



IMUGENE

Developing Cancer Immunotherapies

ASX: IMU

DEVELOPING TRANSFORMATIVE CANCER MEDICINES

November 2023



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INVESTMENT HIGHLIGHTS

MARKET CAPITALISATION

9 November 2023

A\$788M
US\$504M



CASH AS OF

30 September 2023

A\$163M
US\$104M



3 PRIORITY PLATFORM TECHNOLOGIES

Allo CAR T Cell Therapy

onCARlytics

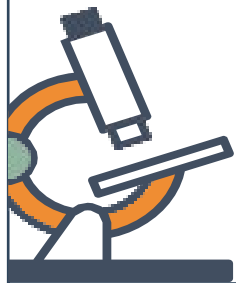
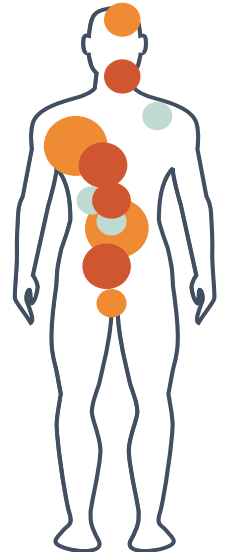
CF33 Oncolytic Virus

IN-HOUSE GMP CELL THERAPY MANUFACTURING FACILITIES



DISEASE AREAS

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



5 CLINICAL STUDIES

azer-cel Ph1b DLBCL (FDA IND)

nextHERIZON: Ph2 HER2+ Metastatic GC (FDA IND)

MAST: Ph1 Solid Tumors (FDA IND)

onCARlytics: Ph1 Solid Tumors (FDA IND)

PD1-Vaxx: Ph1 MSI-H CRC

LONG-LIFE PATENT PORTFOLIO



KEY CATALYSTS FOR THE NEXT 12 MONTHS

Q4 2023

- **AZER-CEL**: FPI on Ph1b
- **PD1-VAXX**: MSI-H activation

Q1 2024

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

Q2 2024

- **AZER-CEL**: Ph1b Enrollment Status
- **ONCARLYTICS**: FPI IT Combo Cohort 2
- **VAXINIA**: IT Mono Expansion Open

Q3 2024

- **AZER-CEL**: Phase 1b enrollment completed
- **ONCARLYTICS**: IV Combination Cohort 2 Open
- **VAXINIA**: IT Combination Expansion Cohort Open

Q4 2024

- **AZER-CEL**: Regulatory meeting with FDA
- **ONCARLYTICS**: IT & IV Combo Expansion
- **AZER-CEL**: DLBCL Phase 2 Pivotal Study Start-up
- **ONCARLYTICS** + **AZER-CEL** in solid tumors

COMMERCIALIZATION STRATEGY

CLINICAL SUCCESS DRIVES VALUE REALISATION OPPORTUNITIES

- Model for biotech commercialization strategy is to out-license the technology to Big Pharma
- 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

