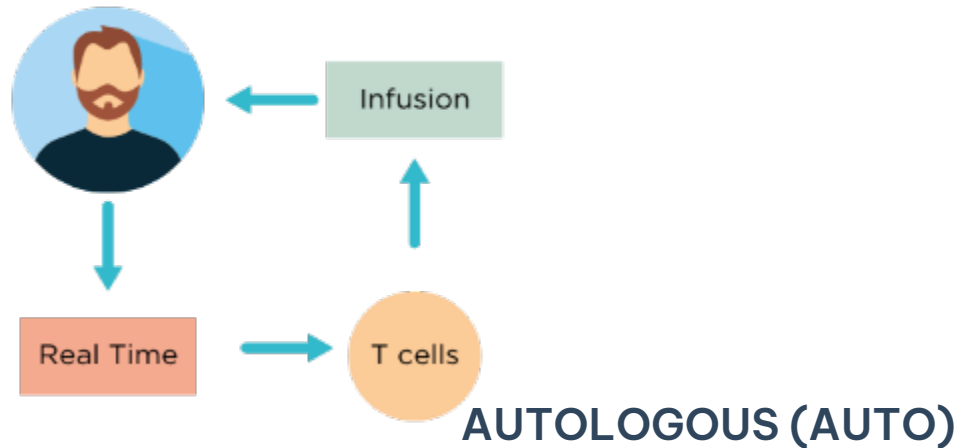


AZER-CEL CD19 ALLOGENEIC CAR T CELL THERAPY



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

AZER-CEL HAS MEANINGFUL CLINICAL ACTIVITY IN B CELL MALIGNANCIES

84 patients treated with azer-cel

61

Non-Hodgkin lymphoma (NHL)
Patients

58% ORR¹

41% CR²



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)



Note: Based on Patients Evaluable for Efficacy

¹N=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

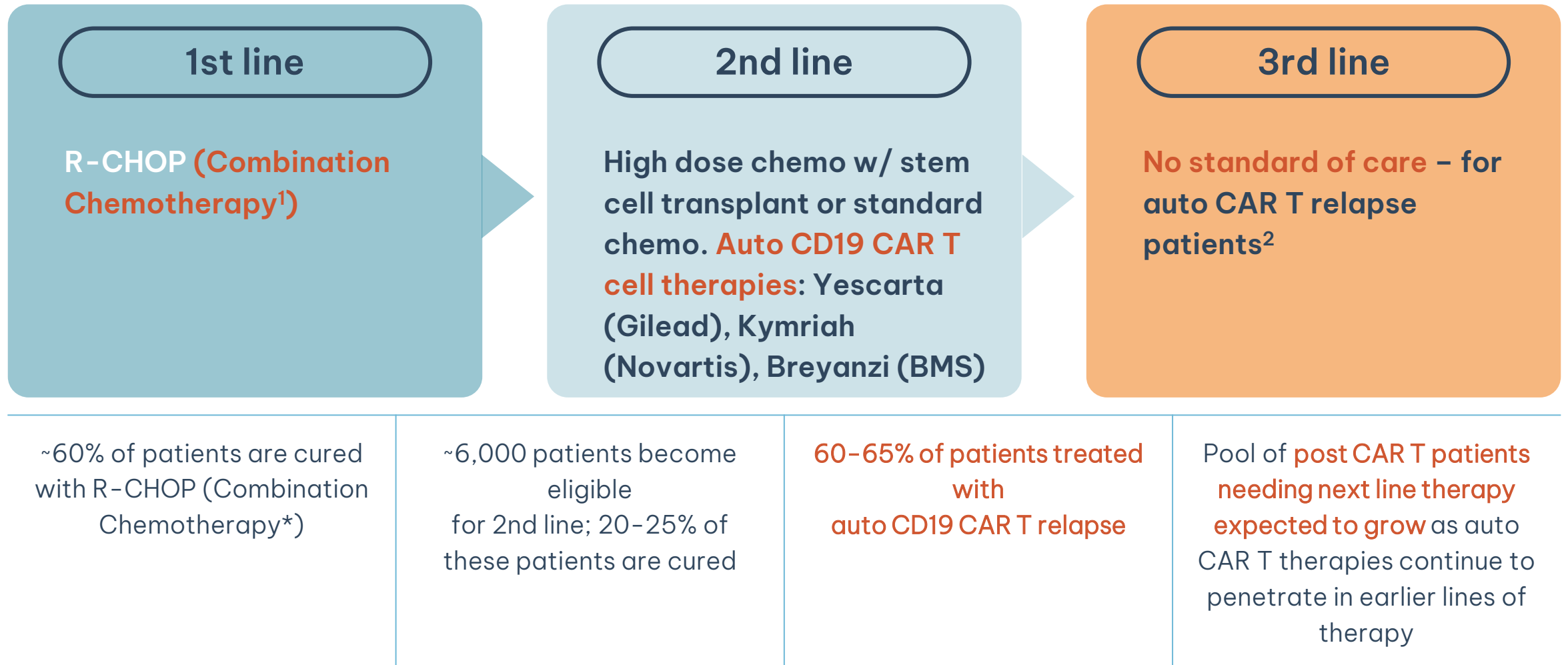
DIFFUSE LARGE B-CELL LYMPHOMA IS AN AGGRESSIVE TYPE OF NON-HODGKIN LYMPHOMA



- 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)



