

**ASX: IMU** 

## AZER-CEL CD19 CAR T LICENSE



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## CAR T THERAPY SUCCESSES IN BLOOD MALIGNANCIES

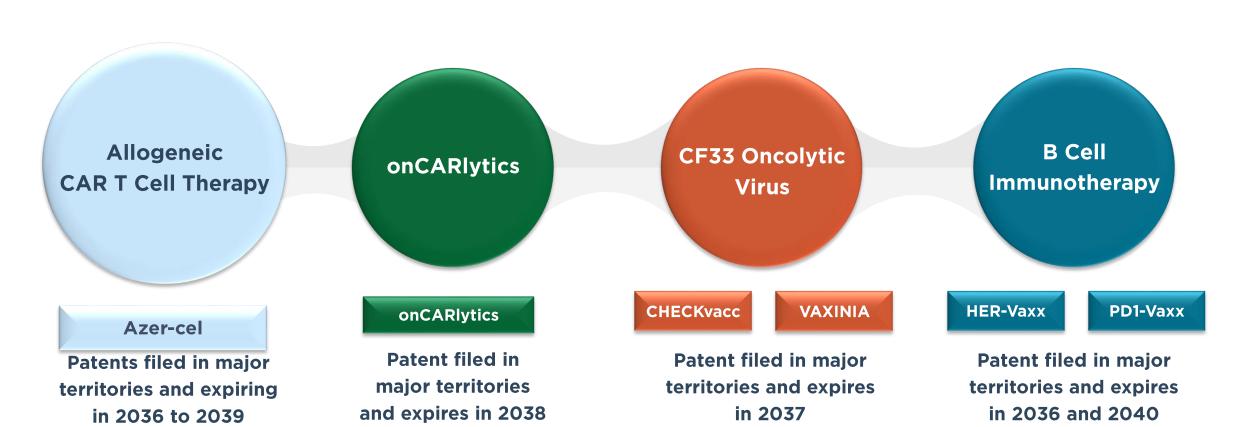


BRAND	COMPANY	FIRST FDA APPROVAL	TARGET	APPROVED CANCERS	OVERALL RESPONSE RATE
(tisagenlecleucel) Dispersion for IV infusion	<b>U</b> NOVARTIS	2017	CD19	B-ALL, DLBCL	53-86%
YESCARTA® (axicabtagene ciloleucel) for its induction	Kite A GILEAD Company	2017	CD19	DLBCL, R/R FL	72-91%
TECARTUS® (brexucabtagene autoleucel) for iV infusion	Kite A GILEAD Company	2020	CD19	R/R MCL	65*-87%
Breyanzi (lisocabtagene maraleucel) anno mondon	ullı Bristol Myers Squibb"	2021	CD19	DLBCL	73-87%
Abecma (idecabtagene vicleucel)	ullı Bristol Myers Squibb"	2021	BCMA	R/R MM	72%
CARVYKTI** (ciltacabtagene autoleucel) Surprovins (rivi Interest) Surprovins (ciltacabtagene autoleucel) Surprovins (ciltacabtagene aut	Janssen Joncology  PHARMACEUTICAL COMPANIES OF Selection Splanes.  Selection Splanes.	2022	ВСМА	R/R MM	98%

# FOUR UNIQUE PLATFORMS MAXIMIZE OPPORTUNITIES IN CANCER



Treatments that can be combined with and enhance outcomes of existing standards of care