COMPANY ACQUISITION

PARTNER WITH BIG PHARMA

LICENSE TECHNOLOGIES SEPARATELY

DEVELOP / COMMERCIALISE INDEPENDENTLY

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

**Allogeneic
CAR T
Cell Therapy**

azercel

**OnCARlytics
CF33-CD19
OV Therapy**

onCARlytics

**CF33
Oncolytic Virus
(OV) Therapy**

VAXINIA

**B Cell
Immunotherapy**

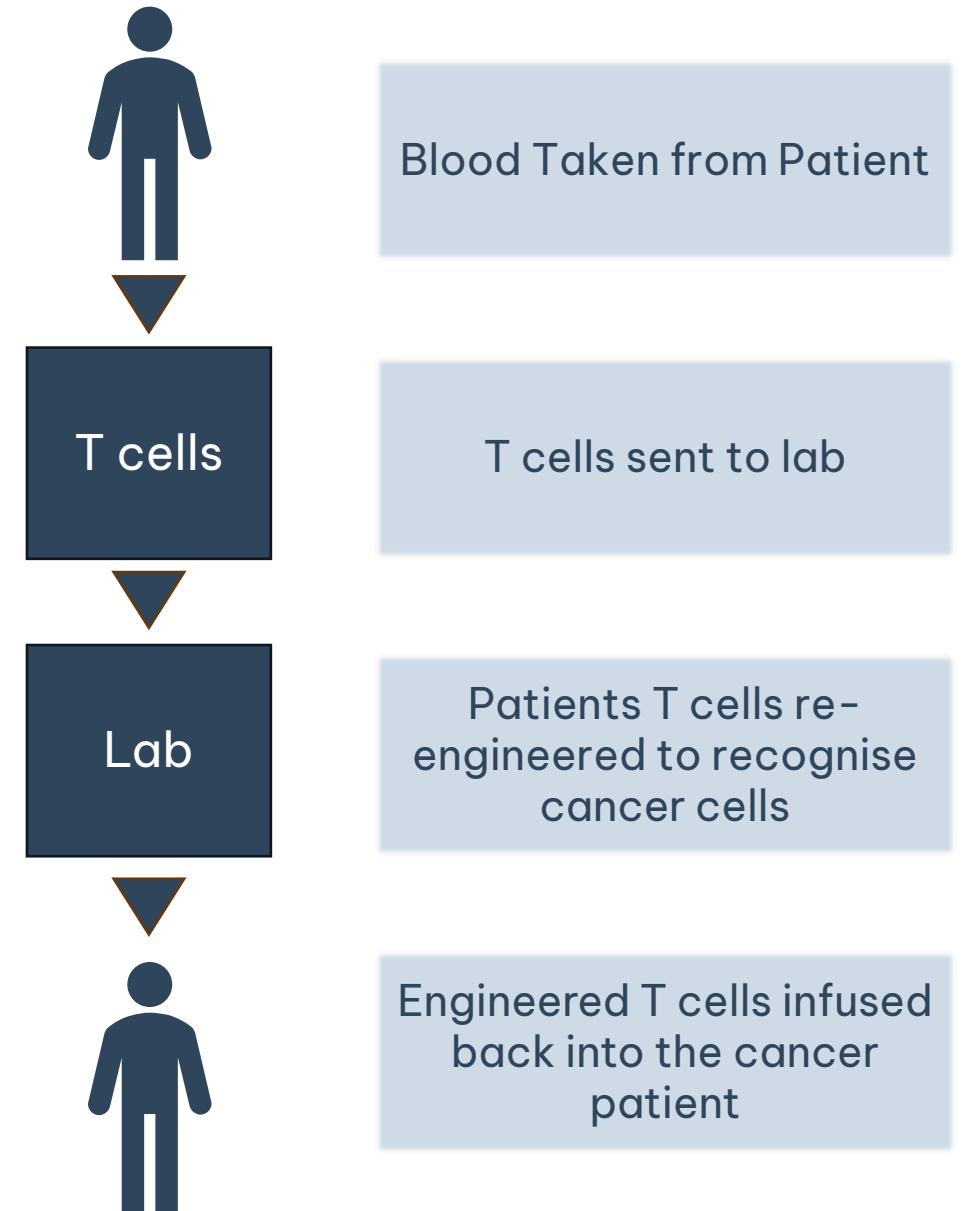
**HER-Vaxx
& PD1-Vaxx**

AZER-CEL CD19 ALLOGENEIC CAR T CELL THERAPY

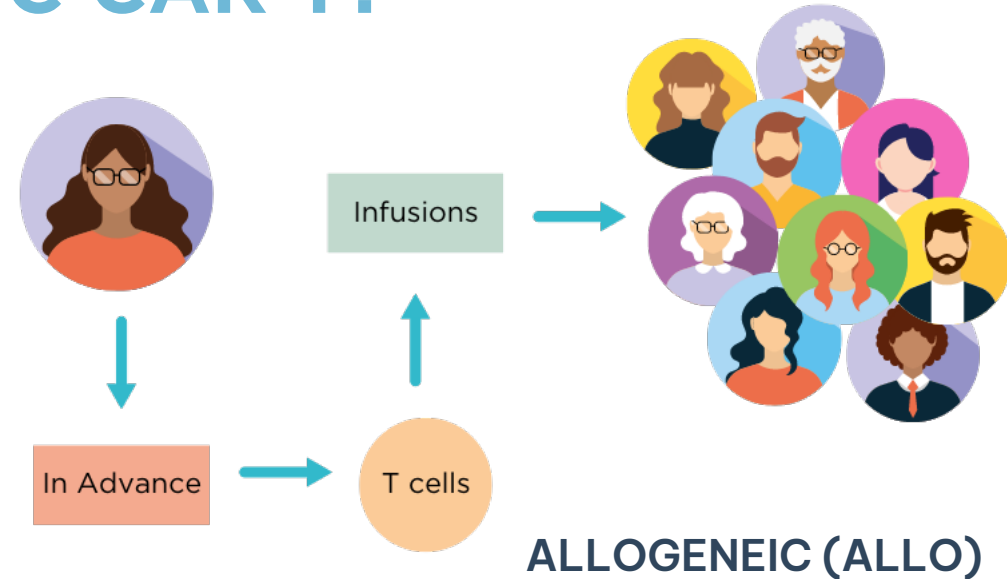
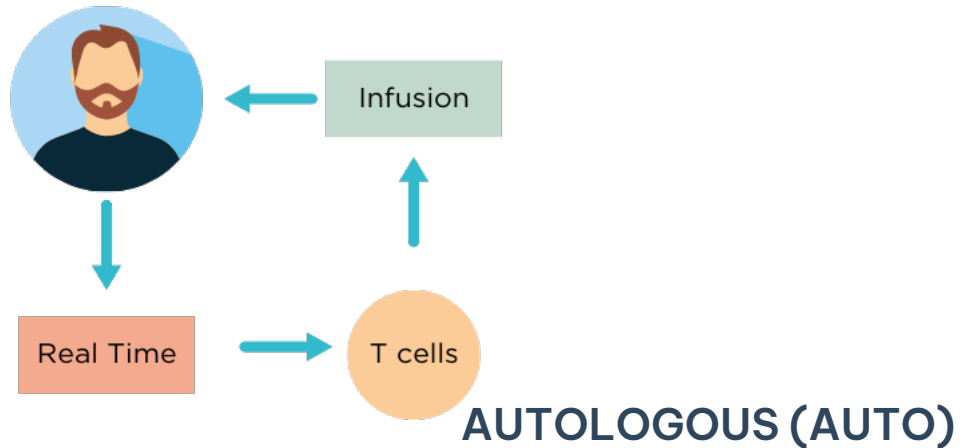


WHAT IS AUTOLOGOUS CAR T THERAPY?

- CAR T is an acronym for **C**himeric **A**ntigen **R**eceptor **T** cell
- Currently, CAR T therapy is a cancer treatment which involves taking a cancer patient's blood and separating the T cells from the blood
- The T cells are then “reprogrammed” in the lab so that they become focused on a molecule found on the surface of cancer cells, for example **CD19**
- The T cells are then injected back into the patient where they kill the cancer cells
- There are six approved autologous CAR T drugs for blood cancers



WHAT IS THE DIFFERENCE BETWEEN AUTOLOGOUS & ALLOGENEIC CAR T?