¹Rituximab, Cyclophosphamide, Doxorubicin Hydrochloride (Hydroxydaunomycin), Vincristine Sulfate (Oncovin), Prednisone

²COLUMVI® received conditional accelerated marketing authorisation in 2023 for 3L+ DLBCL

AZER-CEL CASE STUDY

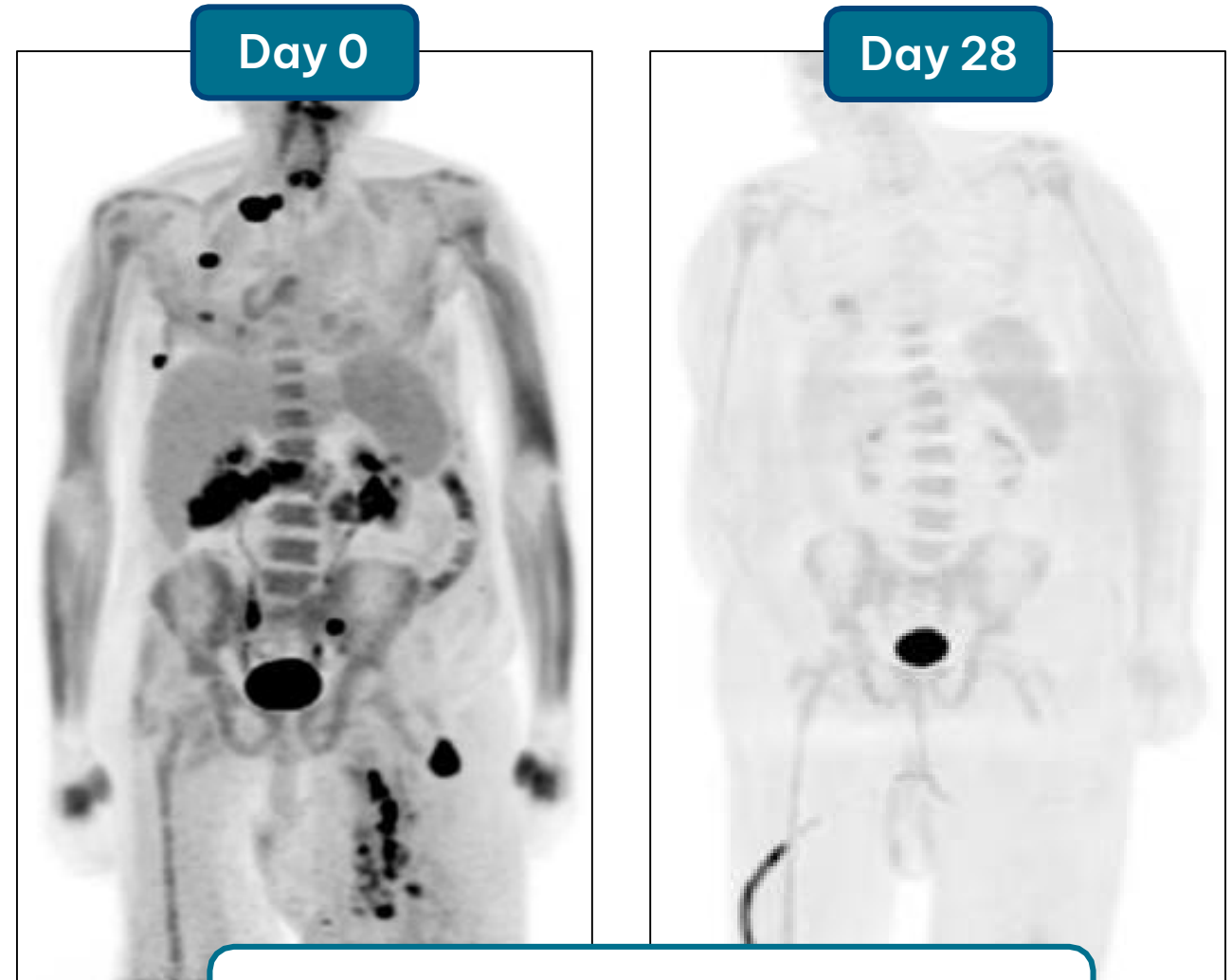
63-year-old Male

Dx: DLBCL

Tumor Burden: 2029 mm²

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)



