



IMUGENE

Developing Cancer Immunotherapies

ASX: IMU

Developing Cancer Immunotherapies

AGM November 2022



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2022 IMUGENE SUMMARY



INVESTMENT HIGHLIGHTS

MARKET CAPITALISATION 16th Nov 2022

A\$1.29B

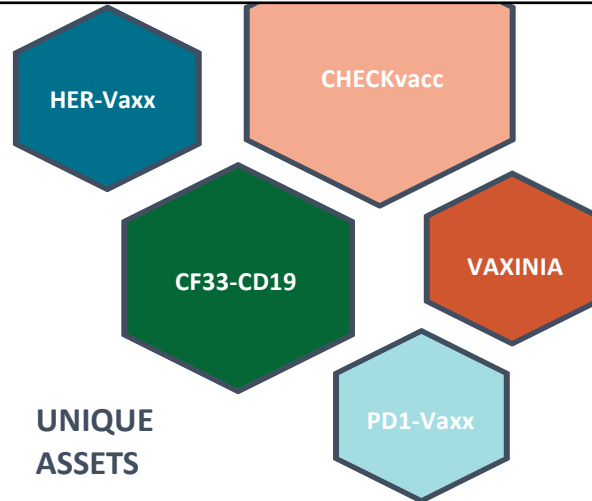


CASH AS OF 30th Sep 2022

A\$163.8M



5 UNIQUE ASSETS



*Multiple potential platform targets

CF33-CD20	LAG3-Vaxx	CTLA4-Vaxx
TIGIT-Vaxx	PDL1-Vaxx	TIM3-Vaxx

3 PLATFORM TECHNOLOGIES

CF33
Oncolytic Virus

onCARlytics

B-Cell Immunotherapies



3 SCIENTIFIC COLLABORATIONS

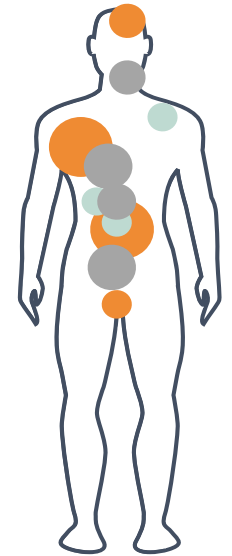
Celularity

Eureka

Arovella

DISEASE AREAS

Breast (TNBC)
Lung (NSCLC)
Gastric
Gastroesophageal
Colorectal (CRC)
Melanoma
Head and Neck
Hepatocellular
Pancreatic
Glioblastoma (GBM)



CLINICAL STUDIES

HERIZON: Ph1b/2 First line Gastric Cancer
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 Tumours (FDA IND)
DOMINICA: Ph1 TNBC (FDA IND)
onCARlytics: Ph1 Solid Tumours (FDA IND)
neuHERIZON: Ph2 Biomarker Study
PD1-Vaxx IST: Ph1 CRC

2 SUPPLY AGREEMENTS

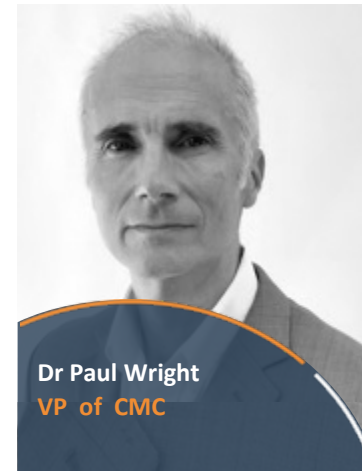
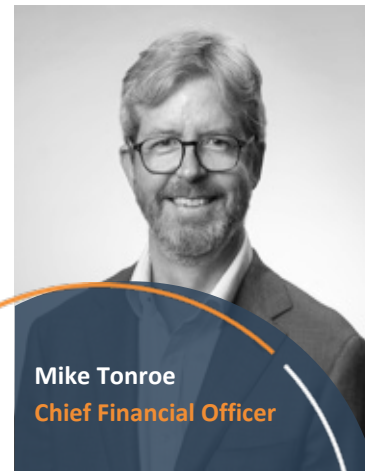
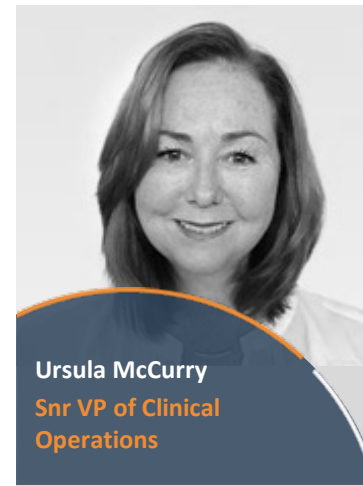