- Auto CAR Ts are made from the patient's own cancer cells-made from individual (highly personalized)
- Long, complex and expensive manufacturing process and wait time (19-42 days and often requires extra chemotherapy treatment until cells are ready)
- Variable potency due to health of patients own T cells
- There are six FDA approved auto CAR T drugs in blood cancers

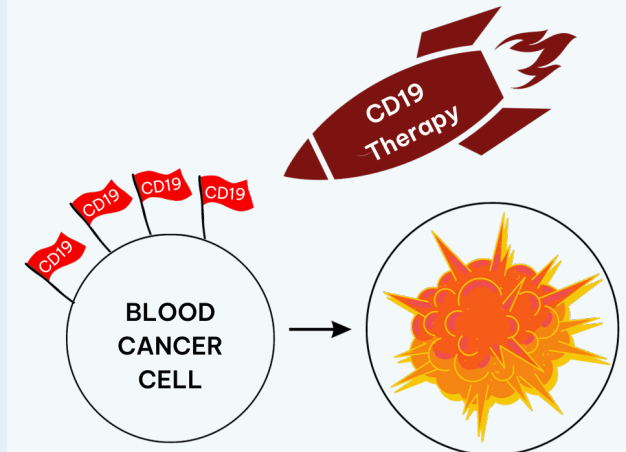
- Allo CAR Ts are made from a universal donor. Broad patient access (multiple patients from a single batch)
- Can be mass produced, available on demand and off-the-shelf immediately. **Ready when you need them.**
- **Faster and Cheaper to make**
- Healthy donor cells engineered for potency and persistence
- No allo CAR Ts yet approved by the FDA

IMUGENE IS AN INDUSTRY LEADER IN ALLOGENEIC CELL THERAPY

- Acquired azercabtagene zapreleucel (azer-cel) in August 2023
- Phase 1 trial was completed in 84 blood cancer patients with encouraging safety and efficacy data
- Patients with Diffuse Large B Cell Lymphoma (DLBCL) who relapsed after autologous (auto) CAR T therapy demonstrated an 83% overall response rate with 61% Complete Response Rate and 55% duration of response was ≥ 6 months
- Positive feedback from the FDA on Phase 1 results (DLBCL relapsed after auto CART)
- Phase 1b confirmatory study to enroll 10 DLBCL patients relapsed after auto-CART: **First Patient In: 10 November 2023**
- Strategy is to commence a Phase 2 registration study in the next 12-18 months

Mechanism of Action

CD19 is a common signal found on blood cancers, so a CAR T therapy designed to attack CD19 is like a deadly missile against a cancer cell with CD19 on its surface



CD19 AUTOLOGOUS CAR T RELAPSE MARKET IS LARGE AND GROWING



~85%

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

In the prospective data, patients continue to have antigen positive disease¹



60-65%

of patients currently treated with autologous CD19 CAR T will relapse²



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 year³

Azer-cel potential blockbuster sales of ~\$2.5B⁴ 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 POTENTIAL REGISTRATION TRIAL



Potential registrational study (subject to FDA approval) to start upon completion of the Phase 1b study H2 2024

Population: Diffuse large B cell lymphoma (DLBCL) patients who have relapsed after auto CAR T therapy

Positive initial FDA guidance on the potential registrational study received in July 2023