### **INVESTMENT HIGHLIGHTS**

IMUGENE

Developing Cancer Immunotherapies

MARKET CAPITALISATION

9 August 2023

A\$591M

US\$389M



PRO-FORMA CASH AS OF

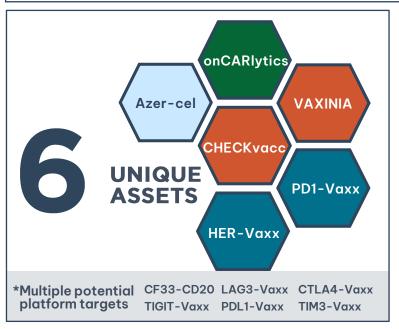
30 June 2023<sup>1</sup>

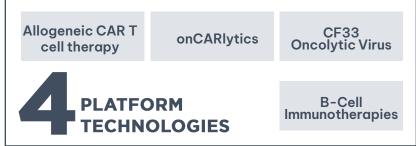
A\$196.6M

US\$143M

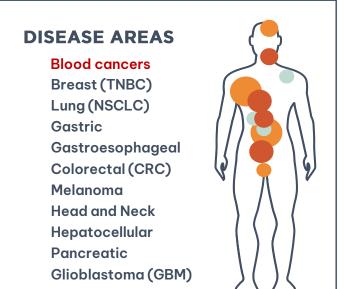


- Imugene is undertaking a capital raising of A\$60m, via a \$30m Placement and \$30m share purchase plan
- Funds raised will support the license of a late-stage allogeneic cell therapy CAR T drug Azer-cel, which targets CD19 to alter blood cancer











#### **CLINICAL STUDIES**

AZER-CEL DLBCL (FDA IND)
IMPRINTER: Ph1 NSCLC (FDA IND)

CHECKvacc COH IST: Ph1 TNBC (FDA IND)

neoHERIZON: Ph 2 Neoadjuvant Gastric Cancer

nextHERIZON: Ph2 Metastatic Gastric Cancer (FDA IND)

MAST: Ph1 Solid Tumors (FDA IND)
DOMINICA: Ph1 TNBC (FDA IND)

onCARlytics: Ph1 Solid Tumors (FDA IND)

neoPolem IST: Ph1 CRC

HERIZON: Ph1b/2 First line Gastric Cancer





Merck KGaA

Roche

### **AZER-CEL CD19 ALLOGENEIC CAR T**





Allogeneic CAR T Cell Therapy

## Azer-cel



### **EXECUTIVE SUMMARY**



Imugene has licensed a near term potential registrational stage, off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to attack blood cancer.

Imugene can also use this drug to combine with its existing on CAR19 to treat solid tumours. The Transaction includes:



Exclusive world-wide license to the FIRST IN CLASS product known as azer-cel with over 84 patients treated in a Phase I trial, demonstrated safety and compelling efficacy

3 ADDITIONAL ASSET TARGETS



Encouraging FDA guidance and feedback on manufacturing for a potential FAST TO MARKET Phase 2 registration trial.

POTENTIAL FOR FIRST FDA APPROVED ALLOGENEIC CAR T



Completed drug material and manufacturing process



MANUFACTURING FACILITY

with a highly technically skilled and specialised work force

### KEY HIGHLIGHTS



Unique opportunity to develop highly promising allogeneic (off the shelf) CD19 CAR T drug in blood cancers with improved safety & strong efficacy

Highly complementary to IMU's existing CD19 OnCARlytics program

Robust & compelling data package from large 84 patient Phase 1 trial with 41% Compete Responses in non-

Hodgkin's Lymphoma, & 61% Complete Responses in CAR T relapse patients

Potential FDA accelerated approval for Phase 2 registrational trial [~18 months] POTENTIAL FOR FIRST IN

#### CLASS FDA APPROVED ALLOGENEIC CAR T CELL THERAPY

Experienced CAR T management team & manufacturing expertise joining from Phase 1 trial

Drug product for registrational Phase 2 study manufactured in state of the art cell therapy facility in North

Carolina

3 Additional Target Assets

Attractive financial licensing terms

Robust IP

### TRANSACTION SUMMARY





A\$11.9M upfront

A\$19.4M deferred consideration (cash and/or equity upon Imagene's discretion)

A\$11.9M (cash and/or equity upon start of Phase 2 registrational trial)

Milestone payments industry standard rates

Royalties based on industry standard rates

# **AUTOLOGUS (AUTO) CAR T THERAPY - A LIVING DRUG; PERSONALISED**



Auto CAR T cell therapy is a type of immunotherapy that uses a patient's own genetically modified T Cells to find and kill cancer