Merck
KGaA/Pfizer

Roche

IMUGENE'S MANAGEMENT TEAM

Experienced management team with significant clinical development expertise



HER-Vaxx 2022 YEAR IN REVIEW

HERIZON:

- ✓ Phase 2 Final OS Readout with positive overall survival
- ✓ Poster at ESMO World GI
- ✓ Oral presentation at ESMO ASIA
- ✓ Oral presentation at ASCO GI 2023

nextHERIZON:

- ✓ FDA IND approval
- ✓ First Patient Dosed
- ✓ Abstract accepted to ASCO GI

neoHERIZON

- ✓ Clinical supply agreement with Merck KGaA and Pfizer

HER-Vaxx Immunotherapy Patents granted in:

- ✓ Europe
- ✓ China
- ✓ South Korea
- ✓ Japan



ASCO[®] Gastrointestinal
Cancers Symposium



KEYTRUDA[®]
(pembrolizumab) Injection 100 mg



ENDPOINT	OVERALL SURVIVAL Final OS Readout	
Treatment	HER-Vaxx + Chemo	Chemo Only
Sample Size	19	17
Events	15	17
Median OS (2-sided 80% CI)	13.9 months (7.5, 14.3)	8.3 months (6.0, 9.6)
Median Duration of Response	30 weeks	19 weeks
HR	0.585 (0.368, 0.930)	
2-sided 80%CI		
Log-rank Test	0.066 +	
(1-sided p-value)*		



PD1-Vaxx 2022 YEAR IN REVIEW



IMPRINTER:

- ✓ Completed Phase 1a monotherapy dose escalation
- ✓ Clinical trial supply agreement with Roche to evaluate PD1-Vaxx in combination with Tecentriq®
- ✓ Abstract was published for ASCO 2022
- ✓ Poster presented at 2022 World Conference on Lung Cancer



Phase 1: IMU-201 (PDI-Vaxx), a B-Cell Immunotherapy as Monotherapy or in Combination with Atezolizumab, in Adults with Non-Small Cell Lung Cancer

G.E. Richardson, J.J. Parki, M. Gutierrez, D. Di Barbano, P. Savvides, P. Kaumayya, T.S. Bekaii-Saab, T.G. Phan, L.M.O. Chang, N. Edeh, B. Nixon, N.P. Withana, A.J. Good, M.J. Boyer
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 Correspondence: Prof. Michael Boyer (Michael.Boyer@qh.org.au)



IMUGENE
Developing Cancer Immunotherapies

P1.15-08

Introduction

Therapies with monoclonal antibodies targeting PD-1 and its ligands are associated with positive clinical outcomes and have revolutionized cancer treatment. However, patients treated with PD-1/PD-L1 blockade may develop a primary or secondary respiratory illness [Barnett, 2017]. Current monoclonal antibodies against PD-1 and PD-L1 may have the advantage of producing B-cell antibodies that competitively induce memory B- and T-cell responses while reducing immune evasion and suppression. The fact is a polyclonal induced B cell antibody response will be more effective or as effective with improved safety over current antibody therapy. KAU-201 (PD-1-Vacc) is being developed using an active immunization approach to treat cancers that over express and induce the production of anti-PD-1 antibodies utilizing a peptide epitope designed to stimulate polyclonal antibodies against PD-1 [2020]. Here we present preliminary data from the ongoing Phase I study (NCT04342207).

Study Design

Patient Population (IMU-201-KC) study is an ongoing open-label dose escalation study of IMU-201 as monotherapy (Phase I) or in combination with pembrolizumab (Phase II) for patients with PD-L1 expressing non-small cell lung cancer (NSCLC). Figure 1 shows the study design.