~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 trial completed

Drug is manufactured Imugene's facility in North Carolina



City of
Hope®

THE OHIO STATE
UNIVERSITY



Masonic Cancer Center
UNIVERSITY OF MINNESOTA

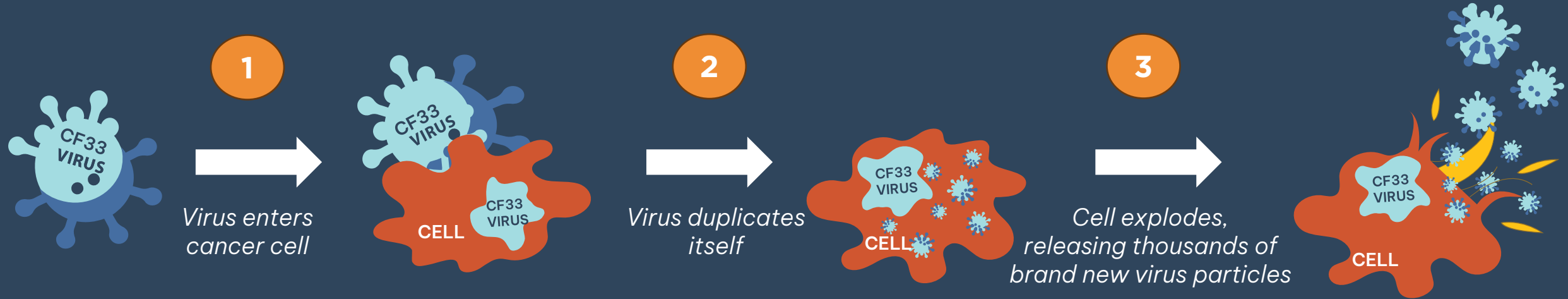


CF33 Oncolytic Virus
IMUGENE

CF33 ONCOLYTIC VIRUS



CF33 CAN INFECT AND SELECTIVELY KILL CANCER CELLS



Engineering & enhancements

- CF33 is an engineered virus closely related to smallpox and does not exist in nature
- Invented by Prof Yuman Fong at City of Hope
- Carry payloads to increase killing

TME: tumour microenvironment

1: Ribas et al., Cell 170:1109, 2017

Multiple ways to kill cancer cells

- Infect and kill only 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)

PHASE 1 CF33 MAST STUDY

MAKING A MEANINGFUL IMPACT FOR PATIENTS



- The Phase 1 study treats advanced cancer patients intravenously (IV) or intratumorally (IT) with CF33-hNIS (VAXINIA) alone, or in combination with pembrolizumab in multiple solid cancers
- 34 heavily pre-treated patients dosed to date; doses have been determined to be safe and tolerable; 25 patients currently evaluable for response (received at least their first scan at 6 weeks)
- One Complete Response (iCR)* in bile duct cancer and one Partial Response (PR)* in melanoma at the mid level dose, 16 patients with Stable Disease (SD)
- 7 patients with gastrointestinal cancers who received CF33 alone including 3 colorectal cancer, 2 bile duct, 1 pancreatic and 1 liver cancer showed disease control (CR, PR and SD) of 86%
- Study expansion is planned for 10 additional patients with bile duct cancer
- Phase 1 trial is conducted at 12 centers in the US and Australia



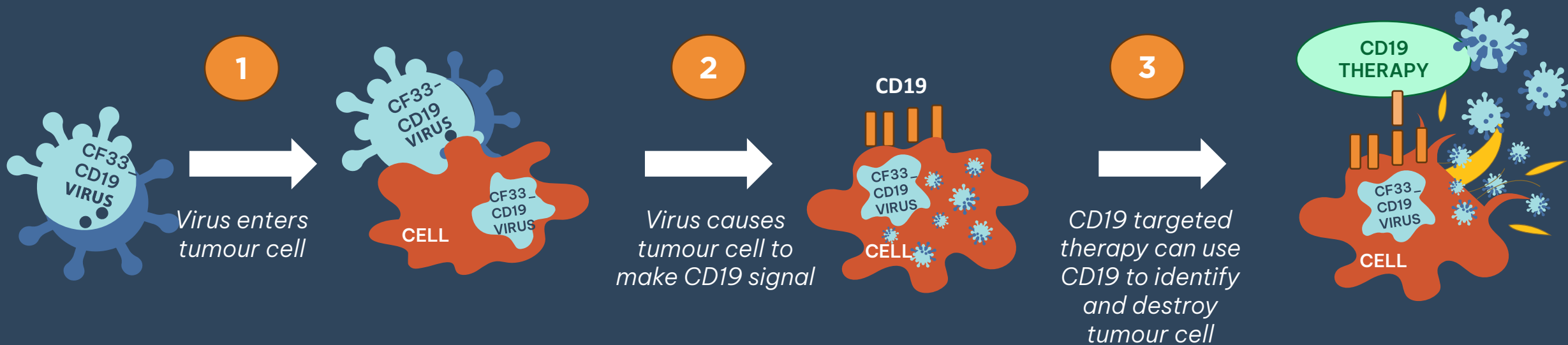
*iRECIST and RECIST: (immune) Response evaluation criteria in solid tumours
*PFU: Plaque Forming Unit

