IMUGENE

Developing Cancer Immunotherapies

ASX: IMU

Developing Cancer Immunotherapies

NWR Healthcare Conference

March 22, 2023

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

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INTRODUCTION TO IMUGENE

Imugene is a biotech company headquartered in Australia and publicly traded on the Australian Securities Exchange (ASX:IMU)

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2013
Licensed HER-Vaxx from the Medical University of Vienna

2015
Leslie Chong from Genentech joins Imugene

2017
HER-Vaxx enters the clinic

2018
Licensed PD1-Vaxx from OSU & Mayo Clinic invented by Prof Pravin Kaumaya

2019
Licensed CF33 oncolytic virus platform from City of Hope invented by Dr Yuman Fong

2020
PD1-Vaxx enters the clinic

2021
Licensed onCARlytics from City of Hope invented by Dr Y Fong, Dr S Priceman & Dr A Park

2021
Strategic Partnership with Celularity

2021
CHECKvacc enters the clinic

2021
Strategic Partnership with Eureka

2021
HER-Vaxx Clinical Trial Supply Partnership with Merck KGaA & Pfizer

2021
PD1-Vaxx Clinical Trial Supply Partnership with Roche

2021
Entered the S&P/ASX 200 Index

2022
VAXINIA enters the clinic

2022
HER-Vaxx Phase 2 Final OS

2022
Strategic Partnership with Arovella

THREE UNIQUE TECHNOLOGY PLATFORMS MAXIMIZE OPPORTUNITIES IN SOLID TUMORS

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Therapeutic approaches with combination potential with existing standards of care

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PLATFORM	onCARlytics IMUGENE	CF33 Oncolytic Virus IMUGENE		B Cell Immunotherapy IMUGENE	
	CF33-CD19 CAR T Combination Therapy	CHECKvacc	VAXINIA	HER-Vaxx	PD1-Vaxx
IP	**IP TO 2038** Filed in major territories	**IP TO 2037** Filed in major territories Granted in Japan/Mexico		**IP TO 2036** Granted in multiple territories (US/EU/Asia)	**IP TO 2037** Filed in major territories Allowed in US
CLINICAL TRIALS	TBC Phase 1	COH TNBC IST Phase 1	MAST Phase 1	HERIZON Phase 1b/2	IMPRINTER Phase 1
		DOMINICA Phase 1		nextHERIZON Phase 2	
				neoHERIZON Phase 2	

TIGIT-Vaxx, PDL1-Vaxx, LAG3-Vaxx, TIM3-Vaxx, CTLA4-Vaxx, Claudin18.2-Vaxx

IMUGENE'S DEEP IMMUNOTHERAPY PIPELINE FOR THE TREATMENT OF SOLID TUMORS

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PLATFORM	PROGRAM/ TARGET	COMBINATION APPROACH	INDICATION	FDA IND	PRECLINICAL / IND / PHASE 1 / PHASE 2	2023 EXPECTED MILESTONES
onCARIytics IMUGENE	**onCARIytics** (CF33-CD19)	CD19 targeted therapies	Metastatic Solid Tumors		**PHASE 1**	FDA IND
CF33 Oncolytic Virus IMUGENE	**VAXINIA** (CF33)	Pembrolizumab	Metastatic Solid Tumors	✓	**MAST**	IV Cohort 2 Cleared Optimal Biological Dose Combination FPI IT and IV Combination OBD IV
	CHECKvacc (CF33-aPD-L1)	Checkpoint Inhibitors	Metastatic TNBC	✓	**CHECKvacc IST**	IT Cohort 3 Cleared Optimal Biological Dose
	CHECKvacc (CF33-aPD-L1)	Checkpoint Inhibitors	Solid Tumors		**DOMINICA**	FDA IND
B Cell Immunotherapy IMUGENE	**HER-Vaxx** (HER2)	Chemotherapy Checkpoint Inhibitors	First Line Gastric Cancer		**HERIZON**	Publication and Presentation (ASCO GI)
			Neoadjuvant Gastric Cancer		**neoHERIZON**	CTA Clearance FPI
			Metastatic Gastric Cancer	✓	**nextHERIZON**	ASCO GI TiP Interim Data Readout
	PD1-Vaxx (PD1)	Chemotherapy Atezolizumab	Metastatic NSCLC	✓	**IMPRINTER**	Combination FPI
			MSI High CRC		**NeoPolem IST**	CTA Clearance FPI

CF33 Oncolytic Virus
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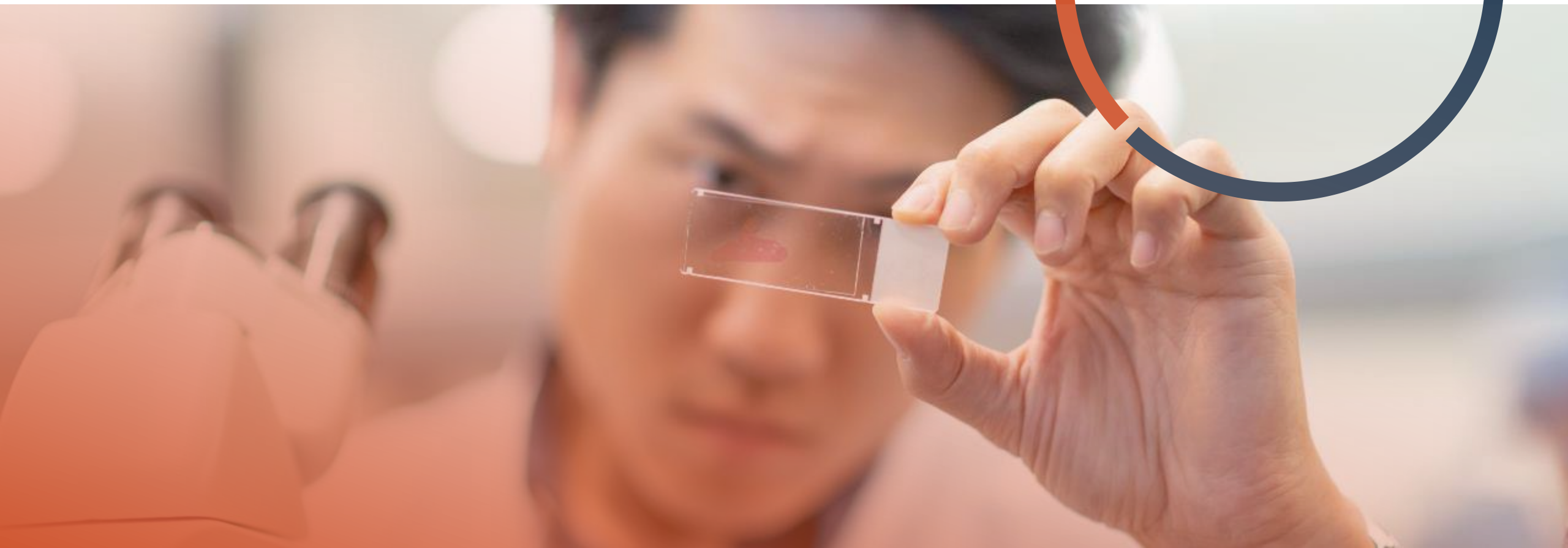
CF33 Oncolytic Virus



ONCOLYTIC VIRUSES OFFER A SELECTIVE IMMUNOGENIC APPROACH TO EFFECTIVELY KILL TUMOR CELLS

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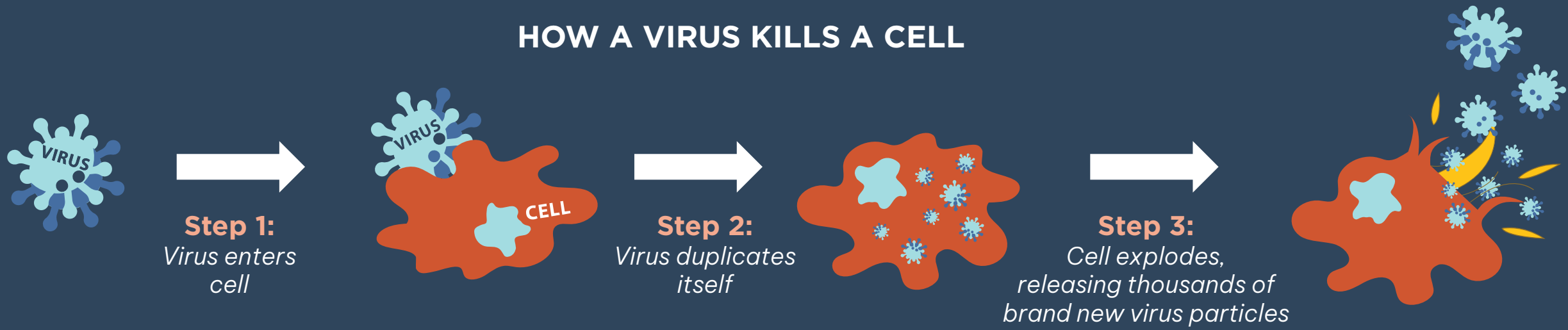
HOW A VIRUS KILLS A CELL