All patients enrolled in phase I of the study must have previously received an immune checkpoint inhibitor (ICI) and experienced progression. Patients enrolled in Phase II of the study are either ICI naïve or have previously received an ICI containing nivolumab or after the treatment. The primary objective is to evaluate the safety and tolerability of IMU-201 at various doses in combination and identify the optimal combination dose of IMU-201 plus pembrolizumab to secondary objectives include to evaluate IMU-201 monotherapy or in combination with atezolizumab. The exploratory objective is to evaluate humoral and cellular immune data includes IMU-201 and PD-1 specific antibodies (Ab), IgG₁ vaccine-specific opsonine levels, and modulator and effector T-

Figure 1. Study Design



Method

In Phase II, IMU-201 is administered by intramuscular (IM) injection on Days 1, 15, 29, 64, and every 63 days subsequently until end of treatment. Dose-limiting toxicity (DLT) assessment is completed after 29 days on treatment. Tumor evaluation is conducted every 42 days according to RECIST 1.1 until progression or discontinuation.

In Phase III, IMU-201 is administered by intramuscular (IM) injection on Days 1, 15, 29, 57, and every 56 days subsequently until end of treatment. Atezolizumab 1200mg is administered every 2 weeks starting at day 15 until end of treatment. Tumor evaluation is conducted every 42 days according to RECIST 1.1 until progression or discontinuation.

- * Histologically confirmed NSCLC tumor stage IIB (not eligible for definitive treatment) or IV. (3 major types of NSCLC are acceptable including squamous, adenocarcinoma, and large cell carcinoma)

- Age of not less than 18 years
- Life expectancy of at least 12 weeks in the opinion of the investigator
- Zubo/ Eastern Cooperative Oncology Group (ECOG) score performance status 0-1
- Prior treatment criteria:
 - Phase I: Progressed on prior PD-1 / PD-L1 containing regimen
 - Phase II: Treatment naïve or progressed on prior PD-1 / PD-L1 containing regimen
- PD-L1 expression criteria:
 - Phase I: TPS/TSR ≥ 50% or Ix3 ≥ 10% (testing by 22C3, SP94, or SP56)
 - Patients with PD-L1 TPS/TSR ≥ 50% or Ix3 ≥ 10% expression may be included with agreement of Sponsor
 - Phase II: Ix3-301 + celecoxib/TPS/TSR ≥ 50% or Ix3 ≥ 10%
 - (Testing by 22C3, SP94, or SP56)
- At least one measurable lesion as defined by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria

Demography

Baseline characteristics of the patients in Phase I are summarised in Table

	POI+ voice	POI+ no voice	POI+ no voice
Median age, years (range)	52 (46–55)	73 (46–83)	73 (56–85)
Age < 55 years, n (%)	2 (4.6)	4 (6.7)	2 (3.4)
Sex, male, n (%)	3 (7.0)	5 (8.0)	3 (5.0)
Sex, female, n (%)	3 (7.0)	5 (8.0)	3 (5.0)
Race, n (%)			
Asian	0 (0.0)	0 (0.0)	1 (1.7)
Caucasian	4 (9.0)	4 (6.0)	3 (5.0)
Prior CD therapy			
Irradiation	1	1	
Chemotherapy	1		
Both	1		
None	1	4	3

Safety Results

Safety data from patients in Phase 1 are shown in Table 2 and Table 3.

Adverse Event *	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Total n (%)
Acute kidney injury	1 (7)			1 (7)
Ate dust obstruction	1 (7)			1 (7)
Cerebrovascular accident		1 (7)		1 (7)
Immune-mediated pneumonitis			1 (7) **	1 (7)
Non-cardiac chest pain	1 (7)			1 (7)
Pneumonia	1 (7)			1 (7)

Table 3: Adverse Events Assessed As Related to Study Drug in All Patients (n=14)

	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Adverse Event *	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Cough	1 (7)					1 (7)
Decreased appetite	1 (7)					1 (7)
Diarrhea	1 (7)					1 (7)
Headaches	1 (7)					1 (7)
Nausea	1 (7)	1 (7)				2 (14)
Unusual, modified pneumonitis		1 (7)				1 (7)
Unusual skin eruptions	2 (14)					2 (14)
Unusual site pain	5 (35)					5 (35)
Unusual site tenderness	8 (50)					8 (50)
Muscle twitching	1 (7)					1 (7)
Mild to upper extremities	1 (7)					1 (7)
Pruritis	1 (7)					1 (7)
Abnormalities	1 (7)					1 (7)

*Source: *Journal of Applied Social Psychology*,
Vol. 18, 1988, pp. 100-110. Reprinted with permission.

