



# IMUGENE

Developing Cancer Immunotherapies

**ASX: IMU**

## DEVELOPING TRANSFORMATIVE CANCER MEDICINES

Annual General Meeting 2023  
CEO Presentation

For personal use only

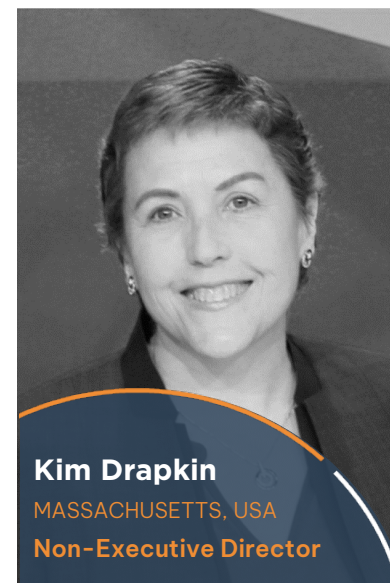
# DISCLAIMER

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.

# INTERNATIONAL LEADERSHIP TEAM WITH EXTENSIVE COMMERCIALISATION EXPERTISE IN THE SECTOR

Imugene has a team with vast oncology drug development experience

For personal use only



# IMUGENE CLINICAL EXECUTIVE TEAM

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

For personal use only



**Leslie Chong**  
Chief Executive Officer & Managing Director



**Dr. Paul Woodard, MD**  
Chief Medical Officer



**Dr Bradley Glover**  
Chief Operating Officer



**Ursula McCurry**  
Snr VP of Clinical Operations



**Dr. John Byon, MD, PhD**  
Snr VP of Clinical Development



**Dr Monil Shah**  
Chief Business Officer

# INVESTMENT HIGHLIGHTS

## MARKET CAPITALISATION

29 November 2023

A\$752M  
US\$496M



## CASH AS OF

30 September 2023

A\$163M  
US\$104M



# 3

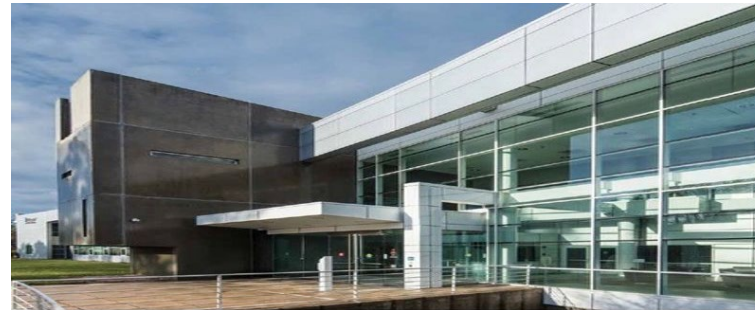
## PRIORITY PLATFORM TECHNOLOGIES

Allo CAR T Cell Therapy

onCARlytics

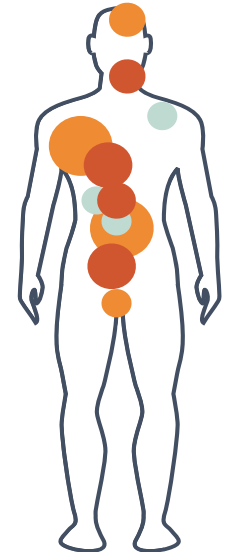
CF33 Oncolytic Virus

## 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



azer-cel Ph1b DLBCL (FDA IND)

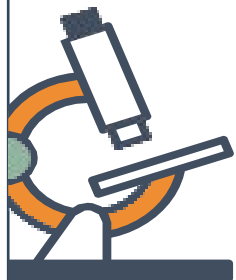
nextHERIZON: Ph2 HER2+ Metastatic GC (FDA IND)

MAST: Ph1 Solid Tumors (FDA IND)

onCARlytics: Ph1 Solid Tumors (FDA IND)

PD1-Vaxx: Ph1 MSI-H CRC

## LONG-LIFE PATENT PORTFOLIO



# 5

## CLINICAL STUDIES

# KEY CATALYSTS FOR THE NEXT 12 MONTHS

For personal use only

## 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**: Phase 1b 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 tumours

Key: **FPI**, First Patient In, **MSI-H**: IV Microsatellite Instability High, **IV**: Intravenous, **IT**: Intratumoural, **Mono**: Monotherapy, **DLBCL**: Diffuse Large B-Cell Lymphoma,

# COMMERCIALISATION STRATEGY

## Clinical Success Drives Value Realisation Opportunities

For personal use only

- Model for biotech commercialisation 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

For personal use only

**Allogeneic  
CAR T  
Cell Therapy**

**azer-cel**

**OnCARlytics  
CF33-CD19  
OV Therapy**

**onCARlytics**

**CF33  
Oncolytic Virus  
(OV) Therapy**

**VAXINIA**

**B Cell  
Immunotherapy**

**HER-Vaxx  
& PD1-Vaxx**



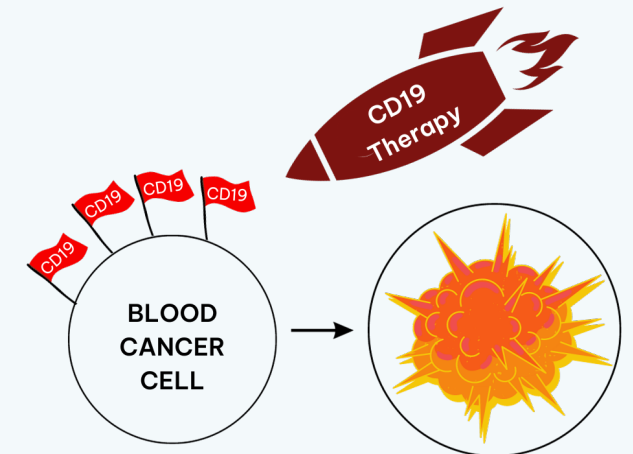
# IMUGENE IS AN INDUSTRY LEADER IN ALLOGENEIC CELL THERAPY

For personal use only

- Imugene 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  $\geq 6$  months
- Positive feedback from the FDA on Phase 1 results
- Phase 1b confirmatory study to enroll 10 DLBCL patients relapsed after auto-CAR T: **First Patient In on 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 molecule 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



