

**ASX:IMU** 





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# Imugene is a clinical stage cancer company developing three drug products in CAR T cell therapy and oncolytic viruses





# onCARlytics IMUGENE



### azer-cel CD19 allo CAR T Phase 1b

Off-the-shelf drug, aka allogeneic CART targeting blood cancers

79% best overall response with best durability at > 16 months and on going

Anticipate to initiate Pivotal Phase 2/3 registrational trial in CY2026 (subject to data and regulatory approvals) – FDA meeting expected in late 2025

FDA IND

# onCARlytics CD19 expressing virus *Phase 1 OASIS Trial*

Novel virus which acts as a CD19 target in solid cancers

Makes solid cancers visible to CD19 drugs

Currently in Phase 1 in solid cancers in combination with Blinatumomab (Approved CD19 drug in blood cancers)

FDA IND

# CF33 Oncolytic Virus Phase 1 VAXINIA MAST Trial

Novel cancer killing virus

Targeting a range of late-stage solid cancers

Early results in bile tract cancer and durable stability of disease

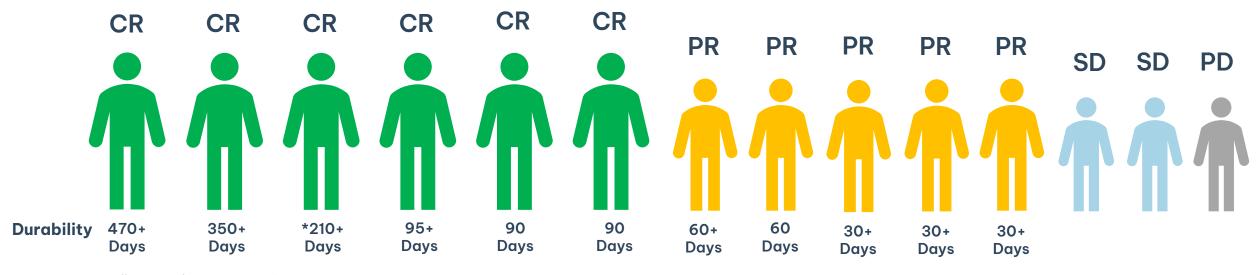
FDA IND

- Manufacturing: Out-Licensed azer-cel Phase 1b product to Kincell along with CAR T engineers to off-set cost and headcount
- Cost Cutting: Headcount reductions, prioritizing programs for value impacting studies are on-going
- Business and Development: Attendance at Bio Singapore and Hong Kong, Meeting at the Mesa as Partnering/Out-licensing
   Opportunity is ongoing
- Potential Science Conferences: Targeting AACR, ASCO, LUGANO, SNO, ASH, SITC etc.

# **Azer-cel 79% Overall Response Rate** N=14



## **Best Response**



\*Allo transplant at Day 148

<u>Overall Response Rate (ORR)</u>: the proportion of patients whose cancer shrinks or disappears after treatment - a measure of how well a treatment is working, specifically in clinical trials

Complete Response (CR): all measurable or visible signs of cancer are no longer detectable after treatment

<u>Partial Response (PR):</u> Significant reduction in tumour size (typically at least 50%) or disease burden, but not complete disappearance of the disease

Durability of Response (DoR): a measure of how long a treatment effect lasts, meaning the cancer remains controlled for a significant period

# **Expected Key Catalysts**

# IMUGENE Developing Cancer Immunotherapies

### Rich News flow 12 months ahead across Imugene's programs

## **Key Achievements**

#### azer-cel

January 2025: First Aus site opened for DLBCL clinical trial and first DLBCL patient dosed in AUS

**February 2025:** Phase 1b data update, 57% Overall Response/Complete Response Rate Achieved

March 2025: Fast Track
Designation granted for treatment
of DL BCL

**July 2025:** Release of additional Phase 1b azer-cel data

#### onCARIytics

April 2025: FPI IV Combo Cohort 1

#### **VAXINIA**

**September 2024:** Orphan Drug Designation received

#### <u>Key</u>

FPI: First Patient In

Combo: Combination Therapy

**DLBCL:** Diffuse Large B-Cell Lymphoma

(Blood Cancer)

IT: Intratumoural, IV: Intravenous

## **Expected Upcoming Milestones**

#### azer-cel

#### **3Q CY25**

- · Release of additional Phase 1b azer-cel data
- Recruitment of CAR-T naïve niche lymphoma patients in Phase 1b
- Potential for FDA Fast Track and/or Orphan Drug Designation for additional niche blood cancer

#### 4Q CY25

- Planned FDA Meeting for registrational strategy/pivotal study, FDA support for niche indications
- Release of additional Phase 1b azer-cel data (DLBCL patients and ongoing durability data)

#### <u>CY26</u>

- Commencement of manufacturing and supply for registration/pivotal study
- Phase 1b data on CAR T naïve lymphoma patients
- Potential for RMAT/Breakthrough designation for accelerated approvals
- Initiate Activity for Registrational/Pivotal study

#### onCARIytics

2025-2026: IV Combo Recommended Phase 2 Dose (RP2D)

#### **VAXINIA**

2H CY25: Study update

#### Other

Partnering/Out-licensing Opportunity
Potential Conference Presentations: at AACR, ASCO, LUGANO, SNO, ASH, SITC



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