^aMin. CV To ensure reproducibility.

- No DLTs were observed
- Treatment was well tolerated

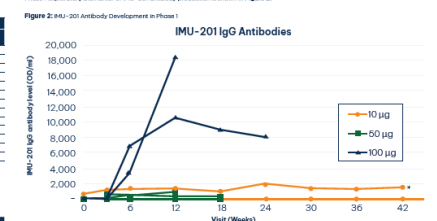
*Adverse events reported as related to study treatment were mainly injection site related and were low grade and non-serious.

*Two events of immune-mediated pneumonitis, one in the 50µg/dose cohort and one in the 100µg/dose cohort. Both patients withdrawn from the study

withdrawing from the stock

Blomarker Results

Phase 1 exploratory biomarker of IMU-201 antibody production is shown in Figure 2.



- By week 6, antibodies to IMU-201 were generated and sustained at high titers during treatment with 100 µg PDI-Vaxx
- There was a dose dependent increase in antibody production in patients receiving the 100 µg dose
- *One patient in the 10 µg cohort exhibited anti-IMU 201 antibody at baseline, believed to be cross reactivity with the assay with prior

Tumor Response Results

- Four patients were in the 10 µg/dose cohort, 6 patients in 50 µg/dose cohort, and 4 patients in the 100 µg/dose cohort
- In the 10 µg/dose cohort, one patient achieved a CR
- In the 50 µg/dose cohort, two patients achieved SD
- In the 100 µg/dose cohort, one patient achieved PR and two patients achieved SD
- Three patients remain on study

Conclusion

IMU-201 was generally safe and well tolerated. The potential for immune related adverse events requires evaluation of additional patients. IMU-201 monotherapy has shown an anti-tumor effect. Exploratory biomarker data indicates that IMU-201 is immunogenic and stimulates a sustained, antibody response. Taken together, these data support further evaluation of IMU-201 in NSCLC. Next steps are to evaluate immune mediated response to IMU-201 and to combine with the checkpoint inhibitor, atezolizumab.

Reference

P. Sharma, et al., Primary, Adaptive, and Acquired Resistance to Cancer Immunotherapy. *Cell*. 2017 Feb 9;168(4):707-723.

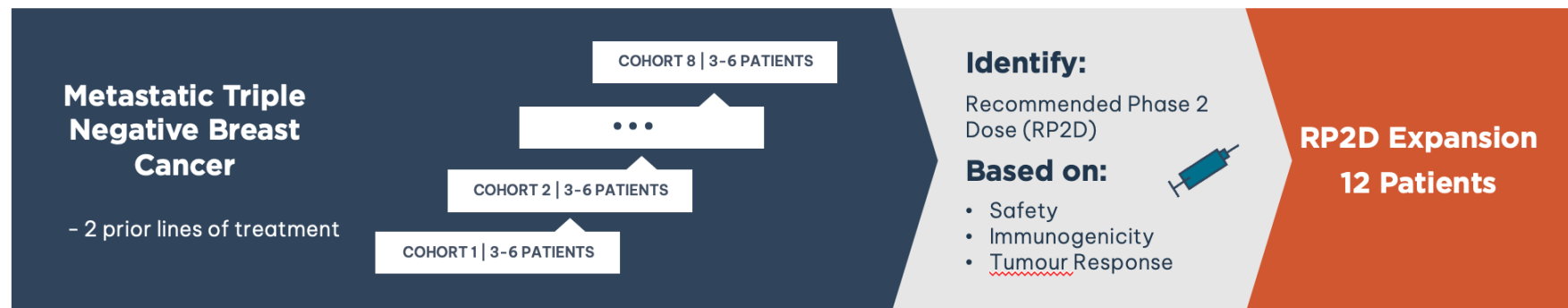
FTP Kaumaya, et al. Immunogenicity and antitumor efficacy of a novel human PD-1 B-cell vaccine (PD1-Vaxx) and combination immunotherapy with dual trastuzumab/pertuzumab-like HER-2 B-cell epitope vaccines (B-Vaxx) in a syngeneic mouse model. *Oncotarget*. 2020;11(1):181B437.