Engineering enhancements

- Infect and kill only cancer cells
- Carry additional payloads to augment killing (check point inhibitors, cytokines, anti-angiogenics)

Multiple ways to kill cancer cells

- Direct Lysis
- Immuno-activation
- Priming of TME to enhance checkpoint inhibitor response[1]

Precedent for approval

- Tvec approved in the United States for melanoma (2015)
- Oncorine approved in China for head and neck cancer (2005)
- Delytact approved in Japan for malignant glioma (2021)

TME: tumor microenvironment

1: *Ribas et al., Cell 170:1109, 2017*

CF33-hNIS: TUMOR TRACKING AND TROPISM

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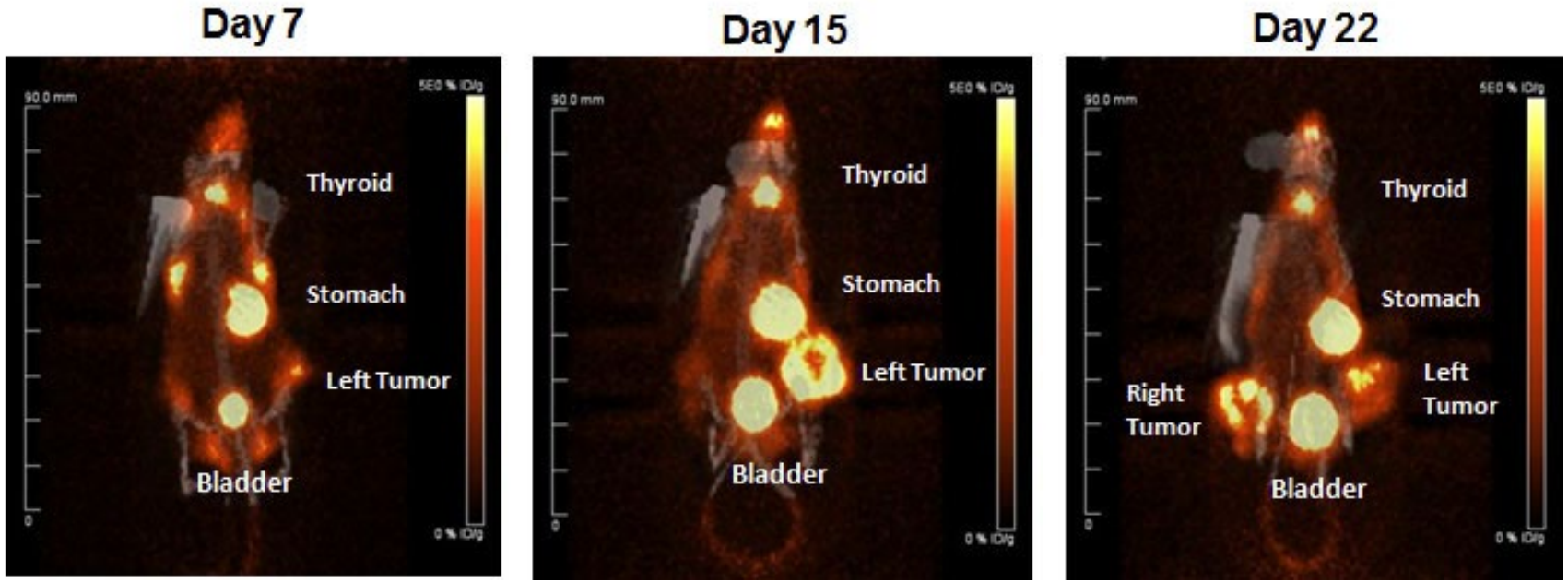
Genetic modification enables tumor tracking and tumor tropism

- hNIS (human sodium iodide symporter) protein is expressed on the tumor cell surface
- hNIS transgene inserted within J2R locus (Tk) to transport radioactive iodine for imaging

Tracked virus supports tumor specificity and systemic delivery

- Cross infection of tumors supported by 124I uptake in right side on day 22 following injection on left side
- Physiologic uptake in thyroid, stomach and bladder

^{124}I PET Imaging of CF33-hNIS-infected HCT116 (colon cancer) from flank xenografts in nude mice over time



Ref: Mol Ther Oncolytics, 2019, **13**, 82

CHECKvacc PHASE 1 TNBC STUDY
CF33+hNIS+aPD-L1 ("Armed" Virus)

SAN ANTONIO BREAST CANCER SYMPOSIUM

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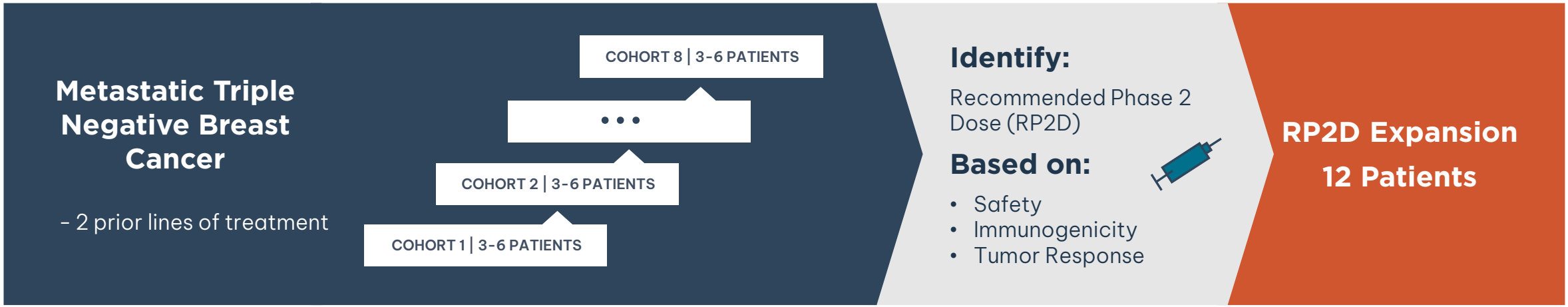
Presented at SABC 2022



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, randomized P2 study

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

CHECKvacc (CF33-hNIS-antiPD-L1) TUMOR TRACKING

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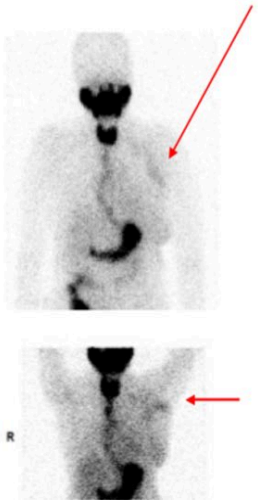
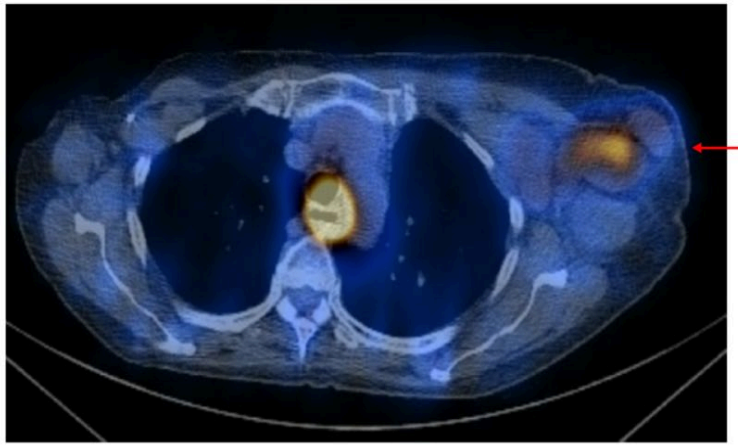
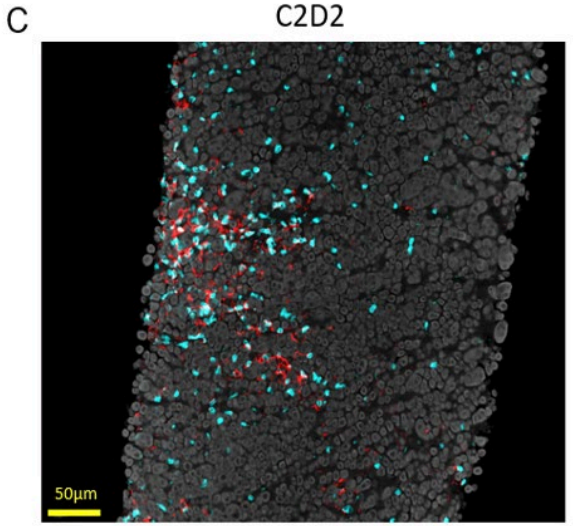


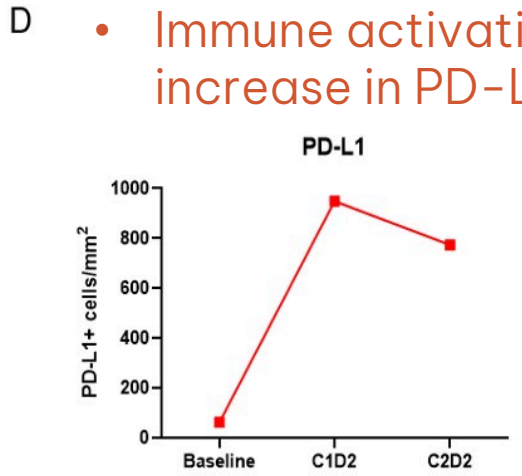


- hNIS 99m uptake in SPECT scan

SAN ANTONIO BREAST CANCER SYMPOSIUM

SPECT imaging of patient using Technetium-99m (C1D8): Patient COH-004 received CHECKvacc at Dose Level 2 ($3x10^5$ PFU). Injected lesion was left axilla showed significant enhancement of injected lymph node.