1

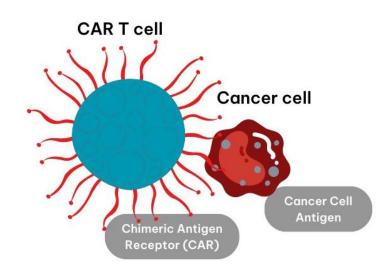


T Cells are taken from patients
(highly dependent on patients'
immune system) with blood
cancers such as leukemia &
lymphoma and reprogrammed to
target CD19 cancer cells

2



The re-programmed CD 19 T Cells are then injected back 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

# 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

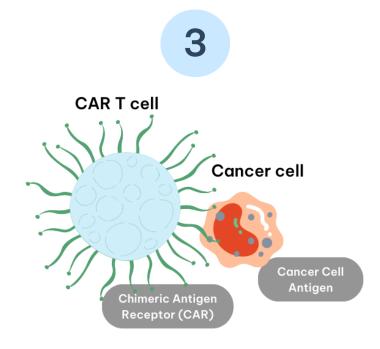


HEALTHY donors provide T Cells to make the CART product candidate.

Donor T cells are processed for "universal match" and incorporated to chimeric antigen receptor designed to attack tumour cells.



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 reprogrammed CD 19 T Cells are then injected into the cancer patient

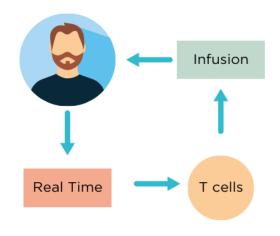


When the CD19 T Cells see the cancer cells with CD19 on them, the T Cells attack and kill them

## THE FUTURE OF CELL THERAPY IS OFF THE SHELF

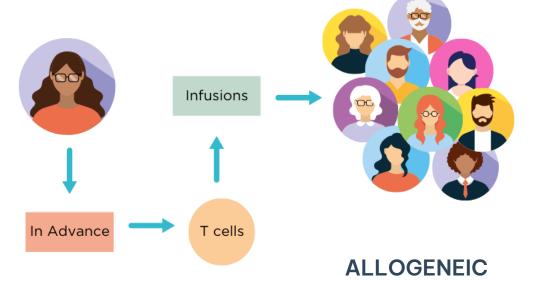


#### Patients shouldn't have to wait for treatment



**AUTOLOGOUS** 

- Limited patient access
- Long and complex manufacturing process and wait time (requires leukapheresis and bridging is often required)
- High manufacturing costs
- Variable potency



- Broad patient access
- Available on demand and off-the-shelf immediately (no leukapheresis and no bridging required)
- More efficient and cost-effective manufacturing
- Healthy donor cells engineered for potency and persistence

### WHAT IS DIFFUSE LARGE B-CELL LYMPHOMA?



#### A lethal type of Blood Cancer



- Diffuse large B-cell lymphoma (DLBCL) is an aggressive type of non-Hodgkin lymphoma (NHL) that develops from the B-cells in the lymphatic system, which are responsible for producing antibodies typically to fight infectious disease.
- DLBCL develops when some of your **B-cells become cancerous**. They grow uncontrollably, are abnormal, and do not die when they should.
- DLBCL is the most common subtype of non-Hodgkin lymphoma (80.5k diagnosis per year) accounting for ~30% of all cases.
- DLBCL can occur at any age but is most common in people aged over 50 years. The average age of diagnosis is 60-65 years; however, DLBCL can also affect children.
- DLBCL is high-grade (fast-growing) and needs to be treated quickly.
- Survival rates are poor with a high unmet clinical need.