CHECKvacc 2022 YEAR IN REVIEW

- ✓ Phase 1, single centre, dose-escalation study in triple negative breast cancer at COH – FDA approval, first patient dosed, cohort 3 open
- ✓ Publication of abstract at American Society of Clinical Oncology Annual (ASCO) Annual Meeting
- ✓ Abstract accepted to San Antonio Breast Cancer Symposium (SABC)

ASCO® AMERICAN SOCIETY OF
CLINICAL ONCOLOGY

 **SAN ANTONIO
BREAST CANCER
SYMPOSIUM®**



First Patient Enrolled October 2021

Disease of need

- 8-13 month survival for metastatic disease with few treatments

Potential target for immunotherapy

- Expresses PD1, PD-L1

Treatment responses to Atezolizumab (JAMA Oncology, 5:74, 2019)

- 1st line: 24%; 2nd line: 6%
- Approved by FDA 8 March 2019

Potential for registration in well-designed, randomised P2 study

Indication	TNBC
FDA IND	<u>CHECKvacc: CF33-hNIS-aPDL1</u>
N	33-78
Location	Single Center: COH
Admin Route	<u>Intratumoral (IT)</u>

VAXINIA 2022 YEAR IN REVIEW

Phase 1 MAST Study:

- ✓ FDA IND Approval
- ✓ First Patient Dosed IT Cohort 1
- ✓ OGTR License Granted
- ✓ First Patient Dosed IV Cohort 1
- ✓ First Patient Dosed IT Cohort 2
- ✓ Partnership with ABL for manufacture of VAXINIA

CF33 Patent Granted:

- ✓ Japan



Dose Administration (Parallel Groups)

n=52-100



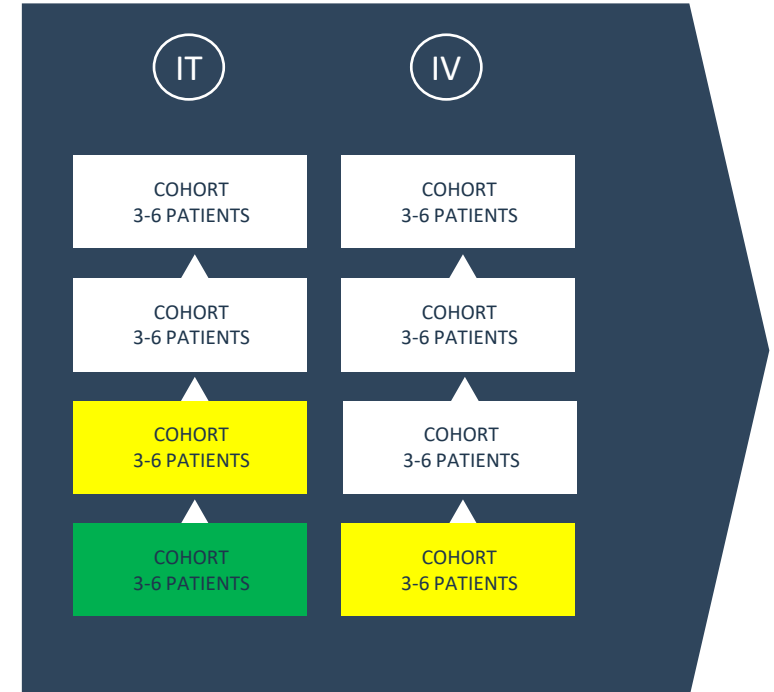
IT Administration
Metastatic and Advanced
Solid Tumours