- Immune activation-increase in PD-L1

Multiplex immunofluorescence (mIF) of COH-004 tumor: C&D immune infiltrates shows increase density of PD-L1+ cells across patient tissue biopsies.

VAXINIA PHASE 1 MAST STUDY
(Metastatic Advanced Solid Tumors)

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First Patient Enrolled for IT and IV combination in March, 2023

Dose Administration (Parallel Groups)

n=52-100

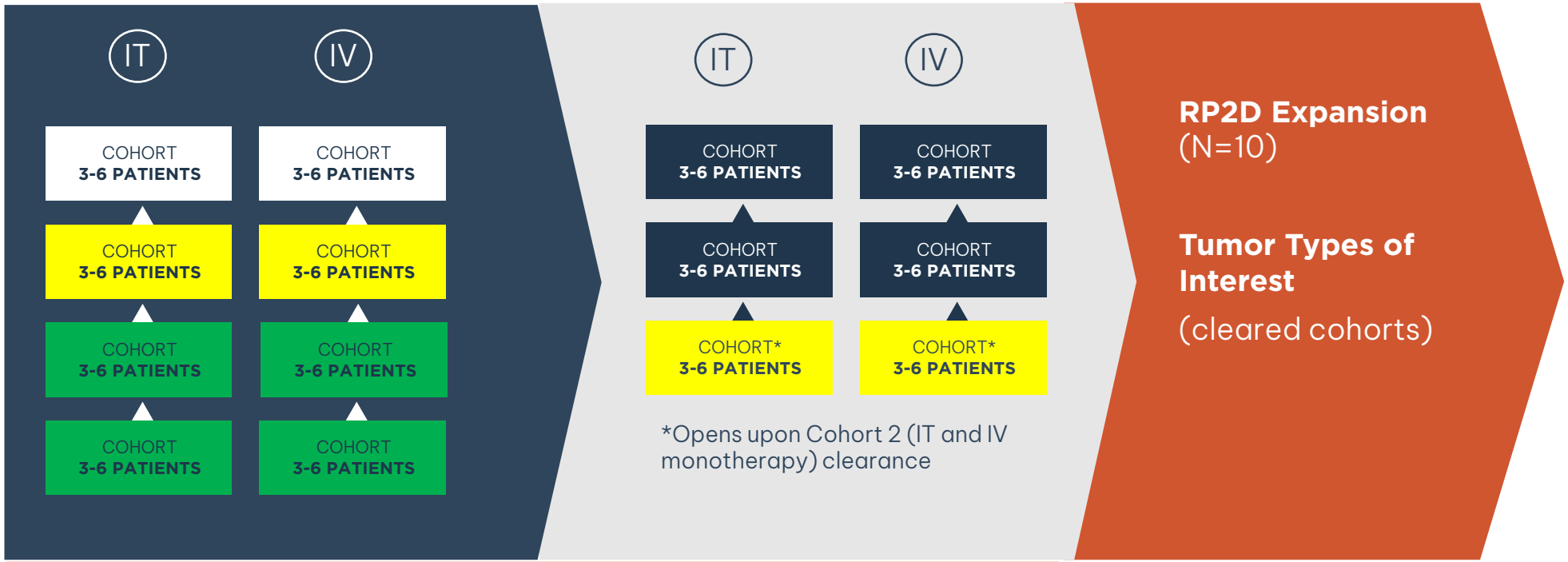
IT

IT Administration
Metastatic and Advanced Solid Tumors

IV

IV Administration
Metastatic and Advanced Solid Tumors

Site Location: USA, AUS



Identify: Recommended Phase 2 Dose (RP2D) – Monotherapy and Combination
Based on: Safety, Immunogenicity, Tumor Response

CF33 oncolytic virus alone and in combination with pembrolizumab

onCARlytics
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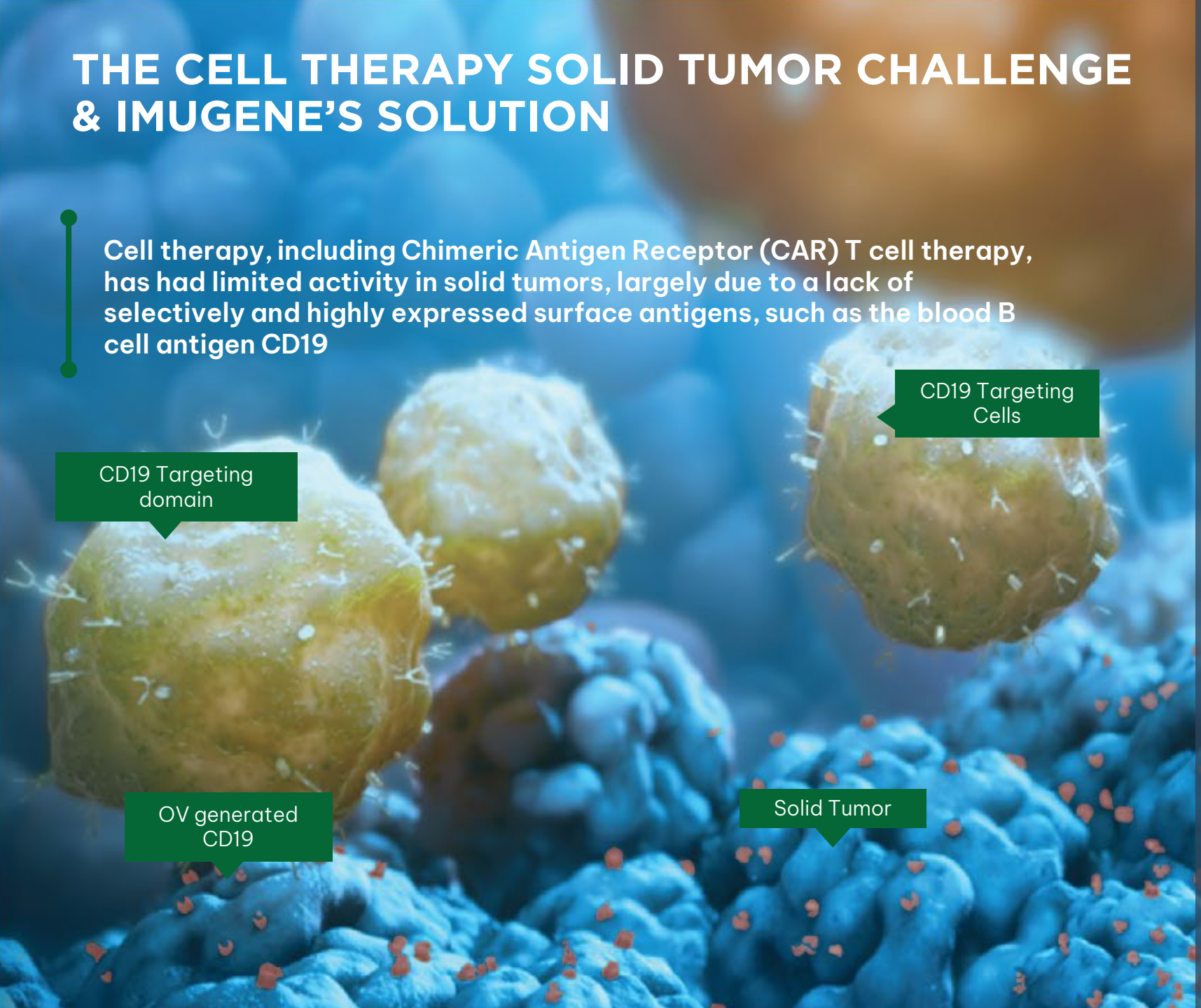
CF33-CD19