Outcome: Day 28 Complete Response

AZER-CEL PHASE 1B STUDY DESIGN

Potentially leading to Phase 2 Pivotal Study in 2025

DOSE ESCALATION

EXPANSION



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 year³



**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



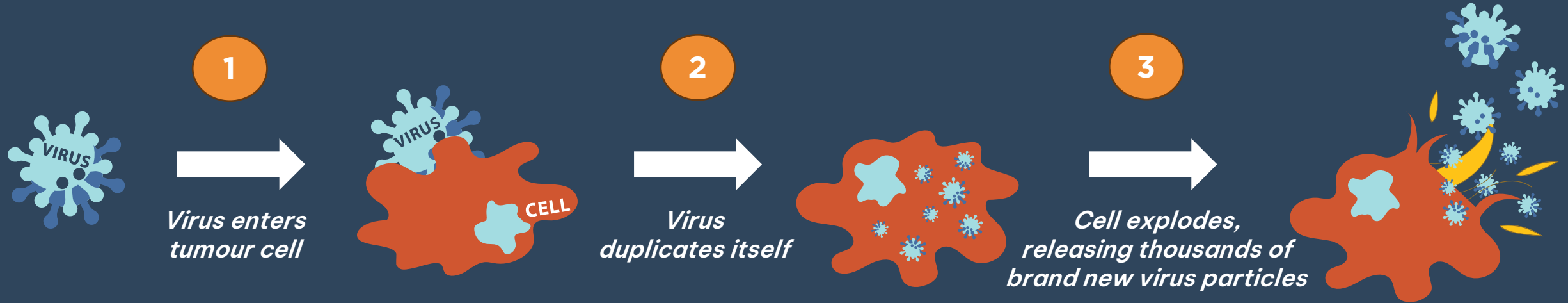
CF33 Oncolytic Virus

IMUGENE

CF33 ONCOLYTIC VIRUS



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 response¹

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



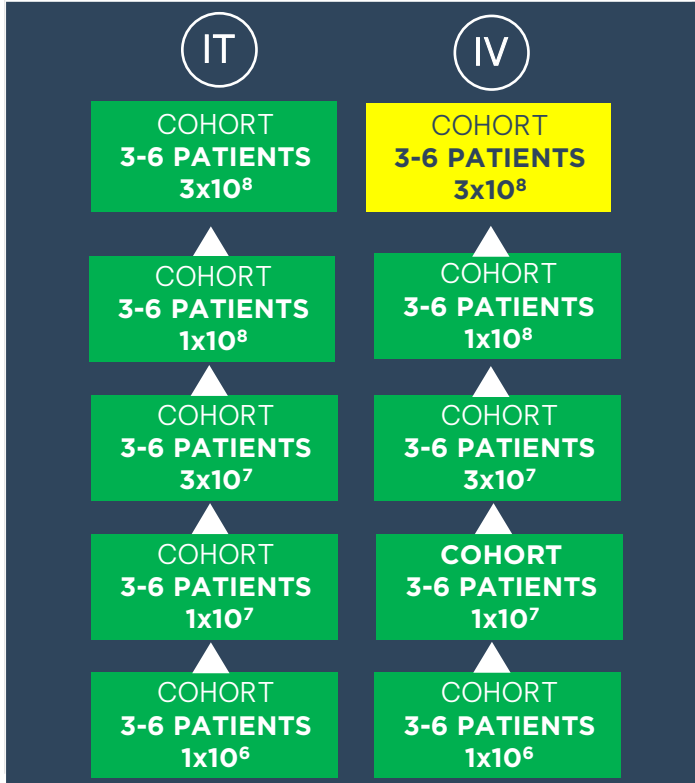
Intratumoural (IT) Administration
Metastatic and Advanced Solid Tumours



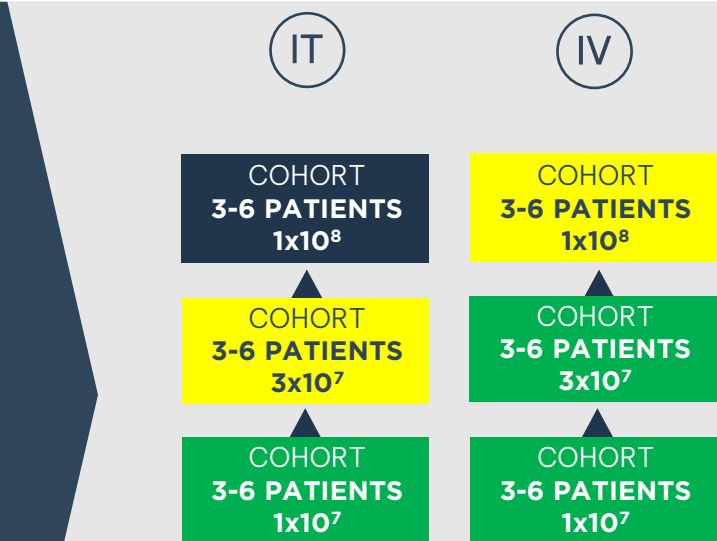
Intravenous (IV) Administration
Metastatic and Advanced Solid Tumours

