

Leading Innovation in Cancer Treatment

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ASX:IMU

Release authorised by the Managing Director and Chief Executive Officer, Imugene Limited.

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Investment Highlights





Three Novel Cancer Technologies In Clinical Trials



	Allo CAR T Cell Therapy	CF33 Oncolytic Virus	onCARIytics IMUGENE	
	azer-cel CD19 CAR T	CF33 Oncolytic Virus VAXINIA MAST Trial	onCARlytics CD19 targeting virus OASIS Trial	
	Phase 1b	Phase 1	Phase 1	
	Off-the-shelf drug, aka "Allo" geneic	Novel cancer killing virus	Novel virus which acts as a CD19 target in solid cancers	
	Targeting blood cancers	Targeting a range of late-stage solid cancers	• Makes solid cancers visible to CD19 drugs	
U	Positive Phase 1 data in 84 patients	Phase 1 trial with >40 patients enrolled	Currently in Phase 1 in combination with Blinatumomab (Approved CD19 drug in	
	Currently in Phase 1b	Encouraging results in bile tract cancer	blood cancers) in solid cancers	
	FDA IND	FDA IND	FDA IND	



AZER-CEL CD19 CAR T FOR BLOOD CANCER

The Future of Cell Therapy is Off-the-Shelf Treatments



Patients shouldn't have to wait for treatment



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 Imugene's azer-cel CAR T?

Allo CAR T Cell Therapy



https://ascopost.com/news/november-2023/novel-strategy-may-improve-outcomes-in-patients-with-treatment-resistant-dlbcl/

Large Phase 1 Blood Cancer Trial Completed in 84 Patients with Encouraging Results



Overall Response Rate: the percentage of patients who have a partial response or complete response to the drug within a certain period of time

Allo CAR T Cell Therapy

Complete Response: disappearance of all signs of cancer in the body

Duration of Response: the time from first dose to disease progression who achieved complete or partial response. Median duration in ≥ 6-months¹

DLBCL is an Aggressive Type of Non-Hodgkin Lymphoma (NHL) with **Improving Options for Patients**

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





CD19 Autologous CAR T Failure Market is Large and Growing

Allo CAR T Cell Therapy

YESCARTA[®] Breyanzi[®]
KYMRIAH[®]

60-65%

tisagenlecleucel) for IV infusion

of patients currently treated with autologous CD19 CAR T will relapse¹



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 year²

Potential blockbuster sales of ~\$2.5B³ per annum in DLBCL (Blood cancer) CAR T relapsed patients

Note: Retrospective Literature states that 12-28% of patients have antigen negative relapse (CD19-) 1. Estimated from ZUMA 1 and ZUMA 7 EFS rates:

G8 includes US, Japan, Canada and EU5 assuming equal access to CAR T therapies; market research, CancerMPac

TAM: total addressable market is total number of treatable patients x price at 100% market share

67% Complete Response Rates Observed in Phase 1b Cohort B



Lymphodepletion(LD)/chemotherapy: Aug Cy: Flu 30mg/m2 x 3d, Cy 750mg/m2 x 3d

	Evaluable patients: Cohort A+B (N=9)	Evaluable patients: Cohort A (N=6)	Evaluable patients: Cohort B (N=3)*
Overall Response Rate %	4 (44%)	2 (33%)	2(67%)
Complete Response %	3 (33%)	1 (17%)	2(67%)
Best Durability (Time of response)		<60 days	>120 days on going

*One patient currently SD, probable pseudoprogression; assessment of response at follow up scans.

Cohort B Results

- The first 2 patients treated achieved a complete response (CR), 1 patient had stable disease (SD)*, 1 patient yet to be evaluated
- Responses were seen in patients who failed multiple prior treatments, including autologous CAR T therapies
- Phase 1b trial continues to enroll patients into Cohort B across 15 leading cancer centres in the U.S. including, Columbia University, University of Minnesota, Emory and Moffitt Cancer Centres and plans are ongoing to open up to 5 sites in Australia.

Azer-cel has a Manageable Safety Profile No evidence of GVHD or GR. >3 CRS

Allo CAR T Cell Therapy

- Manageable CRS occurs within first week but resolves quickly
- In Cohort B, no ICANS has been observed to date
- While infections have occurred, the majority have been Grade 1 or 2



CRS: Cytokine release syndrome CANS: Immune Effector Cell-Associated Neurotoxicity Syndrome

Addition of IL-2 to Dosing Regimen Enhances CAR-T Expansion and Possibly Efficacy *In Vivo*



Allo CAR T Cell Therapy

IL-2 effect on azer-cel persistence

- Limited expansion seen in vivo in the absence of IL-2
- Higher C-Max in patients with IL-2
- Addition of IL-2 increases CAR-T persistence out to at least 60 days
- Increased azer-cel persistence likely correlates with therapeutic response