THE CELL THERAPY SOLID TUMOR CHALLENGE & IMUGENE'S SOLUTION

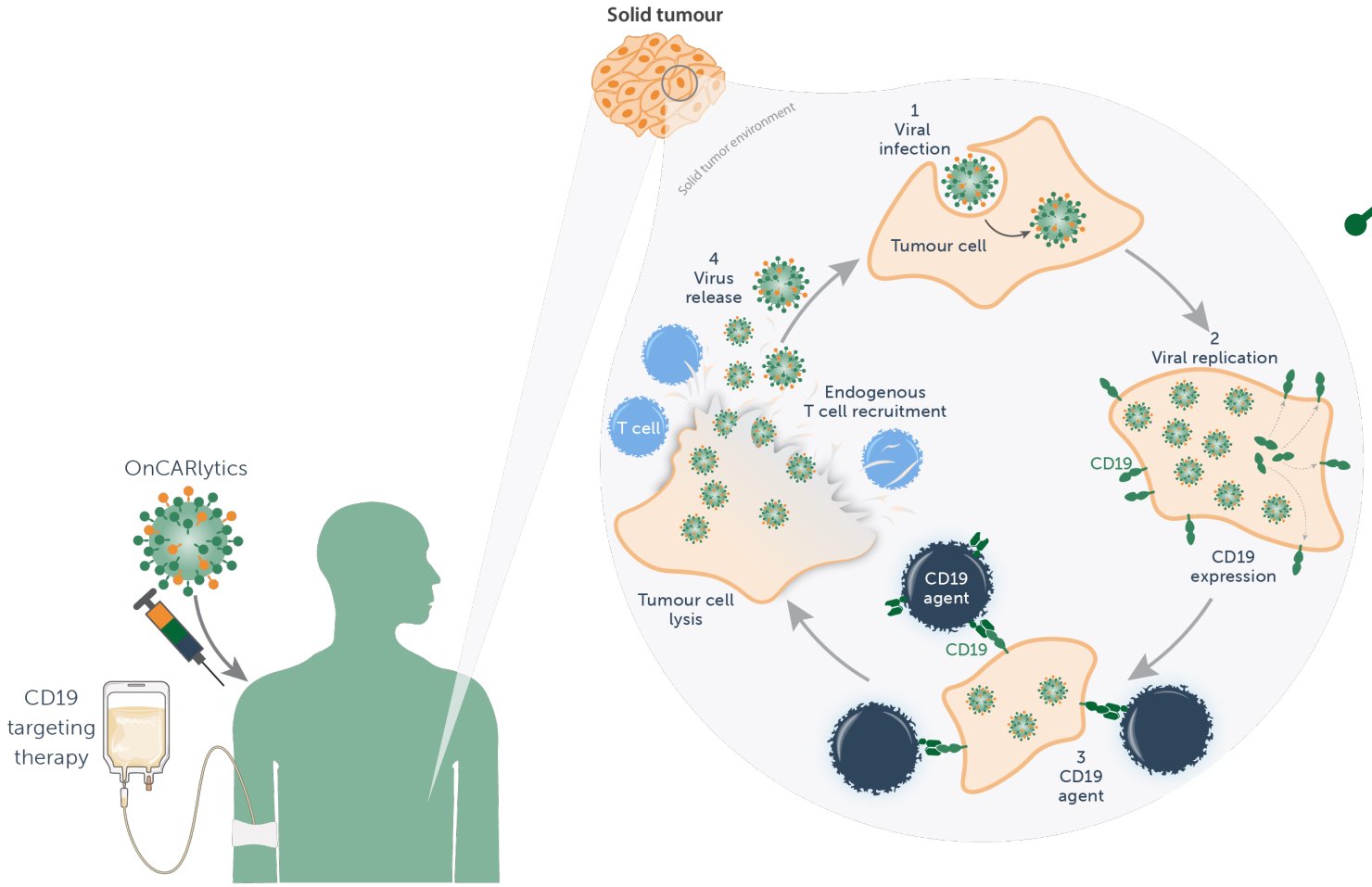
Cell therapy, including Chimeric Antigen Receptor (CAR) T cell therapy, has had limited activity in solid tumors, largely due to a lack of selectively and highly expressed surface antigens, such as the blood B cell antigen CD19



IMUGENE'S APPROACH

- Use onCARlytics (CF33-CD19) to express CD19 antigen on solid tumor cells
- Combine onCARlytics (CF33-CD19) with autologous or allogeneic CD19 CAR T cell therapies for the treatment of solid tumors

MECHANISM OF ACTION: HOW DOES IT WORK?



onCARlytics makes solid tumors "seen" by CD19 targeting therapies

1. OnCARlytics infects Tumor cells
2. Virus replication and production of CF33-CD19 on the cell surface enabling CD19 cell targeting
3. Tumor cell lysis leads to viral particle release and the combination promotes endogenous immune cell recruitment to Tumors
4. Released viral particles re-initiate virus infection of surrounding Tumor cells.

onCARLYTICS DELIVERS TARGETS TO "TARGETLESS" SOLID TUMORS

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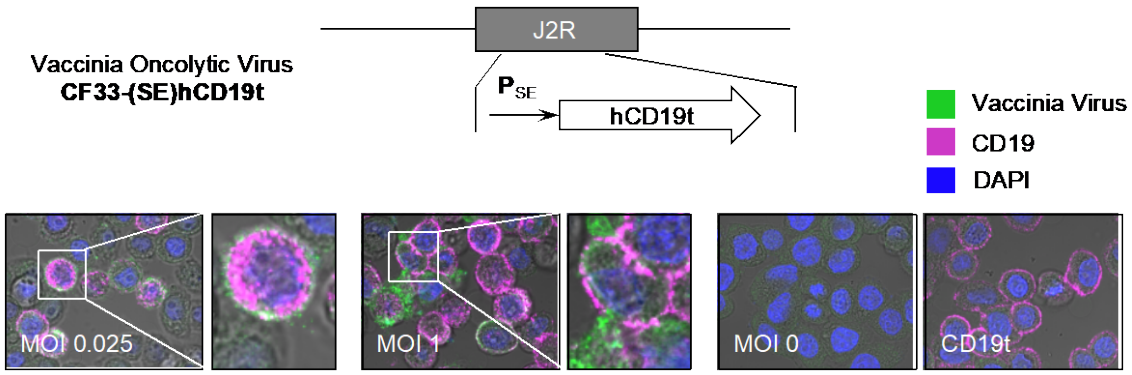
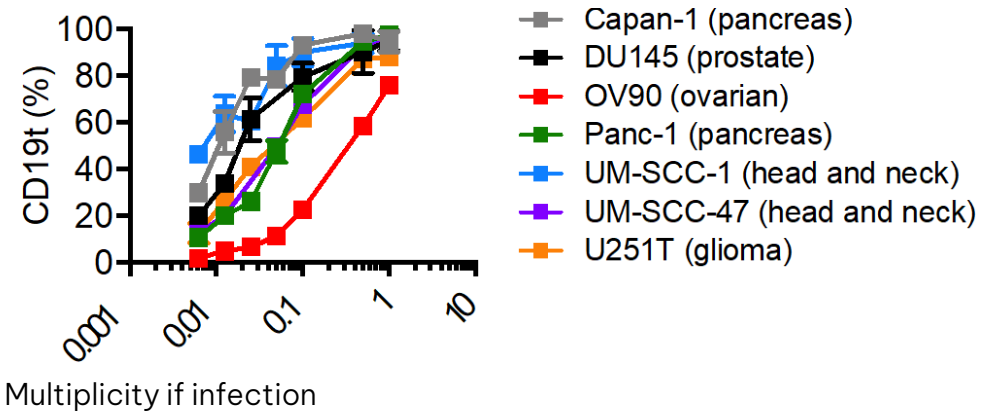
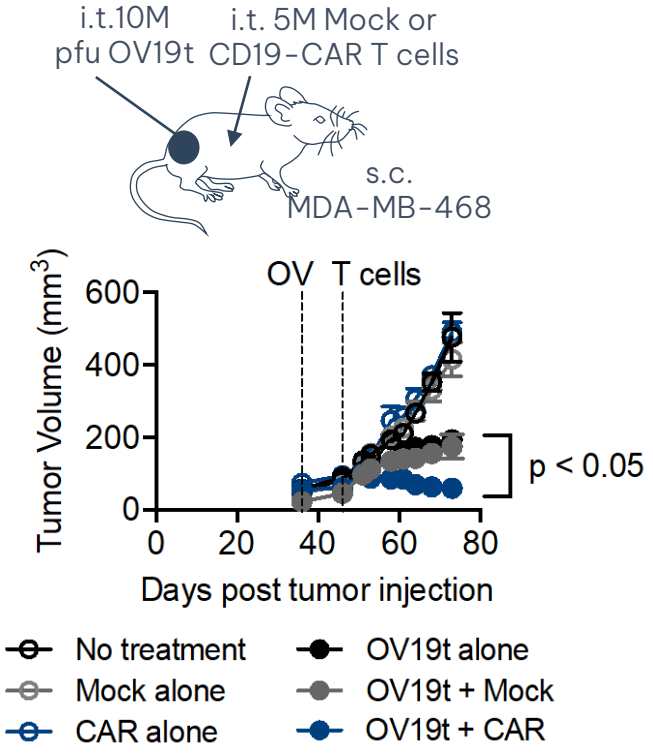


onCARlytics (CF33-CD19) infects a wide array of solid Tumor cell lines, with dose-dependent CD19 cell surface expression



Combination of onCARlytics (CF33-CD19) and CD19-CAR T cells promotes tumor regression in xenograft model of TNBC