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)**

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



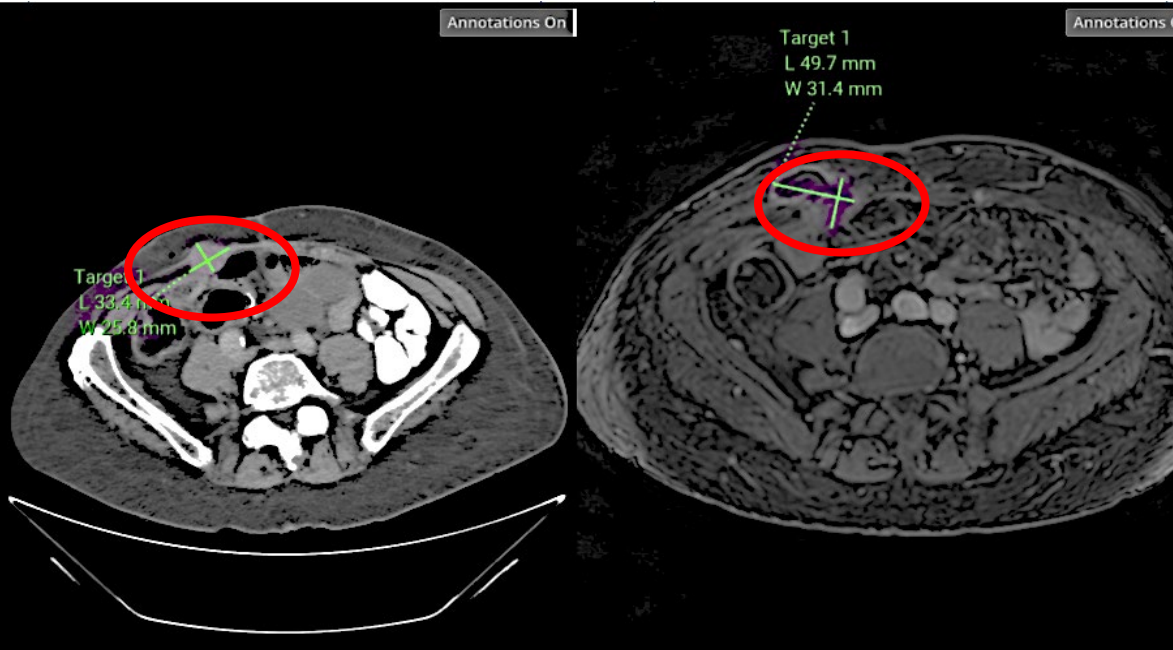
HIGHLANDS
ONCOLOGY



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