*One subject still within D28 assessment window

Representative PET Scans of Complete Responses

Allo CAR T Cell Therapy

Subject Treatment Summary

- 60 yo female, first diagnosed with DLBCL (GCB, w/o c-Myc/BCL-2 rearrangements), stage IV in Apr 2012. Treated at University of Minnesota (UMN).
- Prior to azer-cel, patient failed 5 prior lines of therapy; R-CHOP x 6; Rituxan, RICE x 2 followed by BEAM + auto HCT and maintenance therapy (Rituximab + ADAM17 inhibitor); Yescarta/Flu/Cy; Loncastuximab / ibrutinib
- Pathologist report revealed neoplastic cells were positive (3.9%) for CD19 by flow
- Azer-cel treatment regimen
 - Augmented Cy conditioning regimen (750 mg/m2/d (3d) Cyclophosphamide i.v. + 30 mg/m2/d (3d) fludarabine iv) + low dose SC IL-2
 - DL4b (500 x 106 CAR T cells)
- Notable Safety Events-No CRS/ICANS
- Response PR @ D28, CR @ D60 & D90



Azer-cel Clinical Development Strategy

Allo CAR T Cell Therapy





Milestones:

- Preliminary early DLBCL Phase 1b data update
- Diffused Large B-Cell Lymphoma (DLBCL) Phase 1b interim data update
- Target regulatory meeting with FDA
- FPI in registration Phase 2/3 trial



CF33 VAXINIA ONCOLYTIC VIRUS

CF33 VAXINIA Can Infect and Kill Cancer Cells

CF33 Oncolytic Virus



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)

Phase 1 VAXINIA Metastatic Advanced Solid Tumour (MAST) Trial

1x10⁶

1x10⁶

H-

IV





Signals ST VINCENT'S Patients¹ >40 patients have been dosed and evaluated (at least their first scan at day 42) CANCER INSTITUTE **Disease Control So Far** \$= ==(0 • Nearly half of the evaluable patients (48%) have remained on treatment for >3 months • 3 patients have remained on treatment for >200 days HIGHLANDS ONCOLOGY Responses 🕅 Cityof Hope. • Patient with bile tract cancer who had a complete response (CR); ongoing remission for >1.7 years • 2 patients with melanoma had partial responses (PRs); 17 patients achieved stable disease (SD) **Cancer Center Bile Tract Trial** Bile tract cancer expansion trial opened based on positive response UNIVERSITY OF UTAH Preliminary and early data are expected in the second half 2024 **Fast Track** FDA FDA U.S. FO TRACK Sesignation US FDA Fast Track Designation for bile tract cancer, which allows for faster review

¹Preliminary study update as of June 2024; data and number of evaluable patients subject to change with full statistical analysis

Phase 1 MAST Trial – Encouraging Early

CF33 Oncolytic Virus

Turning Cold Tumours Hot

Complete Remission after Pseudoprogression (immune activity) in a Monotherapy patient with a cold tumour (bile tract cancer)



PD-L1 negative with no response prior to CF33

MAST CF33 Clinical Development Strategy







- Intratumoural (IT) Second Indication Trial open
 - Preliminary early Bile Tract expansion trial update
 - Optimal Biological Dose Established for IT and/or Intravenous (IV) monotherapy
- Phase 2 Study Open
 - Phase 2 First Patient In (FPI)



ONCARLYTICS CD19 VIRUS FOR SOLID CANCERS



Mechanism of Action: How Does it Work?



OnCARlytics



OnCARlytics makes solid tumors "seen" by CD19 targeting therapies



OnCARlytics infects Tumour cells

2

Virus replication and production of CF33-CD19 on the cell surface enabling CD19 cell targeting



Tumour cell lysis leads to viral particle release and the combination promotes endogenous immune cell



Released viral particles re-initiate virus infection of surrounding Tumour cells 23

Imugene has Initiated The OASIS Phase 1 Open Label Trial with CD19 Virus and Blinatumomab





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)



Global blood cancer CAR T market ~USD \$3B in 2023; projected to be ~USD \$23B by 2033, growing at a compound annual growth rate of 23.35%¹

The global solid tumor cancer treatment market size estimated at USD 185.97 billion in 2022 and is projected to grow around USD 532.42 billion by 2032

