



IMUGENE
Developing Cancer Immunotherapies

ASX: IMU

IMUGENE

Investor Presentation

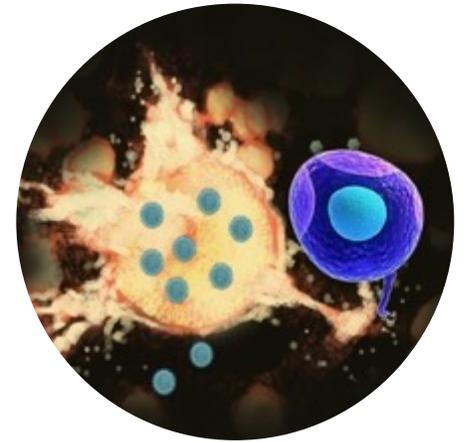
November 2020

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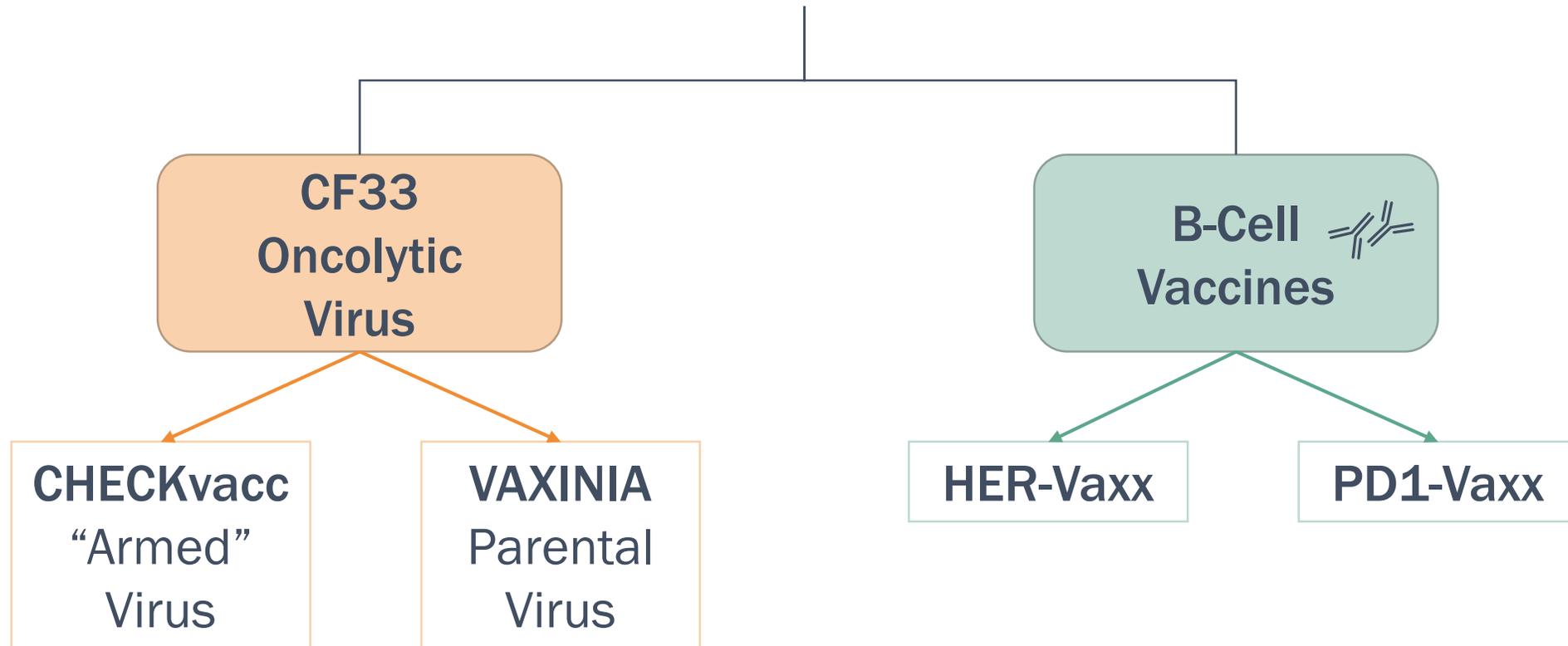
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INVESTMENT HIGHLIGHTS