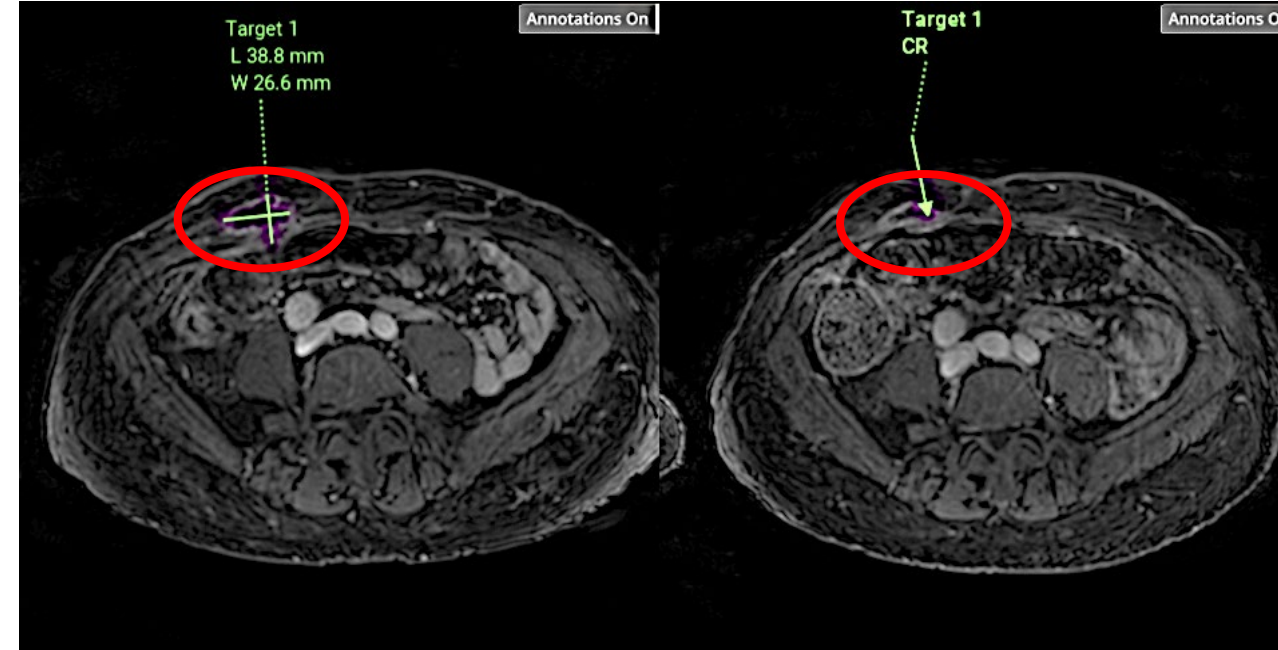
TURNING COLD TUMOURS HOT

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

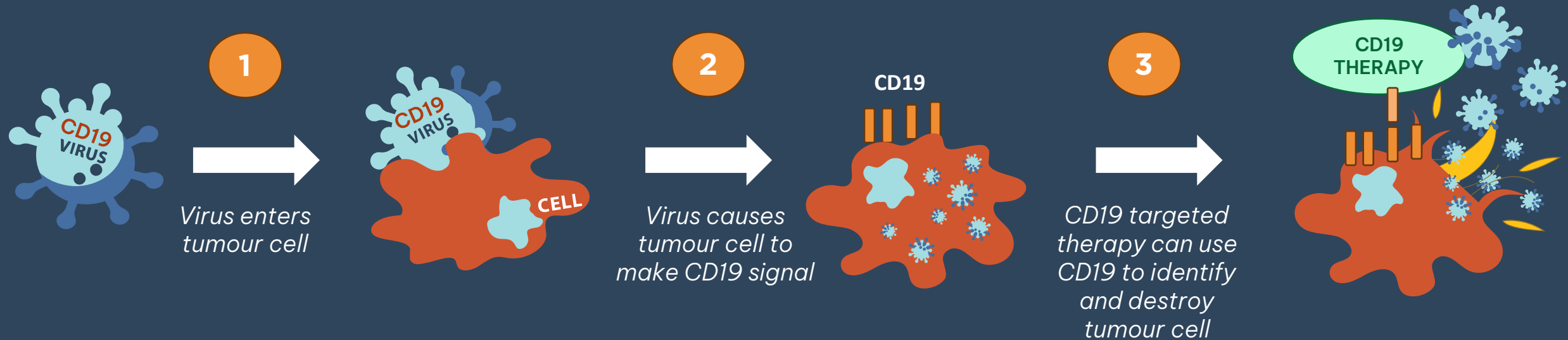
ONCARLYTICS FOR SOLID TUMORS



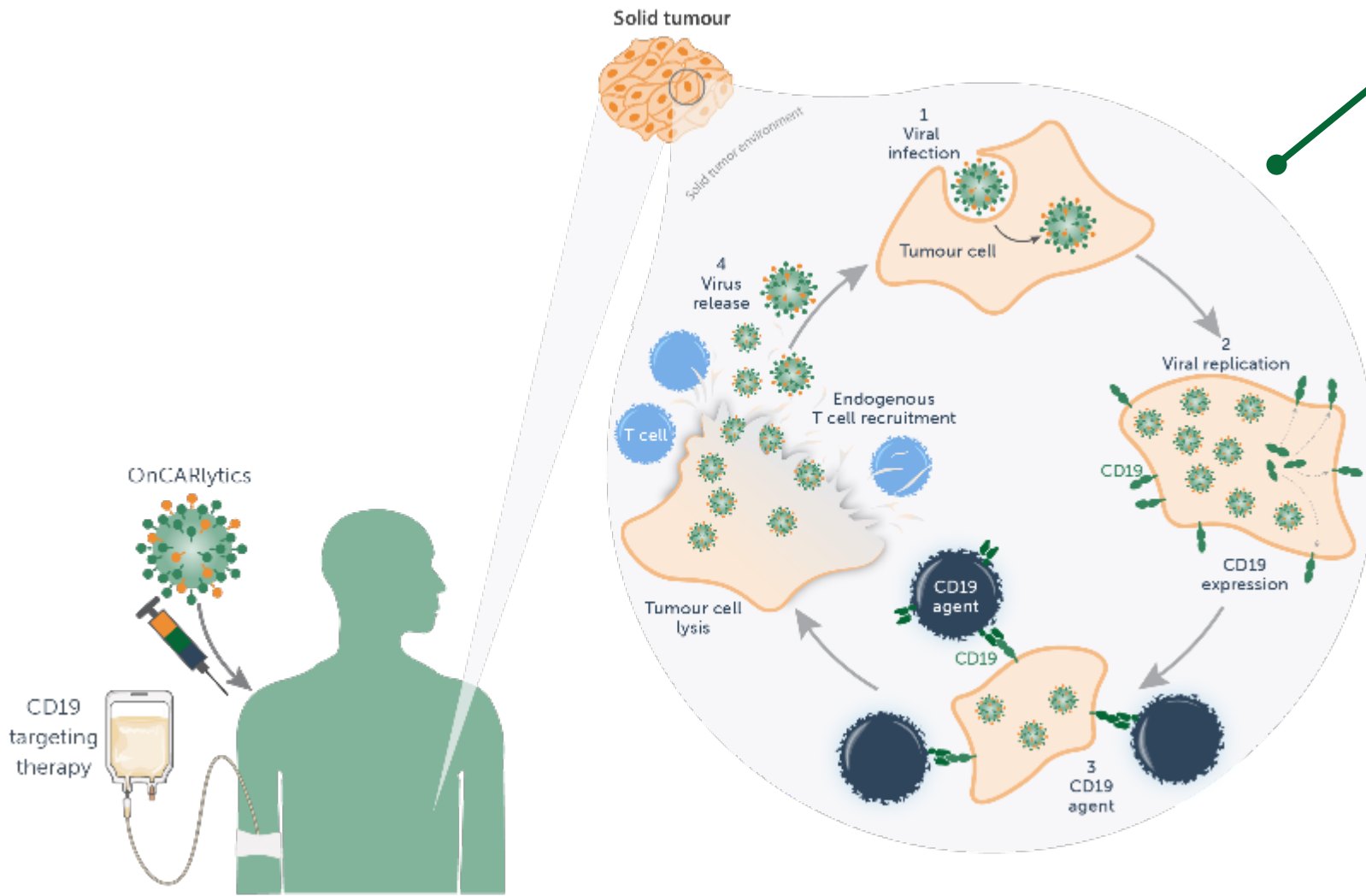
VARIETY OF APPROVED CD19 DRUGS ONLY FOR BLOOD CANCERS