### **HOW IS DLBCL TREATED TODAY?**

~30,000 New Cases in the U.S. Annually (2020 - SEER)



R-CHOP (Combination Chemotherapy\*)

- High dose chemotherapy w/ stem cell transplant
  - Auto CD19 CAR T cell therapies: Yescarta (Gilead), Kymriah (Novartis), Breyanzi (BMS)
- No standard of care for auto CAR T relapse patients

1st line

2<sup>nd</sup> line

3<sup>rd</sup> line

~60% of patients are cured with R-CHOP (Combination Chemotherapy\*)

~6,000 patients become eligible for 2<sup>nd</sup> line; 20-25% of these patients are cured

60-65% of patients treated with auto CD19 CAR T relapse Pool of post CAR T patients needing next line therapy expected to grow as auto CAR T therapies continue to penetrate in earlier lines of therapy

### **TOTAL BODY OF EVIDENCE:**



**Azer-cel has meaningful Clinical Activity across B Cell Malignancies** 

84

**Patients Treated With Azer-cel** 



58% ORR<sup>1</sup>
41% CR<sup>2</sup>

All Doses / All LD\* Regimens

61% ORR 61% CR/CRi

<sup>1</sup>ORR: Overall Response Rate <sup>2</sup>CR: Complete Response

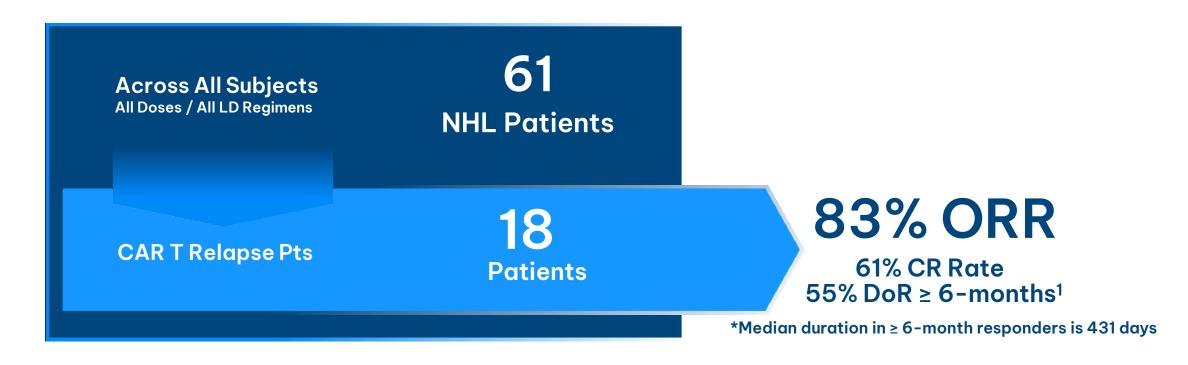
\*lymphodepletion

Note: Based on Patients Evaluable for Efficacy

## AZER-CEL IS ACTIVE IN CAR T RELAPSED PATIENTS:



**Demonstrated high response rates and durability** 



\* Azer-cel has the potential to provide new standard of care for this high-risk population with unmet need

## **CD19 AUTO CAR T RELAPSE MARKET IS LARGE**



**AND GROWING** 

~85% of patients continue to have CD19+ disease 1

In our prospective data, patients continue to have antigen positive disease









60-65% of patients currently treated with Auto CD19 CAR T will relapse (Fail)<sup>2</sup>

★ By 2025, Global CAR T Relapse Patient Pool Is Expected To Grow ~4x as Auto CAR T Drugs become the SoC in 2L+