- Two novel technologies: B-Cell activating immunotherapies and CF33 oncolytic virotherapy
- B-Cell Technologies: HER-Vaxx Positive Interim Data read out for Phase 2 trial in gastric cancer
- B-Cell Technologies: PD1-Vaxx screening patients in Phase 1 for NSCLC
- CF33 from City of Hope Cancer Centre in Los Angeles
- CF33 has demonstrated single agent & combination activity
- CF33 has prolific and compelling pre-clinical data
- CF33 GMP manufacturing complete for both trials
- Highly experienced CF33 team including CMO from ex OV biotech company and ex-Viralytics clinical development team
- Robust, long life IP portfolio over both technologies
- Significant news flow with multiple near & medium term valuation inflections



TWO NOVEL TECHNOLOGY PLATFORMS



IMUGENE'S DEEP PIPELINE

	Pre-Clinical	Clinical development Phase 1	Clinical development Phase 2	Key Data / Results	Intellectual Property
VAXINIA (CF33)		Mixed Advanced solid tumors		<ul style="list-style-type: none"> CF33 has shown strong anti tumour responses in preclinical studies Inhibition of tumour growth in nearly all NCI60 models in TNBC, Lung, Pancreatic etc. Signs of increased tumour growth inhibition with CF33 + anti PD-L1 	Expiring 2037
CHECKvacc (CF33 & aPD-L1)		Triple negative breast cancer		<ul style="list-style-type: none"> Pre-clinical studies showed cancer growth inhibition was better than compared to Amgen or Genelux oncolytic virus. Potentially solves the industry problem of additive toxicity of combined checkpoint inhibitors if safety of CF33 is maintained in combination 	Expiring 2037
HER-Vaxx (HER-2)			Gastric	<ul style="list-style-type: none"> Successful completion of Phase 1b trials, published in AACR, ASCO GI, ASCO, ESMO GI, ESMO, ESMO Asia 2019 Strong trial results with no safety or toxicity issues, all patients had increased antibody response, 11/14 evaluable patients with encouraging clinical responses Phase 2 Interim data: 0.418 HR (80% 2-sided CI: 0.186, 0.942); 14.2 months HER-Vaxx + chemo compared to 8.8 months chemo alone. 	Expiring 2036
PD1-Vaxx		Lung		<ul style="list-style-type: none"> PD1-Vaxx has shown encouraging response in preclinical studies Strong inhibition of tumour growth in mouse models of colorectal cancer (outperformed industry standard mouse PD-1 mAb) Signs of increased tumour growth inhibition when co-administered with B-Vaxx 	Expiring 2037

International Leadership Team with Extensive Commercialization Expertise in the Sector

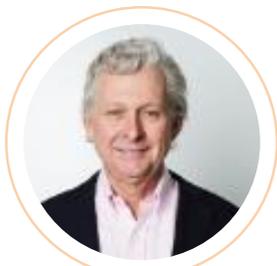


Leslie Chong

SYDNEY, AU

Managing Director & CEO

- 21+ years of oncology experience across Phase I – III clinical development programs
- Ex Senior Clinical Program Lead at Genentech, one of the world's most successful biotech businesses which sold the best selling breast cancer drug Herceptin
- Also worked at global majors GSK and Exelixis
- Non-Executive Director of Cure Brain Cancer Foundation (CBCF)



Paul Hopper

SYDNEY, AU

Executive Chairman

- Founder of Imugene
- Former Chairman of Viralytics
- Founder & Director of Prescient
- Chairman of SUDA Pharmaceutical
- Extensive international & ASX biotech capital markets experience particularly in immuno-oncology & vaccines
- Co-Chairman of Scopus Biopharma based in New York.



Dr Jens Eckstein

CAMBRIDGE, USA

Non-Executive Director

- Managing Partner of Apollo Ventures
- Former president of SR One Ltd., the VC arm of GSK
- 15+ years in VC experience funding early to clinical stage biopharmaceutical companies
- Extensive experience as chairman, board director and founder of several biotechnology and venture capital companies.
- Creator of OneStart, the world's largest life science accelerator



Dr Lesley Russell

PHILADELPHIA, USA

Non-Executive Director

- 25+ years of senior international operational and leadership experience having worked at Amgen, Eli Lilly, Teva, and Cephalon
- Extensive knowledge and experience with new drug development
- Non-Executive Director of Enanta Pharmaceuticals.