Park et al. *Science Translational Medicine* 2020

PUBLISHED FRONT COVER OF SCIENCE TRANSLATIONAL MEDICINE JOURNAL IN 2020

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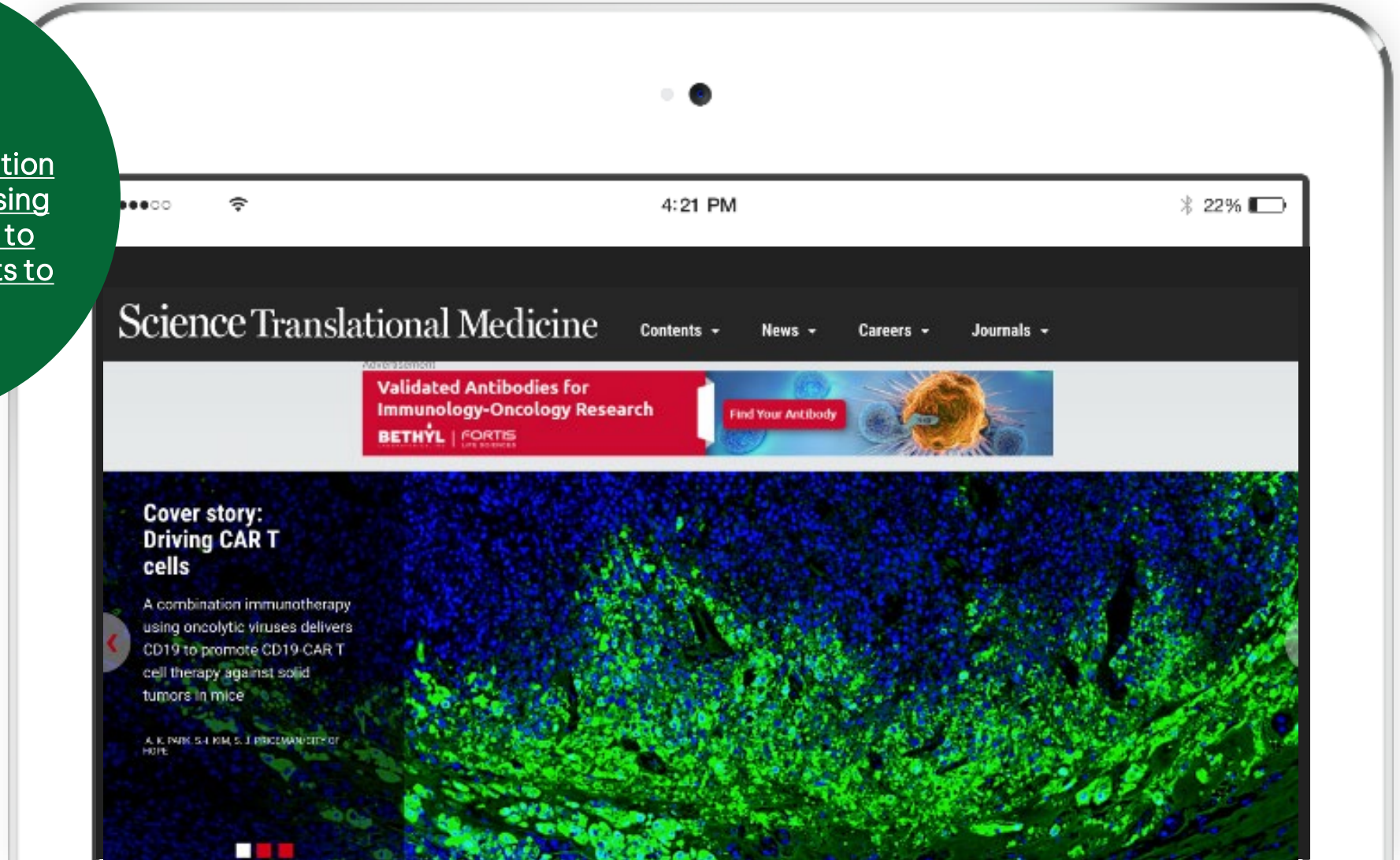
Effective combination immunotherapy using oncolytic viruses to deliver CAR targets to solid tumors



Park AK, Fong Y, Kim SI, Yang J, Murad JP, Lu J, Jeang B, Chang WC, Chen NG, Thomas SH, Forman SJ, Priceman SJ.Sci Transl Med. 2020 Sep 2;12(559): eaaz1863. doi: 10.1126/scitranslmed.aaz1863.PMID: 32878978

onCARLYTICS COMBINATION WITH CD19 TARGETING THERAPIES

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Collaboration with Celularity, Eureka and Arovella for combination with onCARlytics

AUG 2021
Strategic Partnership with Celularity

celularity

Allogeneic CyCART19® T cells

NOV 2021
Strategic Partnership with Eureka

EUREKA THERAPEUTICS

Autologous ARTEMIS® **T cells**

SEP 2022
Strategic Partnership with Arovella

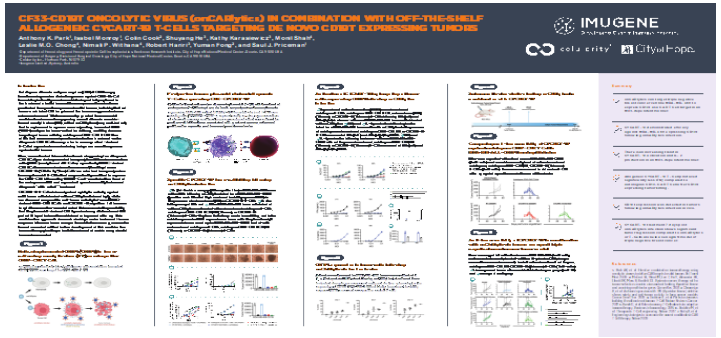
arovella THERAPEUTICS

Allogeneic invariant natural killer (iNKT) cells

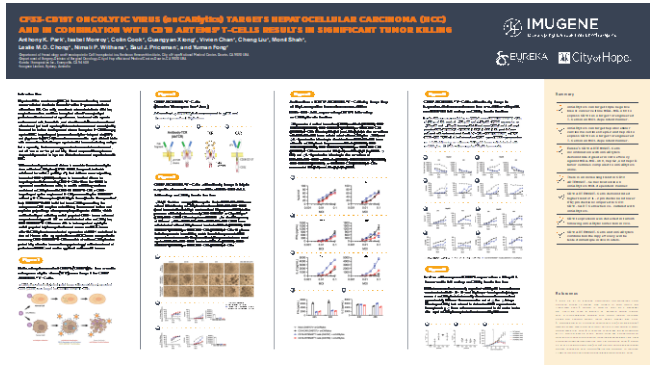
sitc
Society for Immunotherapy of Cancer

3 POSTERS PRESENTED AT SITC 2022

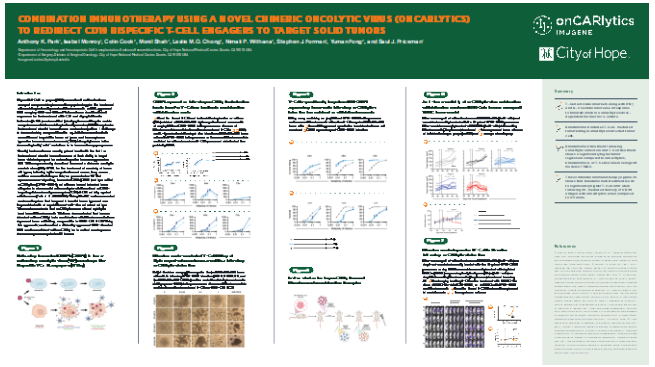
CyCART19® celularity



Artemis® EUREKA THERAPEUTICS



BLINCYTO® (blinatumomab) for injection
35 mcg single-dose vial



B Cell Immunotherapy
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HER-Vaxx

B CELL BASED ANTIBODIES HAVE DISTINCT COMPETITIVE ADVANTAGES TO EXISTING TREATMENTS

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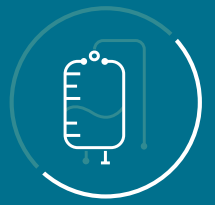
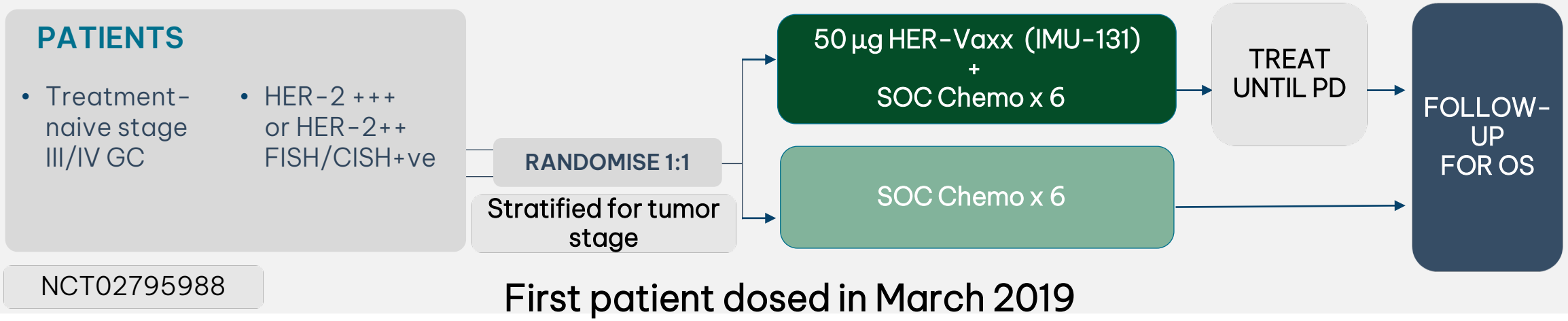
B cell vaccines offer a unique opportunity to intervene at multiple points in the immune system and create immune memory which enhances durability of response.