IV Administration
Metastatic and Advanced
Solid Tumors

Site Location: USA, AUS

VAXINIA Monotherapy Dose Escalation

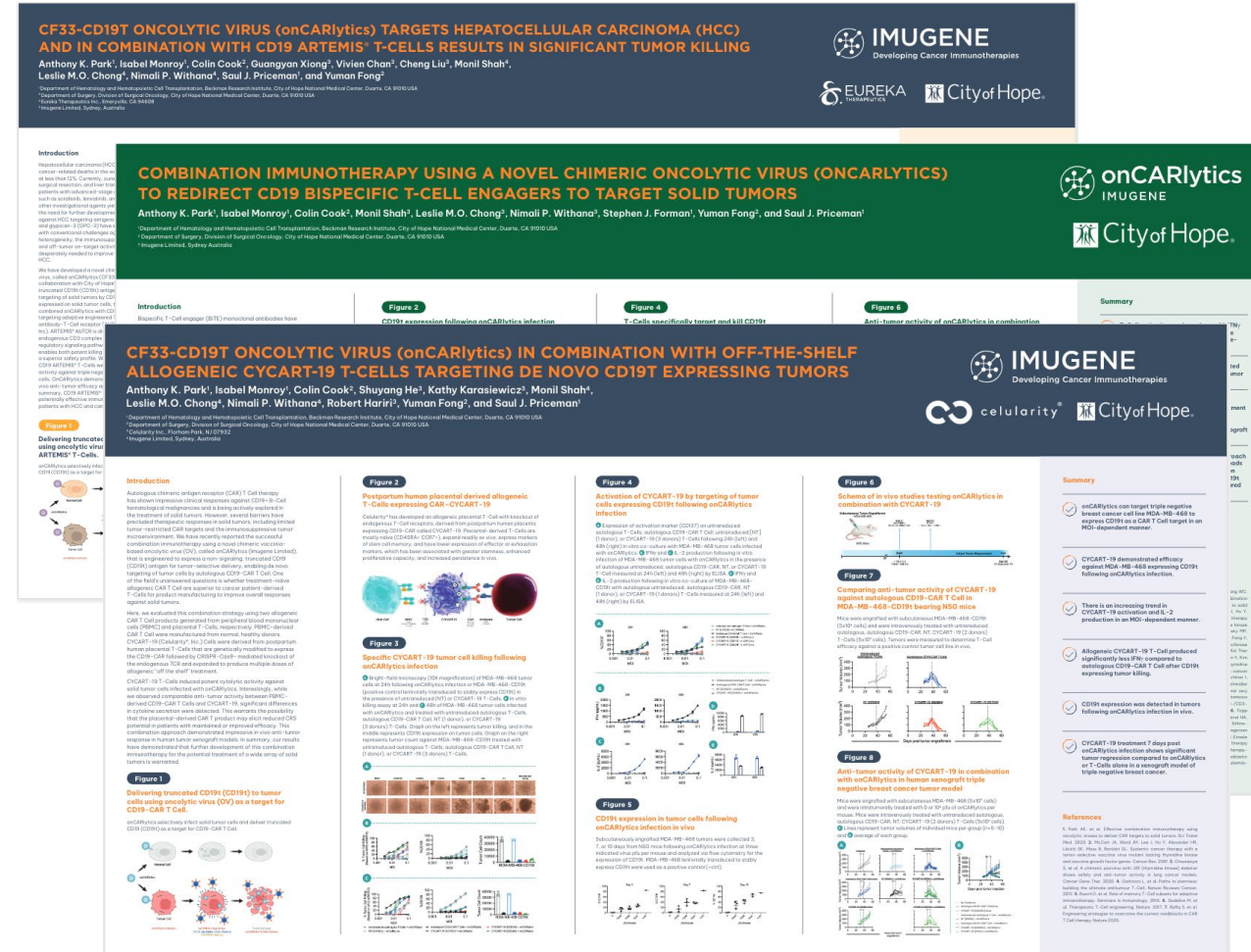


onCARlytics 2022 YEAR IN REVIEW

Showcased three abstracts at SITC :

- ✓ Combination immunotherapy using a novel chimeric oncolytic virus to redirect CD19 bispecific T cell engagers to target solid tumors
- ✓ CF33-CD19T oncolytic virus (onCARlytics) in combination with off-the-shelf allogeneic CYCART-19 T-cells targeting de novo CD19T expressing tumors
- ✓ CF33-CD19t oncolytic virus (onCARlytics) targets hepatocellular carcinoma (HCC) and in combination with CD19-Redirected ARTEMIS® T cells results in significant tumor killing

New preclinical trial to be conducted with Arovela Therapeutics CAR19-iNKT cell therapy



PROFESSOR YUMAN FONG



The Sangiacomo Family Chair in Surgical Oncology and chair of The City of Hope Dept of Surgery is an internationally recognized expert in liver and pancreatic cancer. He has developed many new surgical techniques and instruments. He helped usher in robotic surgery for liver cancer. He has also led research efforts to use genetically modified viruses to destroy cancer cells.