Dr Axel Hoos

PHILADELPHIA, USA

Non-Executive Director

- Senior Vice President and Head of Oncology at GSK
- Former Medical Lead for Yervoy, the first immuno-oncology treatment to improve first survival .
- Board of Director of TCR² Therapeutics in Boston
- Chairman of the Sabin Vaccine Institute
- Co-Chair of the Cancer Immunotherapy Consortium Think-Tank



Mr Charles Walker

BRISBANE, AU

Non-Executive Director

- Experienced listed biotech CEO and CFO (ASX:ACL and ASX:IMU)
- Extensive financial markets experience having executed 50+ cross border transactions
- Clinical experience includes managing pipeline of drugs in all stages from discovery, through to Phase III to product launch
- CEO, Founder and NED of RedEarth Energy Storage

Imugene has a team with oncology drug development experience

Experienced management team which have significant clinical development expertise



Dr Rita Laeufle

SAN DIEGO, USA

Chief Medical Officer

- 27+ years of oncology experience in academia and industry
- Clinical development experience with bevacizumab, trastuzumab, abrituzumab, CPIs and oncolytic viruses from Phase I – to post marketing Phase IV
- Former CMO at Oncolytics Biotech, Ex Genentech, Ex Hoffmann-La Roche, and Ex Novartis



Dr Nick Ede

MELBOURNE, AU

Chief Technology Officer

- 25+ years peptide vaccine and drug development
- Former CEO Adistem and CEO of Mimotopes , VP Chemistry Chiron (now Novartis), Research Fellow CRC Vaccine Technology



Dr Anthony Good

SYDNEY, AU

VP of Clinical Research

- 20+ years experience in global clinical development
- Integral to the development of significant new medicines including Viagra, Revatio, Lipitor, and Somavert
- Ex Pfizer Global Research and Development, Ex Covance Clinical Services



Bonnie Nixon

SYDNEY, AU

Project Manager

- 5+ years of oncology experience across Phase I – IV clinical trials
- Ex North America Study Manager at Genentech, Ex Roche Clinical Operations Australia

Imugene has a team with oncology drug development experience



**B-Cell
Immunotherapy**

B CELL BASED ANTIBODIES HAVE DISTINCT ADVANTAGES TO EXISTING TREATMENTS

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, 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

Potentially low numbers of vaccinations required per year

Requires regular infusion

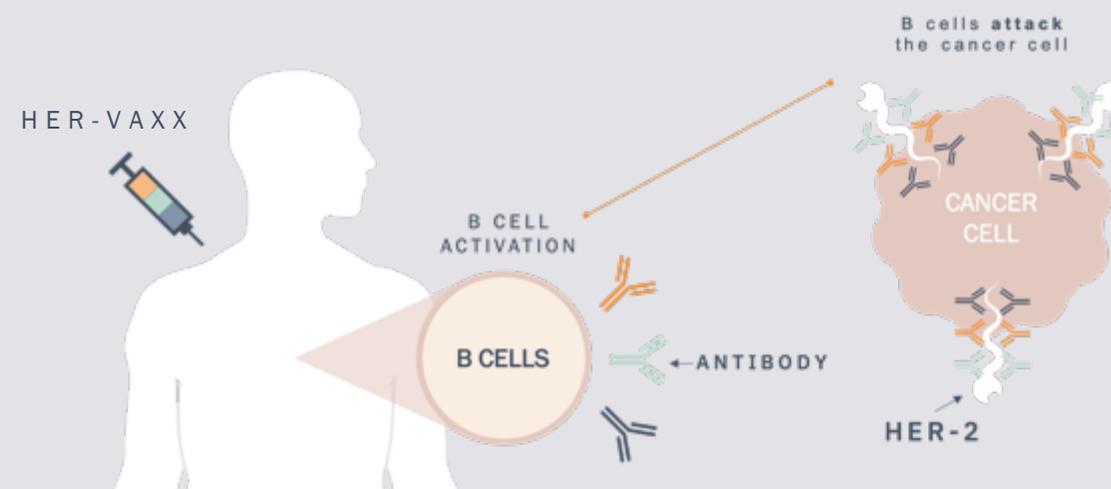
Cost

Low cost of production enables greater pricing flexibility facilitating combination