	NATURAL B CELL DERIVED ANTIBODIES 	MONOCLONAL ANTIBODIES 
Safety	Stimulates the immune system to produce Abs, which may be potentially safer	Synthetic Ab, with side effects (including ventricular dysfunction, CHF, anaphylaxis, infusion reactions, immune mediation)
Efficacy	Polyclonal Ab response reduces risk of resistance and potentially increases efficacy	Monoclonal Ab – may develop anti-drug antibodies
Durability	Antibodies continuously produced with lasting immune response to potentially inhibit tumor recurrence	Half life necessitates recurrent dosing
Usability	After priming, low numbers of vaccinations required per year	Requires regular infusion
Cost	Low cost of production enables greater pricing flexibility facilitating combination	Expensive course of treatment >US$100K per year

HERIZON PHASE 1B/2 OPEN LABEL, MULTICENTER STUDY



First patient dosed in March 2019

HER-Vaxx	C1D1, C3D1 then Q9 weeks till PD
Chemotherapy	6 cycles Q3 weeks (Cisplatin + 5FU or Capecitabine; Oxaliplatin + Capecitabine)

PRIMARY ENDPOINT OS (pre-spec 1-sided alpha 0.10, power 90% with critical HR 0.6 and 24 events)

SECONDARY ENDPOINTS PFS, Safety, Immune Response

NO. OF PATIENTS 36

SITE LOCATION Eastern Europe, India

HER-Vaxx SIGNIFICANTLY PROLONGS OVERALL SURVIVAL IN 1L PATIENTS WITH HER-2+ GASTRIC CANCER

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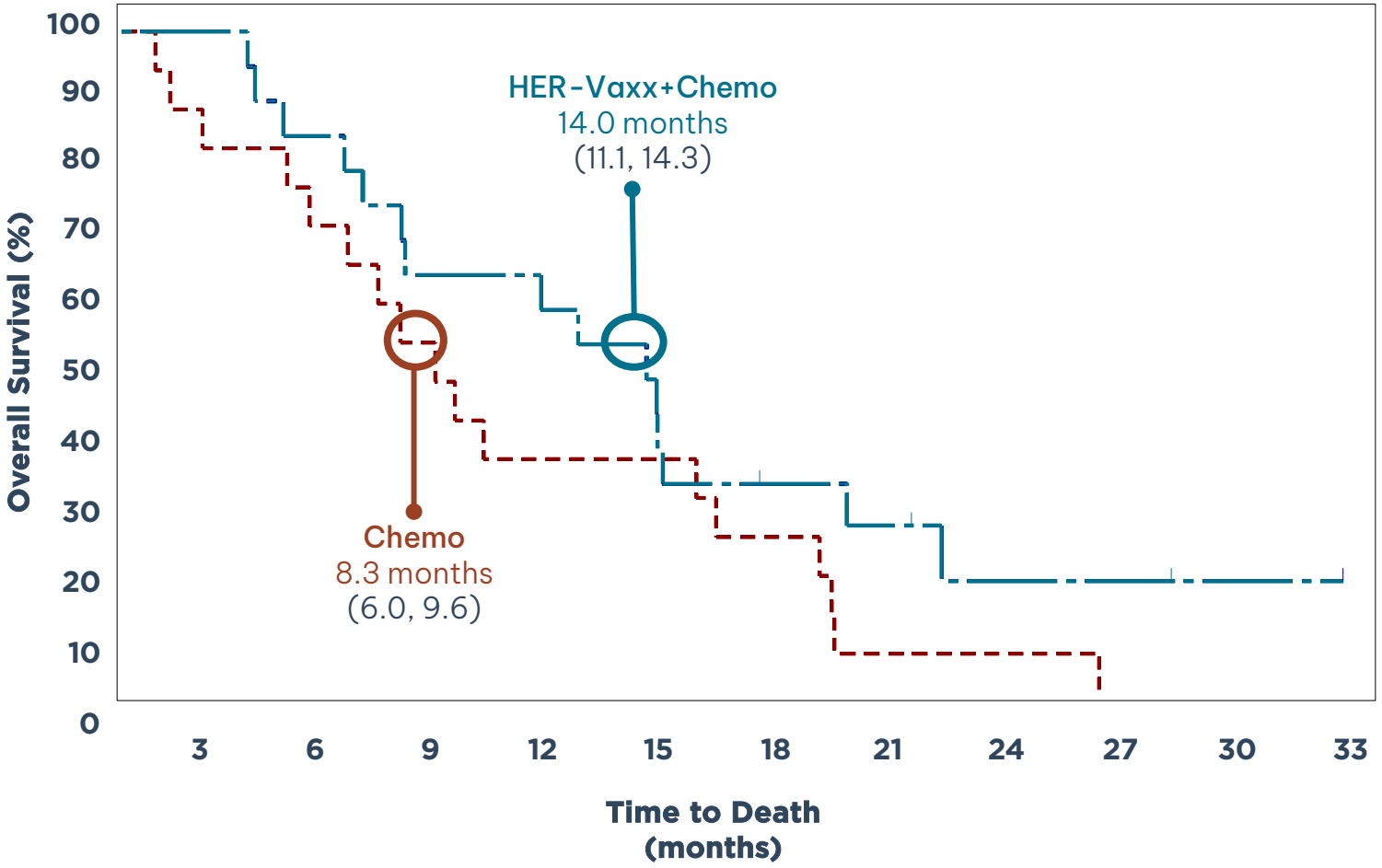
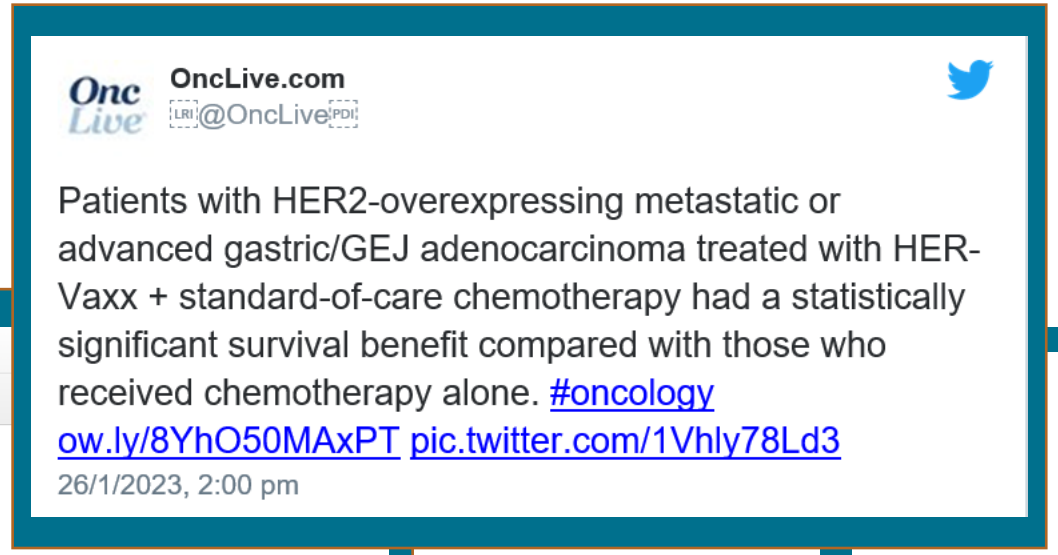
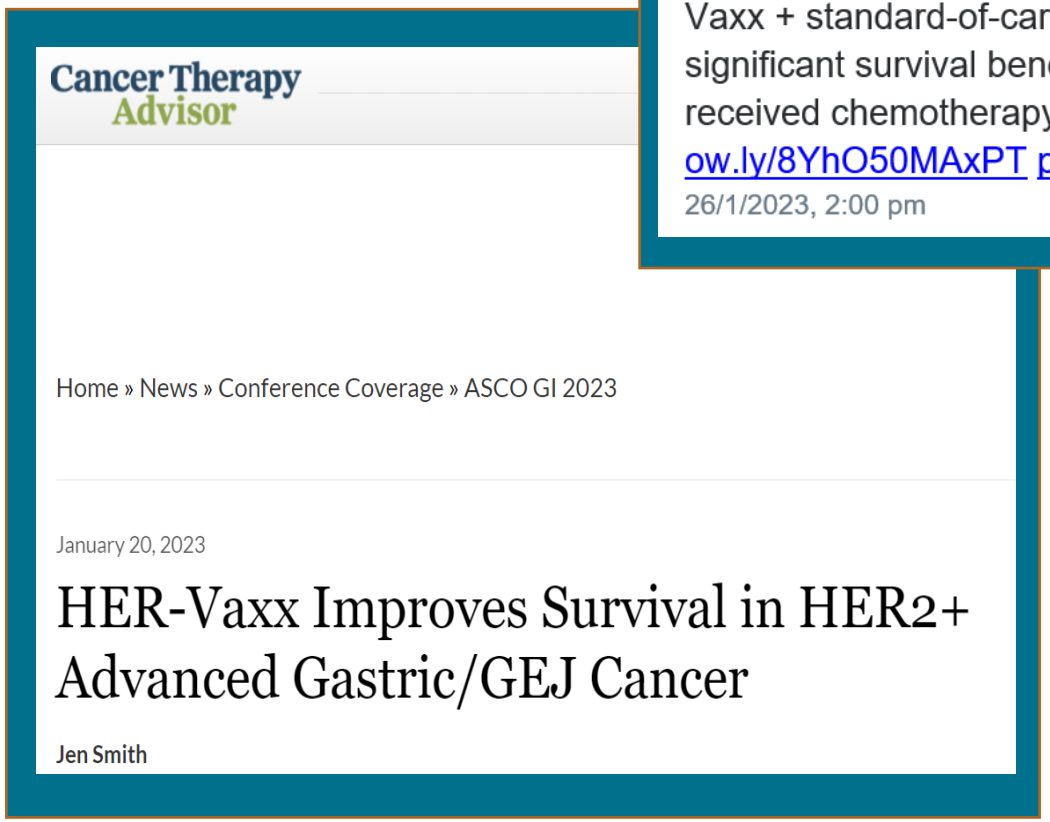