Dr. Fong joined City of Hope in 2014 after more than three decades at Memorial Sloan-Kettering Cancer Center in New York City.

Dr. Fong has written and edited >1000 scholarly articles as well as 22 textbooks. He is the founding Editor-in-Chief of Molecular Therapy Oncolytics (Cell Press).

He is a fellow of the American Institute of Medical and Biologic Engineering, and the National Academy of Medicine.

Dr. Fong has had leadership roles in regulatory aspects of gene therapy, including serving as Chair or the Recombinant DNA Advisory Committee of the National Institutes of Health of the United States.



City of Hope, in Los Angeles, is a leading research and treatment center for cancer, diabetes and other life-threatening diseases. Founded in 1913, it is designated as a comprehensive cancer center, the highest recognition bestowed by the National Cancer Institute. City of Hope is also a founding member of the National Comprehensive Cancer Network, with research and treatment protocols that advance care throughout the US.

City of Hope has been ranked as one of the nation's "Best Hospitals" in cancer by U.S. News & World Report for over 10 years.

City of Hope has GMP facilities that produces clinical trials materials for many academic centers and is the alpha clinic trials site for CIRM



DR SAUL PRICEMAN

Saul Priceman, Ph.D., is an assistant professor and associate director of Translational Sciences & Technologies in the T Cell Therapeutics Research Laboratories at City of Hope, as well as a trained tumor immunologist with expertise in T cell biology and cancer immunotherapy. He is developing chimeric antigen receptor (CAR)-based T cell immunotherapy primarily for solid cancers, with a strong focus on metastatic disease in breast, prostate and pancreatic cancer.

Dr. Priceman received his B.S. in microbiology at University of California Santa Barbara, and his Ph.D. in molecular and medical pharmacology at University of California Los Angeles.

Dr. Priceman is a principal investigator on a Prostate Cancer Foundation Young Investigator award, a co-principal investigator on a Prostate Cancer Foundation Challenge Award and a principal investigator on a National Comprehensive Cancer Network Young Investigator award, leading the development of HER2-specific CAR T therapy for metastatic breast cancers and working with his team optimizing new CAR T cell therapies for various other solid cancers.

Dr. Priceman is deeply committed to rapidly advancing potentially paradigm-shifting immunotherapy on behalf of patients with cancer, in part because of personal experiences with family and friends who have struggled with the disease. His overarching goal is to develop a range of effective immunotherapies for solid cancers, based on the powerful CAR T cell platform, with the knowledge that any single therapy will not likely provide durable responses in advanced disease.



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MILESTONES

✓	TECHNOLOGY	MILESTONE
	onCARlytics	Phase 1 - 1 st Patient Dosed
	HER-Vaxx	nextHERIZON Arm 2 Cleared
	CHECKvacc	Sponsored Study FDA IND
	VAXINIA	Combination – 1 st Patient Dosed
	onCARlytics	FDA IND
	PD1-Vaxx	Combination - 1 st Patient Dosed
	CHECKvacc	Cohort 3 Cleared
	VAXINIA	IV Cohort 1 Cleared & IT Cohort 2 Cleared
	CHECKvacc	Publication and Presentation (SABC)
	HER-Vaxx	Publication and Presentation (ESMO Asia & ASCO GI)
✓	onCARlytics	Publication and Presentation (SITC)
✓	onCARlytics	Strategic Partnership with Arovella on CAR19-iNKT
✓	VAXINIA	IV Arm - 1 st Patient Dosed
✓	HER-Vaxx	nextHERIZON Phase 2 - 1 st Patient Dosed
✓	HER-Vaxx	Phase 2 Final OS
✓	VAXINIA	IT Cohort 1 Cleared
✓	VAXINIA	IT Arm - 1st Patient Dosed
✓	CHECKvacc	Cohort 1 and 2 Cleared