onCARlytics could open up 90% of the market in solid tumours

1/https://www.precedenceresearch.com/solid-tumor-cancer-treatment-market

Combination Opportunities					
	First FDA Approval	Target	Approved Cancers		
ပံ novartis	2017	CD19 Auto CAR T	B-ALL, DLBCL		
Kite	2017	CD19 Auto CAR T	DLBCL, R/R FL		
Kite	2020	CD19 Auto CAR T	R/R MCL		
ر ^{ال} Bristol Myers Squibb	2021	CD19 Auto CAR T	DLBCL		
morphosys	2020	CD19 Monoclonal Antibodies (MAbs)	DLBCL		
HORIZON	2020	CD19 MAbs	NMOSD		
AMGEN	2014	CD19-CD3 Bispecific MAbs	ALL		
	2021	CD19 Antibody- drug conjugate (ADC)	B-Cell Lymphoma		
	Combi	Combination Op First FDA Approval © NOVARTIS 2017 2017 2017 2017 2020 © Bristol Myers Squibb" 2021 Imorphosus 2020 Imorphosus 2020	Combination OpportunitiesFirst FDA ApprovalTargetImage: Novartis2017CD19 Auto CAR TImage: CD19 Auto CAR T2017CD19 Auto CAR TImage: CD19 Auto CAR T2020CD19 Auto CAR TImage: CD19 Auto CAR T2021CD19 Auto CAR TImage: CD19 Auto CAR T2020CD19 Auto CAR TImage: CD19 Auto CAR T2020CD19 Auto CAR TImage: CD19 Auto CAR T2020CD19 Monoclonal Antibodies (MAbs)Image: CD19 Auto CAR T2021CD19 Auto CAR T		

CD19 Virus Clinical Development Strategy







Milestones

- FPI IT Combo Cohort 1
- Early IT and/or IV Combo data
- Optimal Biological Dose (OBD) Established
- Phase 2 FPI
- OnCARIytics + azer-cel FDA IND and FPI in solid tumours

Future Combination Phase 1 Trial with azer-cel and CD19 virus

Preclinically, Azer-cel in combination with on CARlytics demonstrated sustained, robust activity against multiple tumour types

Showed 100% killing of Triple Negative Breast Cancer and Gastric Cancer at 72 hours

Expected Upcoming Key Catalysts



H2 2024

- **azer-cel**: Preliminary early DLBCL Phase 1b data update
- onCARlytics: FPI IT Combo Cohort 1
- onCARlytics: Early IT and/or IV Combo data
- VAXINIA: Second indication trial open
 VAXINIA: Preliminary early Bile Tract
 expansion trial update

Key FPI: First Patient In Combo: Combination Therapy Mono: Monotherapy DLBCL: Diffuse Large B-Cell Lymphoma (Blood Cancer) IA: Intra-arterial, IP: Intraperitoneal IT: Intratumoural, IV: Intravenous

2025-2026

- azer-cel: DLBCL Phase 1b interim data update
- azer-cel: Target regulatory meeting with FDA
- **azer-cel**: FPI in registration Phase 2/3 study
- azer-cel: Expansion into additional blood cancers (Phase 1b Expansion Cohort)
- onCARlytics: Data update and trial expansion
- onCARlytics: Optimal Biological Dose (OBD) Established
- onCARIytics + azer-cel FDA IND and FPI in solid tumours
- onCARlytics: Phase 2 FPI
- VAXINIA: Optimal Biological Dose Established for IT and/or IV monotherapy
- VAXINIA: Phase 2 Study Open
- VAXINIA: Phase 2 FPI
- VAXINIA: IP & IA Phase 1 FPIs



Investment Highlights



Robust platform technologies supporting 4 clinical trials with >200 patients treated to date in US and Australia, all under FDA INDs



Experienced Leadership Team has brought > 17 FDA Approved Drugs to Market







Dr. Paul Woodard, MD Chief Medical Officer

Bellicum

Genentech A Member of the Roche Group



Dr. Bradley Glover, PhD MBA Chief Operating Officer





illumına[®]



Ursula McCurry Chief Clinical Operations Officer



Genentech A Member of the Roche Group







Dr. John Byon, MD, PhD Senior VP of Clinical Development













Dr. Monil Shah Head of Business Development (consultant)



الله Bristol Myers Squibb



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HEALTH VENTURES

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SOFINNOVA

Apexigen









Corporate Snapshot



Stock Code	ASX IMU
12 Month Trading Range	3.9-15 cents
Market Capitalisation (2 September 20	24) \$500 million
Shares on Issue	7.4 B
Average Monthly Trading Volume	583 million shares
Cash at Bank (30 June 2024)	A\$93.1 million
No of Shareholders	29,465
Board & Management Ownership	7.8%
100% Shareholders 3.8% 8.5% 80.36%	 Board & Management US Instos Australian Instos Retail

Top 15 Shareholders

Paul Hopper	409,071,906	5.50%
Vanguard	315,683,712	4.24%
Mann Family	265,582,609	3.57%
Private Clients of AustralianSuper	120,688,917	1.62%
Dr Nicholas Smith	118,000,000	1.59%
Precision BioSciences Inc	87,999,186	1.18%
Ms Leslie Chong	85,710,416	1.15%
BlackRock Investment Mgt	54,791,056	0.74%
State Street Global Advisors	53,269,804	0.72%
Thorney Investments	50,328,041	0.68%
5 Financial	49,812,888	0.67%
UBS Financial Services Inc	37,922,410	0.51%
Goldman Sachs Asia	35,054,415	0.47%
Netwealth Investments	34,943,717	0.47%
UBS AG Zurich	33,967,341	0.46%

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