	HER-Vaxx + Chemotherapy	Chemotherapy
Sample Size	19	17
Events	15	17
Median OS (2-sided 80% CI)	14.0 months (11.1, 14.3)	8.3 months (6.0, 9.6)
Median Duration of Response	30 weeks	19 weeks
HR	0.558	
2-sided 80%CI	(0.362, 0.927)	
Log-rank Test (1-sided p-value) *	0.054 *	

*Significant, 1-sided p < 0.10

HERIZON IN THE NEWS !





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HER-Vaxx Studies

HER-Vaxx PHASE 2:
nextHERIZON IN METASTATIC GASTRIC CANCER AFTER PROGRESSION ON TRASTUZUMAB

ASCO Gastrointestinal Cancers Symposium

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TRIAL
- Phase 2
- Open label
- USA, Australia, Asia
- Treat until progression/toxicity

PATIENTS
- > 1L
- Advanced or metastatic Gastric Cancer
- HER-2/neu overexpressing
- Progressed on prior trastuzumab

STUDY
- Non-Randomised
- HER-Vaxx in combination with paclitaxel + ramucirumab
  OR
  HER-Vaxx in combination with pembrolizumab

ENDPOINTS
Primary
- Objective Response Rate
- Safety

Secondary
- Overall Survival
- Progression-free survival
- Duration of Response

First Patient Enrolled Sept 2022

mGC/GEJ cancer
HER-2/neu overexpressing
Progressed on or after trastuzumab & previously received PD-1/PD-L1 treatment

→ **Arm 1: HER-Vaxx + SOC Chemotherapy**

mGC/GEJ cancer
HER-2/neu overexpressing
Progressed on or after trastuzumab

→ **Arm 2: HER-Vaxx + pembrolizumab**

PRIMARY ENDPOINTS:
ORR
Safety

SECONDARY ENDPOINTS:
OS
PFS
DoR

EXPLORATORY ENDPOINT:
Biomarker/Immune Response

HER-Vaxx PHASE 2:
neoHERIZON IN RESECTABLE GASTRIC CANCER

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TRIAL

- Phase 2
- Open label
- Randomised
- Germany

PATIENTS

- Neoadjuvant Gastric Cancer
- HER-2+++/HER-2++ FISH/CISH +ve

STUDY

- Arm 1 – FLOT + HER-Vaxx
- Arm 2 – FLOT + Avelumab + HER-Vaxx

ENDPOINTS

Primary
- Pathological Complete Response

Secondary
- Safety
- Immune Response
- Duration of Response/Overall Survival

B Cell Immunotherapy
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PD1-Vaxx

IMPRINTER:
PD1-Vaxx NSCLC PHASE 1 STUDY DESIGN

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Phase 1: PD1-Vaxx Monotherapy Dose Escalation & Expansion
2L+ NSCLC Progressed on/after ICI

Cohort 1
10 µg
PD1-Vaxx
n = 3-6

→

Cohort 2
50 µg
PD1-Vaxx
n = 3-6

→

Cohort 3
100 µg
PD1-Vaxx
n = 3-6

→

MONOTHERAPY OBD

→

Expansion
mOBD
PD1-Vaxx
n = 10

COMPLETED

Phase 1b: PD1-Vaxx NSCLC Combination Dose Escalation & Expansion

ARM 1: TPS/TC ≥ 50% or IC ≥ 10%

Cohort 1
10 µg
PD1-Vaxx +
atezolizumab
n = 3-6

→

Cohort 2
50 µg
PD1-Vaxx +
atezolizumab
n = 3-6

→

Cohort 3
100 µg
PD1-Vaxx +
atezolizumab
n = 3-6

ARM 2: Any PD-L1 Level

Cohort 1
10 µg
PD1-Vaxx +
atezolizumab +
chemotherapy
n = 3-6

→

Cohort 2
50 µg
PD1-Vaxx +
atezolizumab +
chemotherapy
n = 3-6

→

Cohort 3
100 µg
PD1-Vaxx +
atezolizumab +
chemotherapy
n = 3-6

→

COMBINATION OBD*

→ **ARM 1: Progressed on/after ICI TPS/TC ≥ 50% or IC ≥ 10%**
cOBD PD1-Vaxx + atezolizumab
n = 10

→ **ARM 2: Naïve to ICI TPS/TC ≥ 50% or IC ≥ 10%**
cOBD PD1-Vaxx + atezolizumab
n = 10

→ **ARM 3: Naïve to ICI Any PD-L1 Level**
cOBD PD1-Vaxx+ atezolizumab +
chemotherapy
n = 10

mOBD = monotherapy optimal biological dose
cOBD = combination optimal biological dose
**cOBD will be determined per arm*

VALUE INFLECTION POINTS EXPECTED IN THE NEXT 12 MONTHS

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VAXINIA	MAST: Combination OBD IV
onCARlytics	FPI
HER - Vaxx	neoHERIZON: FPI
HER - Vaxx	nextHERIZON: Interim Data Readout
VAXINIA	MAST: Optimal Biological Dose (Mono IV and/or IT)
HER - Vaxx	neoHERIZON: CTA Clearance
CHECKvacc	DOMINICA: FDA IND
PD1 - Vaxx	neoPOLEM (CRC IST)
CHECKvacc	COH IST: Optimal Biological Dose
PD1 - Vaxx	IMPRINTER: Combination FPI
onCARlytics	FDA IND

RECENTLY ACHIEVED

VAXINIA	MAST: Combination FPI IT and IV
VAXINIA	MAST: IV Cohort 2 Cleared
HER - Vaxx	HERIZON: Publication and Presentation (ASCO GI)
HER - Vaxx	next HERIZON: Trial in Progress Poster (ASCO GI)
VAXINIA	MAST: IV Cohort 1 Cleared
onCARlytics	3 Presentation at SITC
VAXINIA	MAST: IV Arm - 1st Patient Dosed
HER-Vaxx	nextHERIZON: Phase 2 – 1st Patient Dosed
HER-Vaxx	HERIZON: Phase 2 - Final OS readout