- 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?



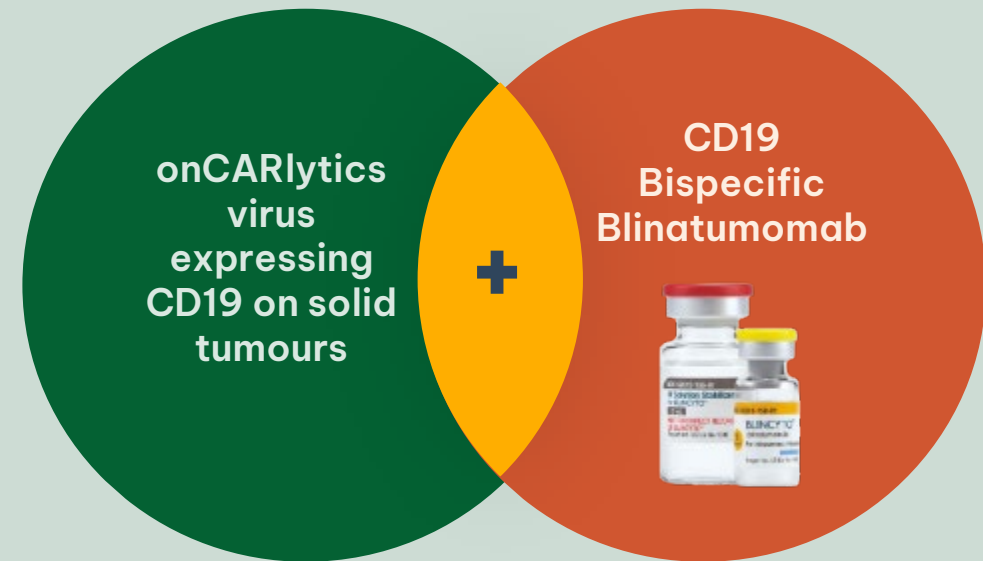
onCARlytics makes solid tumors “seen” by CD19 targeting therapies

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.