CF33-CD19 ONCARLYTICS FOR SOLID TUMOURS



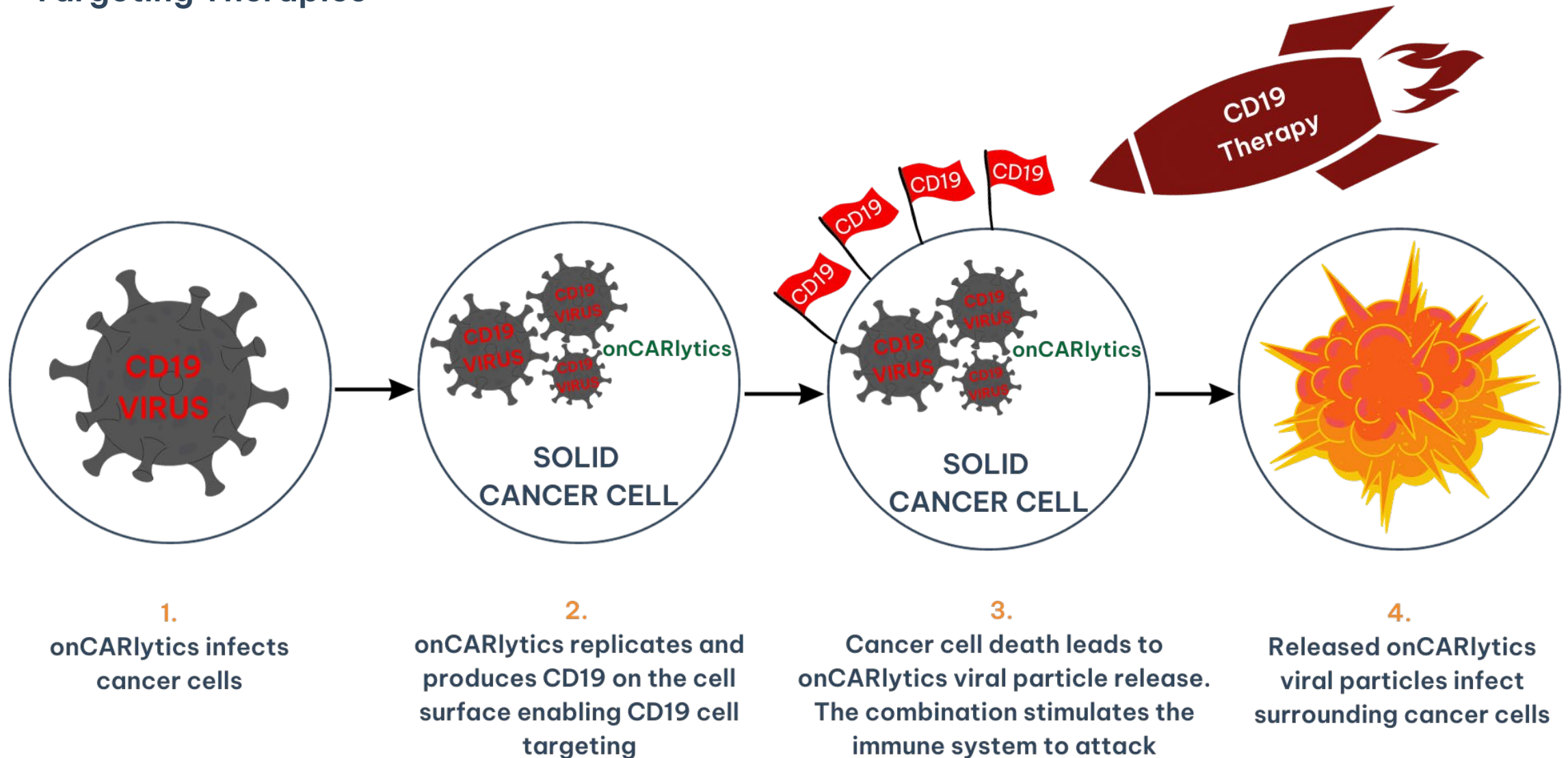
WHAT IS THE CF33 CD19 ONCOLYTIC VIRUS (ONCARLYTICS) WHY CD19?