FINANCIAL SUMMARY

PUBLIC MARKET OVERVIEW (16 Nov 22)

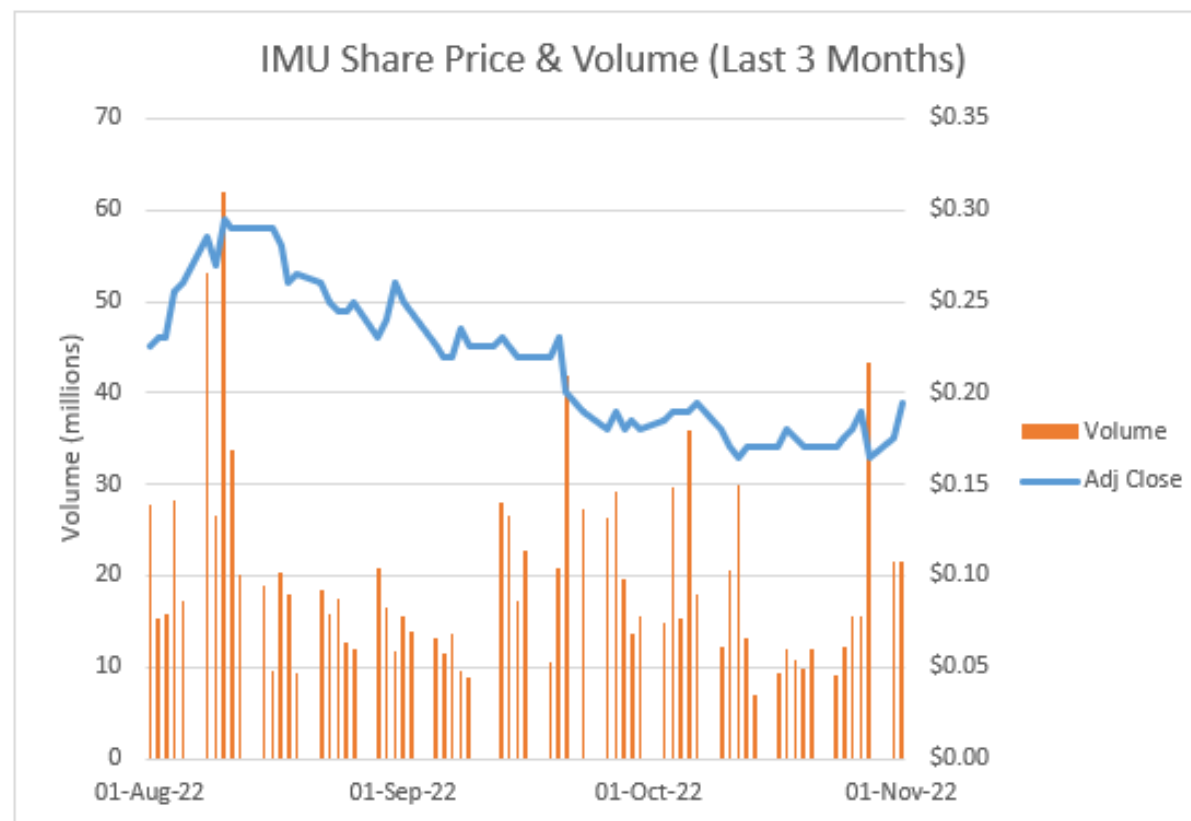
Share Price	A\$0.205
52 week range	\$0.13 - \$0.625
Market Capitalisation ¹	A\$1.29B
Cash equivalents (30 Sep 22)	A\$163.8M
Enterprise Value	A\$1.07B

TOP 5 SHAREHOLDERS (AS AT 11 NOVEMBER 2022)[`]

JP Morgan Nominees Australia Pty Limited	7.10%
HSBC Custody Nominees (Australia) Limited	6.00%
Paul Hopper	5.04%
Citicorp Nominees Pty Limited	4.76%
Mann Family	4.61%

Note:
1. Market capitalisation calculations based on ordinary shares (6.294 bn) only and excludes the dilutive impact of options outstanding (0.543 bn)

SHARE PRICE PERFORMANCE



Contact

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