Estimate total Global G8 markets to be ~18k patients per year<sup>3</sup>

### MARKET SIZE: DIFFUSE LARGE B-CELL LYMPHOMA





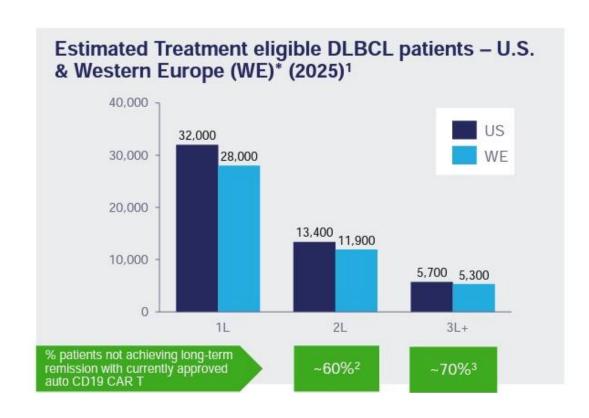
- ~30,000¹ patients with DLBCL in the US with 33% likely to be relapsed/refractory setting (1st line chemo combo)
- 60%-65% will be refractory or relapsed post an autologous CD19 CART therapy (estimated 6,400 patients)
- Approved auto CAR T priced at \$375,000 per one-time treatment
- Azer-cel DLBCL post-auto peak sales potential of ~\$2.5B<sup>2</sup> US
- Other lines of therapy and Indications (ie acute lymphoblastic leukemia {ALL})

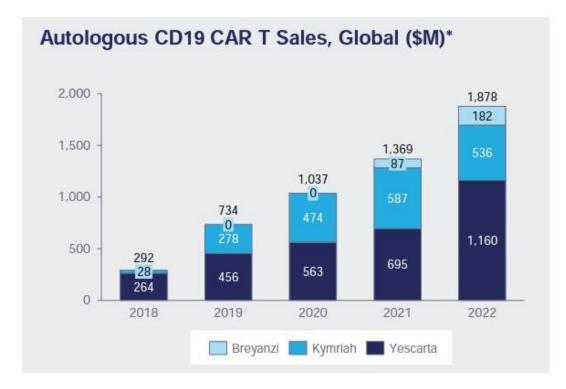
<sup>1.</sup> SEER 2020 Estimate

## UNMET NEED IN POST CAR-T: 60-70% OF PATIENTS PROGRESS



## Autologous CD19 CAR T Market \$2.2B Annual Projected for 2023 Growing: ~60-70% of Patients Progress





# PHASE 2 TRIAL ASSUMPTIONS (POTENTIAL REGISTRATIONAL/TO MARKET)



- Potential registrational study (FDA approval) to start upon completion of the Phase 1B study H2 2024
- Population: auto CAR T failures in DLBCL patients
- Positive formal and informal FDA guidance on the potential registrational study
- ~35+ sites in the U.S.: Phase IB trial currently conducted at Dana Farber, Moffit, MDACC, COH, Karmanos, U Minnesota, Cornell, Columbia
- Drug material manufactured in North Carolina at our facility









MASONIC CANCER CENTER

University of Minnesota

MDAnderson Cancer Center

### **CMC & MANUFACTURING**







- Manufacturing 32,800 (17,300 manufacturing +15,500 expansion) sq ft facility in Durham, NC
- GMP compliant / FDA inspected
- Turn-key solution ready for final registrational trial drug product supply
- Robust and validated process for 84 patients dosed to date (optimized along the way)
- Drug product for Phase 1B confirmatory trial completed
- Experts transitioning to Imagene for continuity of drug manufacturing

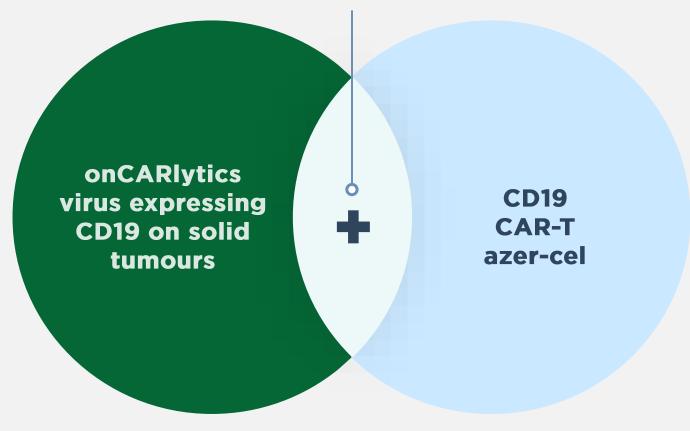
# AZER-CEL OFFERS on CARIYTICS AN IN-HOUSE (S) COMBINATION APPROACH FOR SOLID TUMOURS