- The backbone of onCARlytics is CF33 (invented by City of Hope) engineered with CD19 inserted to express (grow) when it infects in cancer cells
- 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
- 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 and makes solid cancer cells visible and vulnerable to CD19 targeted therapies



HOW DOES ONCARLYTICS WORK?

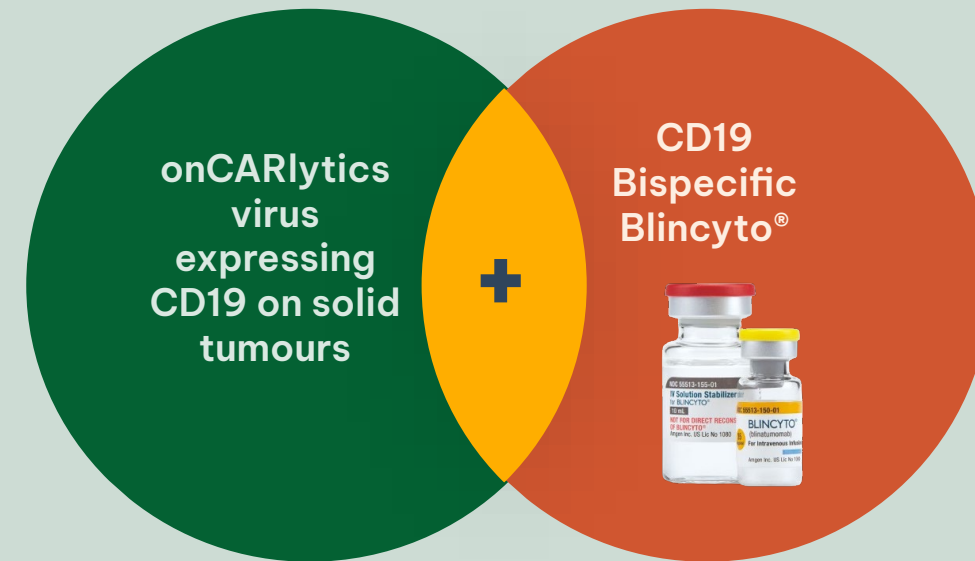
onCARlytics (CF33 CD19 oncolytic virus) makes solid tumours “seen” by CD19 Targeting Therapies