# PHASE 2 POTENTIAL REGISTRATION TRIAL

For personal use only

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 US: 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



**DukeHealth** 

 City of Hope<sup>®</sup> **THE OHIO STATE UNIVERSITY**

**MOFFITT**  
CANCER CENTER 

 **Masonic Cancer Center**  
UNIVERSITY OF MINNESOTA

# PHASE 1 CF33 MAST STUDY

## Making a Meaningful Impact for Patients



For personal use only

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

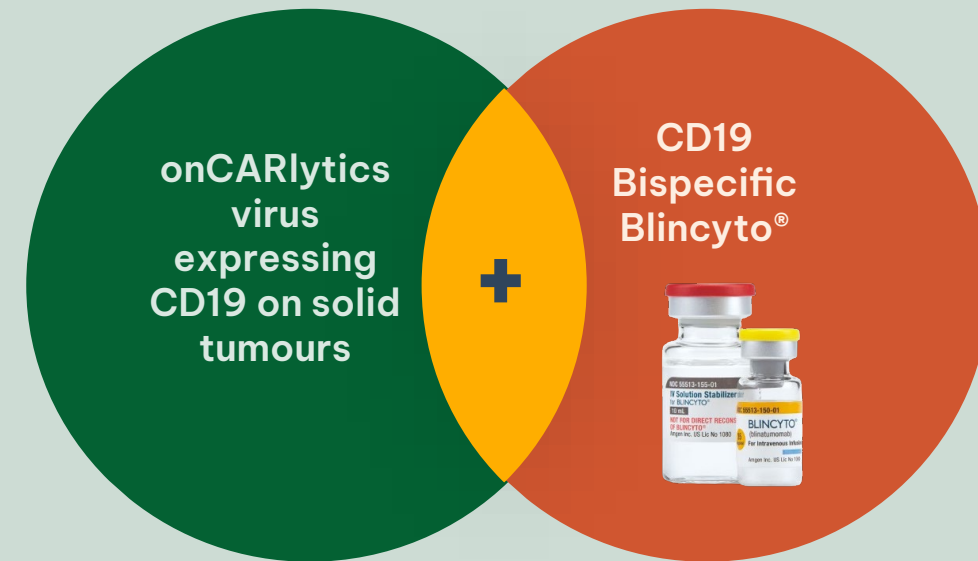
\*PFU: Plaque Forming Unit

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

For personal use only

- 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 intratumourally (IT) in metastatic advanced patients across multiple solid tumours
- 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)

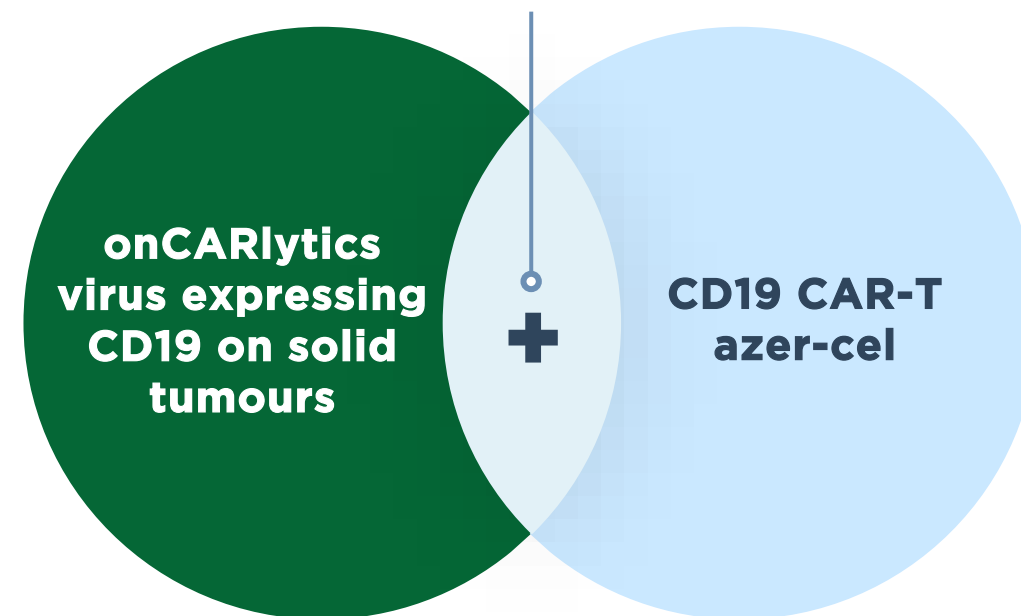
## Combination treatment for solid tumours



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

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

## Combination treatment for solid tumours





**IMUGENE**

Developing Cancer Immunotherapies

ASX:IMU

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

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

For personal use only