### Enables Imugene to progress its own combination solution in multiple solid tumour indications

- Strengthen current development of onCARlytics by adding an in house off the shelf CD19 CAR T
- Enables and boosts Imugene's footprint in the blood cancer and continued solid tumour oncology markets

#### **Combination treatment for solid tumours**



## RECENT DEALS IN ALLO CAR T CELL THERAPY IMUGENE Developing Cancer Immunother



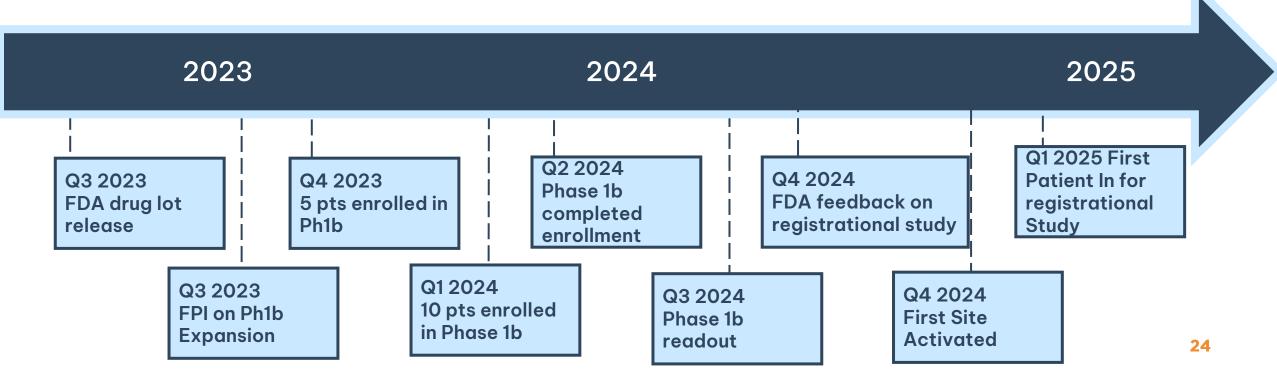
Date	Deal Type	Deal Summary ( <b>Licensor</b> , Licensee)	Technology	Indication	Stage	Financials (\$USD)
Aug 2023	Exclusive worldwide license	Precision Bio Imugene	Allo CAR T cell therapy	Blood and Solid Tumour Oncology	Phase 1B/2 (registrationa I to market)	\$8m upfront + \$13m deferred consideration
Aug 2023	Right of first refusal only	Poseida Therapeutics, Astelllas	Allo CAR T cell therapy	MUC1-C expressing solid tumors	Phase 1	\$25m upfront + \$25m equity investment*
July 2023	Right of first refusal only	Caribou Biosciences, Pfizer	Allo CAR T cell therapies (CD19)	Blood malignancies	Phase 1	\$25m equity investment*

# **AZER-CEL VALUE INFLECTION POINTS EXPECTED IN THE NEXT 12-18 MONTHS**



#### **Key Events:**

- Q3, 2023: FDA Process 1.2 Drug Lot Release (validating Phase 2 registrational study drug)
- Q4, 2023: First Patient in for Phase 1b Expansion
- Q4, 2023 Q2, 2024: Patient recruitment status and completion of enrolment of Phase 1b
- Q3, 2024 Q4, 2024: Phase 1b readout and FDA feedback on registrational study
- Q4, 2024: Status on Site approval activity
- Q1, 2025: First Patient Dosed on registrational Study