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)

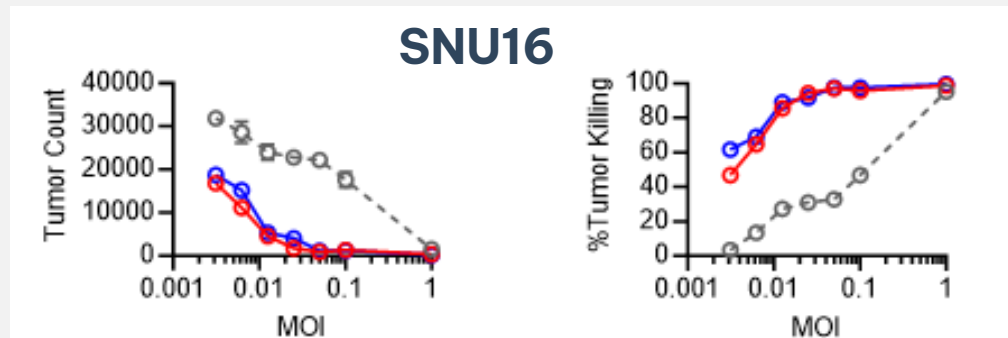
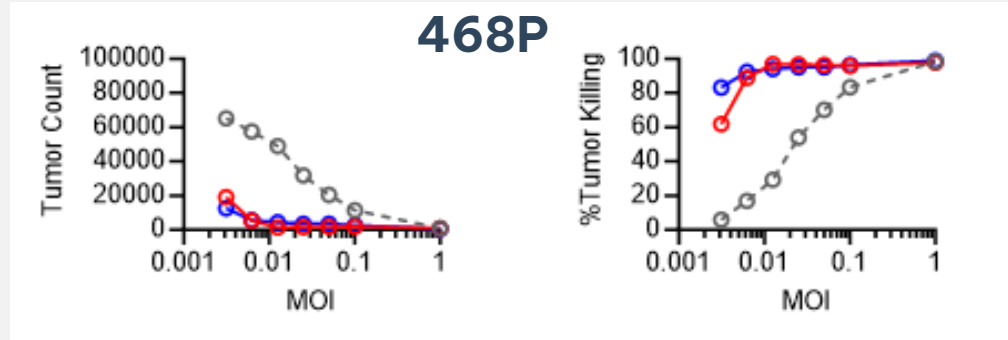
Combination Opportunities

- 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
 KYMRIAH [®] (tisagenlecleucel)  NOVARTIS	2017	CD19 Auto CAR T	B-ALL, DLBCL
 YESCARTA [®] (axicabtagene ciloleucel)  Kite	2017	CD19 Auto CAR T	DLBCL, R/R FL
 TECARTUS [®] (brexucabtagene autoleucel)  Kite	2020	CD19 Auto CAR T	R/R MCL
 Breyanzi [®] (lisinatumab)  Bristol Myers Squibb	2021	CD19 Auto CAR T	DLBCL
 MONJUVI [®] (tafasitamab-cxix)  morphosys	2020	CD19 Monoclonal Antibodies (MABs)	DLBCL
 Uplizna [®] (lelizumab)  HORIZON	2020	CD19 MABs	NMOSD
 BLINCYTO [®] (bintrafuspimab)  AMGEN	2014	CD19-CD3 Bispecific MABs	ALL
 Zynlonta [®] (bintrafuspimab)  ADC	2021	CD19 Antibody- drug conjugate (ADC)	B-Cell Lymphoma