FIRST PATIENT TREATED WITH ONCARLYTICS IN PHASE 1 OASIS STUDY OF METASTATIC ADVANCED SOLID TUMOURS

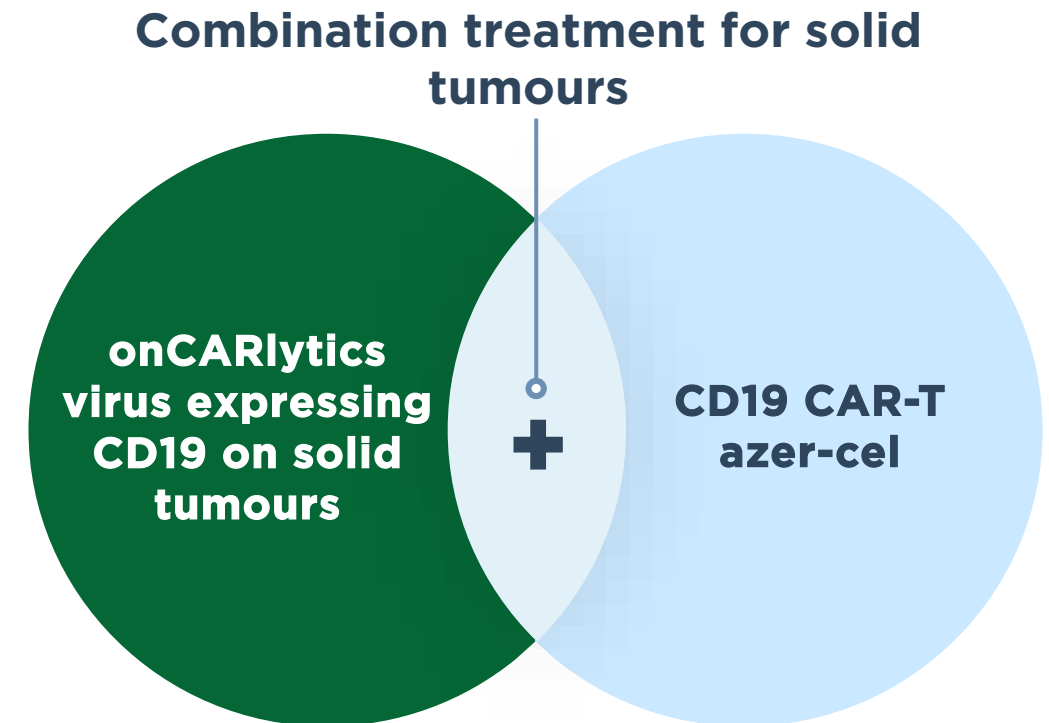
- The Phase 1 study is designed to treat with onCARlytics (CF33-CD19) alone, or in combination with Blincyto® (bispecific antibody targeting CD19) and either dosed intravenously (IV) or intratumorally (IT) in metastatic advanced patients across multiple solid tumors
- First patient enrolled (ovarian 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)

Combination treatment for solid tumours



ONCARLYTICS + AZER-CEL ERADICATES MULTIPLE TUMOR TYPES IN EARLY PRECLINICAL STUDIES

- Azer-cel in combination with onCARlytics demonstrated sustained, robust activity against multiple tumor types
- 100% impressive killing of Triple Negative Breast Cancer and Gastric Cancer lines was observed compared to controls



ACRONYM GLOSSARY

ADC – Antibody Drug Conjugate

AUTO – Autologous – personal

ALLO – Allogeneic – off the shelf

B-ALL and ALL – (B-Cell) Adult lymphoblastic leukaemia

CAR T – Chimeric Antigen Receptor T cell

CD19 – Cluster of Differentiation 19 – molecule on the surface of blood cancer cells

DLBCL – Diffuse Large B Cell Lymphoma – aggressive form of blood cancer

DoR – Duration of Response

IV – Intravenous

IT – Intratumoral

MABs – Monoclonal Antibodies

MSI-H – Microsatellite Instability High

NHL – Non-Hodgkin lymphoma

NMOSD – Neuromyelitis Optica Spectrum Disorder

ORR – Overall Response Rate

OS – Overall Survival – measures how long patients who undergo a certain treatment regime, live compared to patients who are in a control group

PFU – Plaque Forming Units

RECIST and iRECIST – (immune) Response evaluation criteria in solid tumours

PD – Progressive Disease: After beginning treatment, at least a 20 percent growth in the size of the tumour or spread of the tumour

SD – Stable Disease: treatments are causing tumour to either not grow or shrink while no new tumours to develop

PR – Partial Response: Response to treatment, but still did not go away

CR – Complete Response: the absence of all detectable cancer after your treatment

iCR – Immunological Complete Response: Immune related to absence of all detectable cancer after your treatment

R/R FL – Relapsed/Refractory Follicular Lymphoma

R/R MCL – Relapsed/Refractory Mantle Cell lymphoma

SPECT – Single-photon emission computed tomography



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