### **EXECUTIVE SUMMARY**



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3 ADDITIONAL ASSET TARGETS



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POTENTIAL FOR FIRST FDA APPROVED ALLOGENEIC CAR T



Completed drug material and manufacturing process



with a highly technically skilled and specialised work force

MANUFACTURING

### **CAPITAL RAISING OVERVIEW**



## Imugene is conducting a capital raising of up to approximately A\$60.0 million via an institutional placement and share purchase plan

	institutional placement and shale purchase plan
Placement	<ul> <li>Placement to raise approximately A\$30.0 million ("Placement")</li> <li>Approximately 357.1m new Shares under the Company's existing placement capacity under ASX Listing Rules 7.1</li> </ul>
Placement Pricing	<ul> <li>The offer price of A\$0.084 per share ("Placement Price") represents:</li> <li>A discount of 10.64% to the last close of A\$0.094 on 15 August 2023</li> <li>A discount of 12.38% to the 20-day VWAP of A\$0.096 up to and including 15 August 2023</li> </ul>
Share Purchase Plan	<ul> <li>Imugene intends to offer eligible shareholders an opportunity to subscribe for up to A\$30,000 of new Shares under a Share Purchase Plan (SPP), to raise approximately A\$30 million<sup>1</sup></li> <li>The SPP will be offered at the lower of: <ul> <li>\$0.084 per New Share, being the Placement Price; and</li> <li>2.5% discount to the VWAP of the Company's shares traded on the ASX during the five trading days up to the closing date of the SPP</li> </ul> </li> <li>Record date for determining eligibility for the SPP is 7:00pm on Thursday, 17 August 2023</li> <li>Further details in relation to the SPP, including the scale-back policy, will be provided to eligible shareholders in transaction-specific prospectus</li> </ul>
Attaching Option	<ul> <li>Shares will be offered under the Placement and SPP with one free attaching option for every New Share issued (Options)</li> <li>The Options are intended to be listed on the ASX with an exercise price of \$0.118 and will expire on 31 August 2026.</li> <li>The Options will be offered under a transaction-specific prospectus and the issue of Options will be conditional on shareholder approval at an EGM.</li> <li>The Options offer is also conditional on the Options meeting the ASX's quotation conditions.</li> </ul>
Ranking	New Shares issued under the Placement will rank pari passu with existing Shares from their date of issue
Lead Manager	Bell Potter Securities Limited

### **USE OF FUNDS**



Pro-forma cash of A\$196.6m post capital raising<sup>1</sup>, with the potential for a further A\$45m from the exercise of attaching options

USE OF FUNDS	A\$'M
Upfront payment	11.9
Equity or cash on successful completion of Phase 1b	11.9
Equity or cash 12 months after signing	19.4
Phase 1b Clinical trial costs	8.7
CAR T CMC/Manufacturing	8.1
Total	60.0

<sup>&</sup>lt;sup>1</sup> Assumes capital raising is fully subscribed and includes upfront payment under license agreement and an introduction fee of US\$3 million to Chimeric Therapeutics Limited. Excludes offer costs. If funds raised are less than A\$60m any shortfall will be met through existing cash reserves.

### **OFFER TIMETABLE**



Event	AEST
Trading halt	Wednesday, 16 August 2023
Record Date for SPP	Thursday, 17 August 2023
Placement announced & Shares resume trading on ASX	Friday, 18 August 2023
Placement settlement of new Shares	Thursday 24 August 2023
Placement issue of new Shares	Friday, 25 August 2023
SPP opens	Monday, 28 August 2023
SPP closes	Thursday, 14 September 2023
Issue of new Shares under SPP	Friday, 15 September 2023
EGM for approval of attaching options	Tuesday, 26 September 2023
Issuance of attaching options	Wednesday, 27 September 2023

The timetable is indicative only and subject to change by the Company and Lead Manager

### INTERNATIONAL OFFER JURISDICTIONS



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- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
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- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

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No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities. The contents of this Deal Sheet have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this Deal Sheet, you should obtain independent professional advice.

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The New Shares and New Options will only be offered and sold in the United States to:

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dealers or other professional fiduciaries organized or incorporated in the United States that are acting for a discretionary or similar account (other than an estate or trust) held for the benefit or account of persons that are not US persons and for which they exercise investment discretion, within the meaning of Rule 902(k)(2)(i) of Regulation S under the US Securities Act.

### **Contact**

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