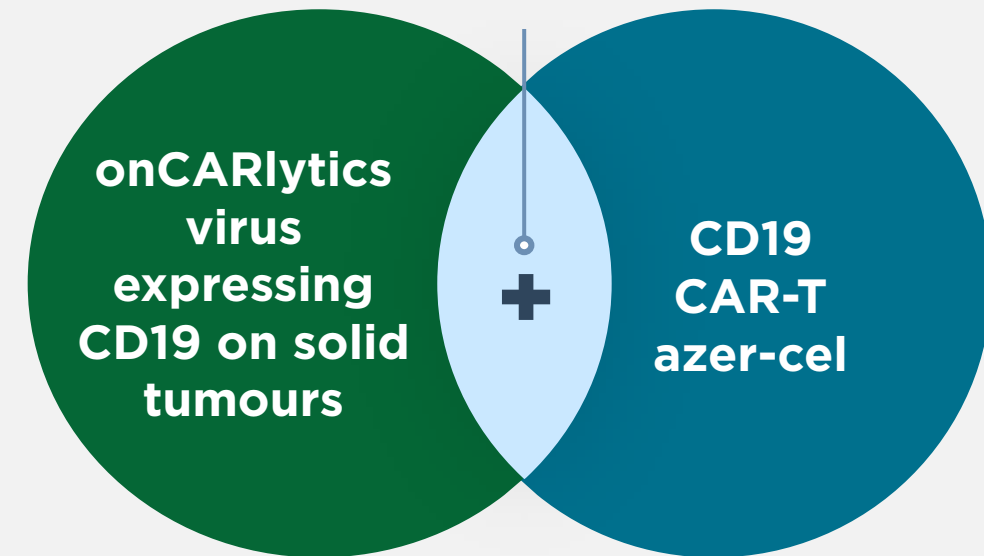
AZER-CEL OFFERS ONCARLYTICS AN IN-HOUSE COMBINATION APPROACH FOR SOLID TUMOURS

- 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



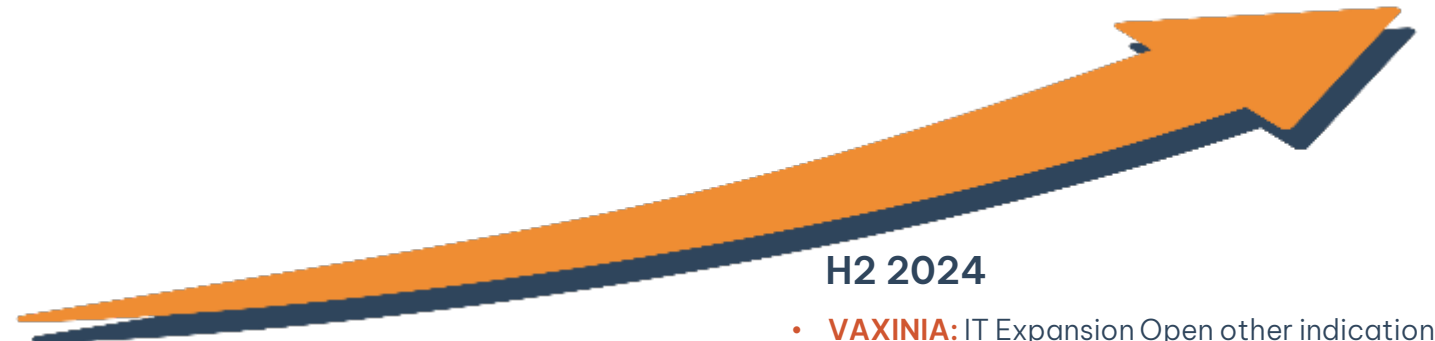
RECENTLY ACHIEVED AND UPCOMING KEY CATALYSTS

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

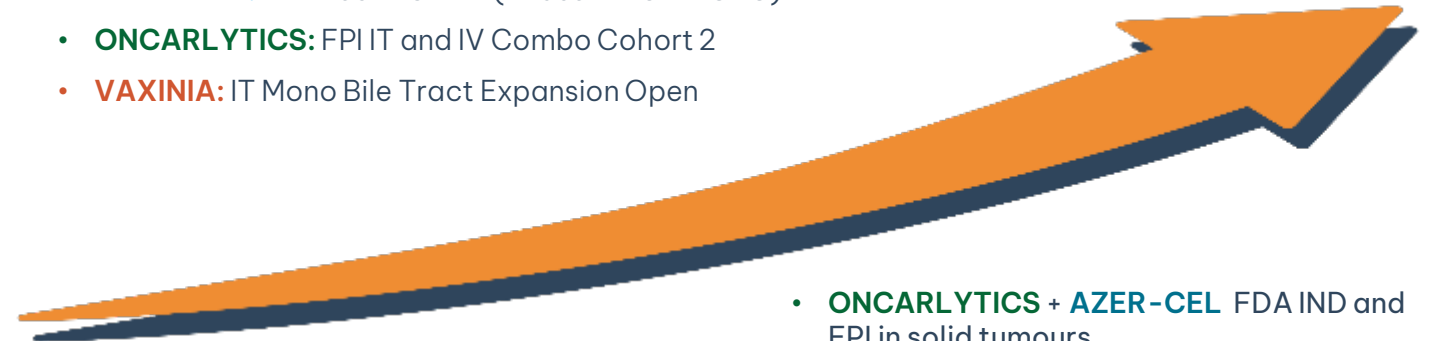


H2 2024

- **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)

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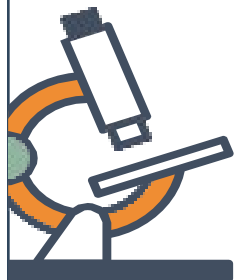
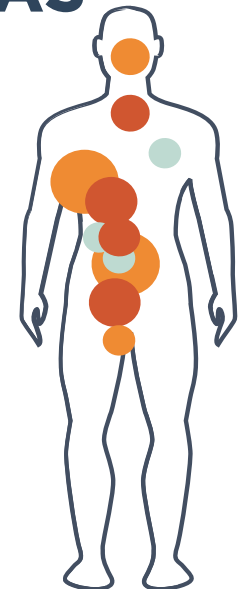
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IMUGENE

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ASX:IMU

shareholderenquiries@imugene.com
imugene.com