FINANCIAL SUMMARY

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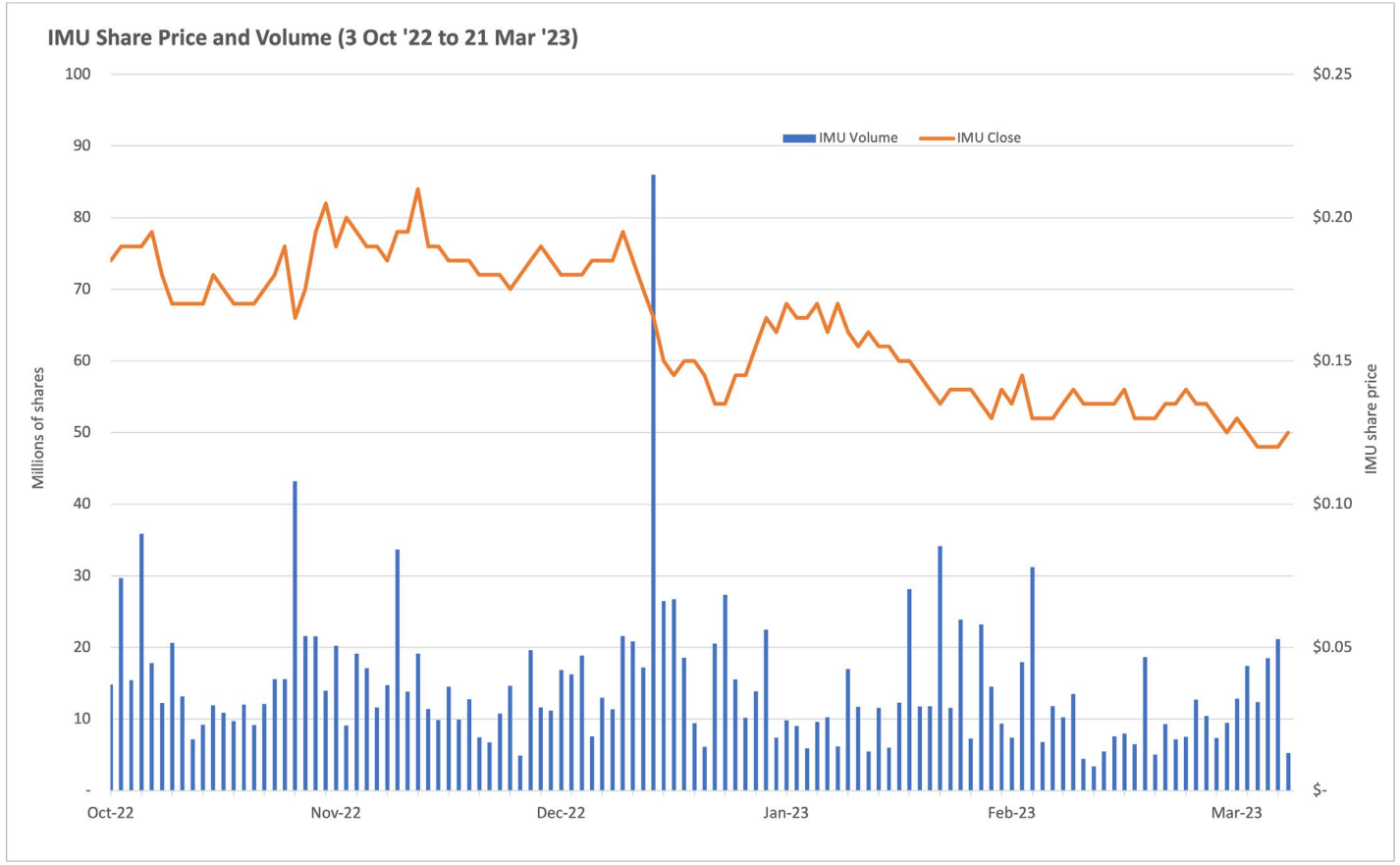
PUBLIC MARKET OVERVIEW (March 21, 2023)

Share Price	A$0.13
52 week range	A$0.12 - A$0.32
Market Capitalisation[1]	A$835M
Cash equivalents (31 December '22)	A$162M
Enterprise Value	A$673M

TOP 5 SHAREHOLDERS (as at March 21, 2023)

JP Morgan Nominees Australia Pty Limited	9.02%
HSBC Custody Nominees (Australia) Limited	5.51%
Paul Hopper	4.94%
Citicorp Nominees Pty Limited	4.65%
Mann Family	4.60%

SHARE PRICE PERFORMANCE



Note:
1. Market capitalisation calculations based on ordinary shares (6.423 bn) only and excludes the dilutive impact of options outstanding (0.477 bn)

INVESTMENT HIGHLIGHTS

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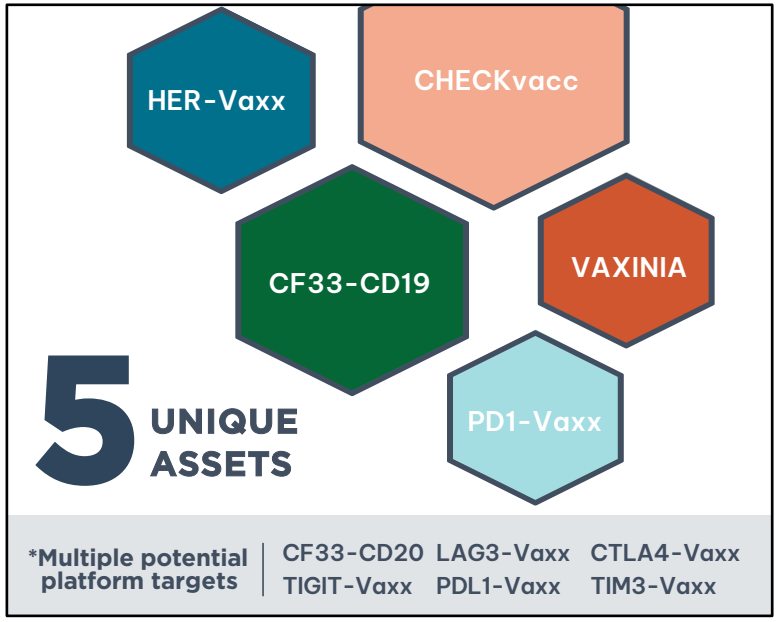
MARKET CAPITALISATION 21st March 2023 A$835M

CASH AS OF 31st December 2022 A$162M

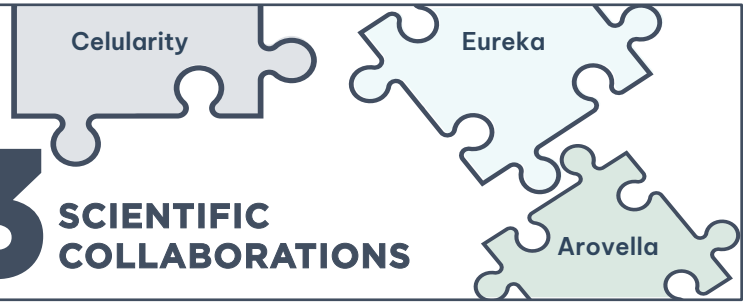


5 UNIQUE ASSETS

*Multiple potential platform targets | CF33-CD20 LAG3-Vaxx CTLA4-Vaxx TIGIT-Vaxx PDL1-Vaxx TIM3-Vaxx

CF33 Oncolytic Virus | onCARlytics | B-Cell Immunotherapies

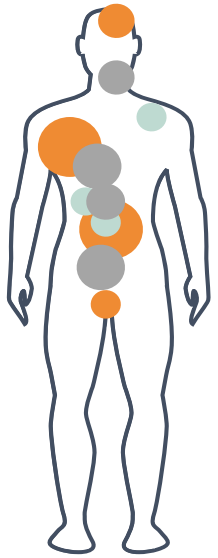
3 PLATFORM TECHNOLOGIES



3 SCIENTIFIC COLLABORATIONS

DISEASE AREAS

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



9 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 Tumors (FDA IND)
DOMINICA: Ph1 TNBC (FDA IND)
onCARlytics: Ph1 Solid Tumors (FDA IND)
neoPolem IST: Ph1 CRC

2 SUPPLY AGREEMENTS

Merck KGaA/Pfizer | Roche

Contact

shareholderenquiries@imugene.com
www.imugene.com

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ASX: IMU

INTERNATIONAL LEADERSHIP TEAM WITH EXTENSIVE COMMERCIALISATION EXPERTISE IN THE SECTOR

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Imugene has a team with oncology drug development experience

IMUGENE'S MANAGEMENT TEAM

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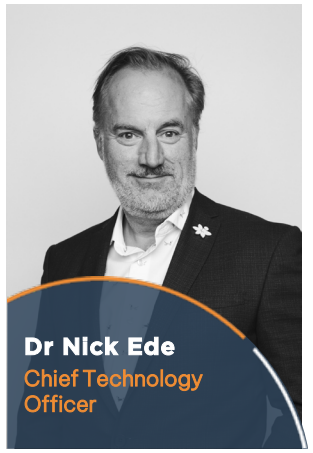
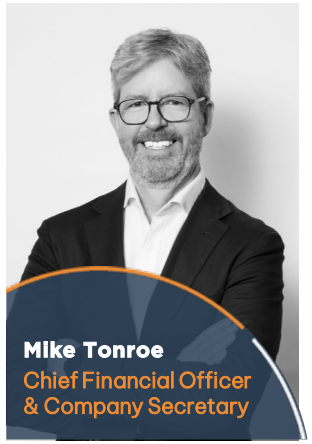
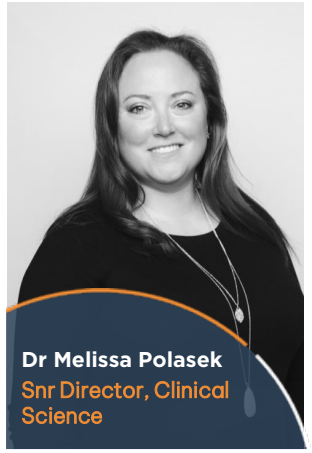
Experienced management team with significant clinical development expertise







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Dr Prasad Adusumilli
Memorial Sloan Kettering Cancer Center, USA

Dr Rebecca Auer
University of Ottawa, CAN

Prof Tanios Bekail Saab
Mayo Clinic, USA

Prof Pravin Kaumaya
Ohio State University, USA

Prof Yuman Fong
City of Hope, USA

Dr Yelina Janjigian
Memorial Sloan Kettering Cancer Center, USA

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