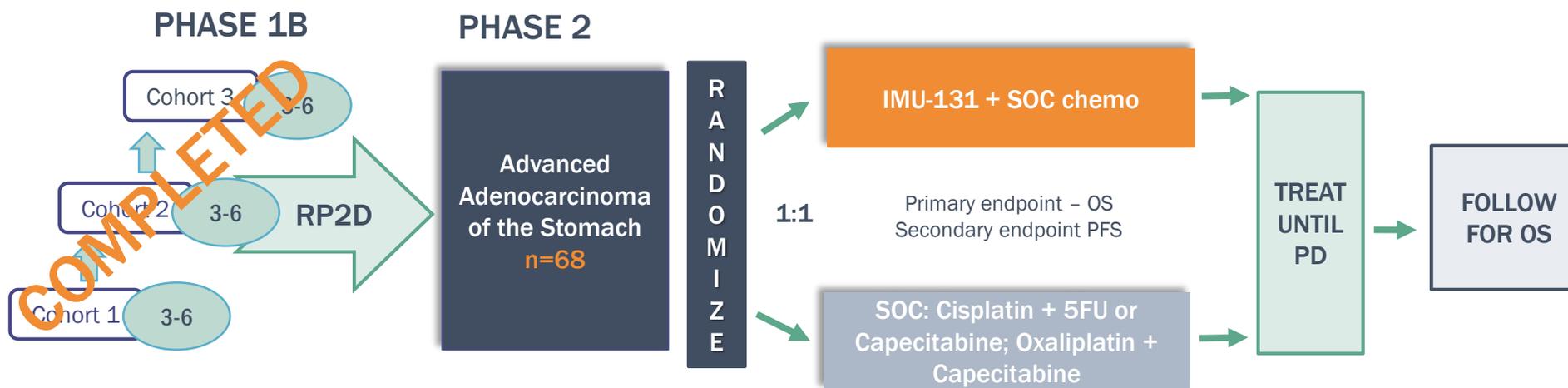
Expensive course of treatment >US\$100K per year

B-CELL IMMUNOTHERAPY VACCINE AGAINST HER-2

- HER-Vaxx is a **B-cell immunotherapy** designed to treat tumours that over-express the HER2/neu receptor, including **gastric and breast cancer**
- The immunotherapy is **constructed from three B cell epitopes** derived from the extracellular domain of HER2/neu
- HER-Vaxx is **under development for the treatment of HER2-positive gastric cancer**, and also has the potential to treat other HER2-overexpressing cancers
- HER-Vaxx has been shown in pre-clinical studies and now in a Phase I study to stimulate a **potent polyclonal antibody response** to HER2/neu, a well-validated cancer target



HER-Vaxx PHASE 1B/2 STUDY DESIGN



Phase	Phase 1B	Phase 2
Indication	Newly diagnosed HER2+ gastric cancer	Newly diagnosed HER2+ gastric cancer
Objectives	Safety & Tolerability, Immunogenicity, RP2D	Primary: OS, Secondary: PFS, Safety & Tolerability, Immune Response
No. of Patients	14	68
Site Location	Asia, Eastern Europe, India	Eastern Europe, India

HER-Vaxx PHASE 1B: DESIGN & RESULTS



Trial

- HER2 Gastric or GEJ cancer
- Phase 1b
- Open label
- Dose escalation
- 14 sites in Asia and Eastern Europe



Patients

- Advanced stage IIIb or IV
- 7 HER2+++, 3 HER2++ (FISH positive), 4 HER2++ expressing tumors
- Age 57yo (21 - 79)
- ECOG 1(7) and 0(7)
- 9 Asian, 5 Caucasian
- 5 female, 9 male



Study

- 14 patients in 3 cohorts (10µg (3), 30µg (6) and 50µg (5))
- Dosed on D0, D14, D35
- IMU-131 in combination with chemo: cisplatin and 5FU or capecitabine



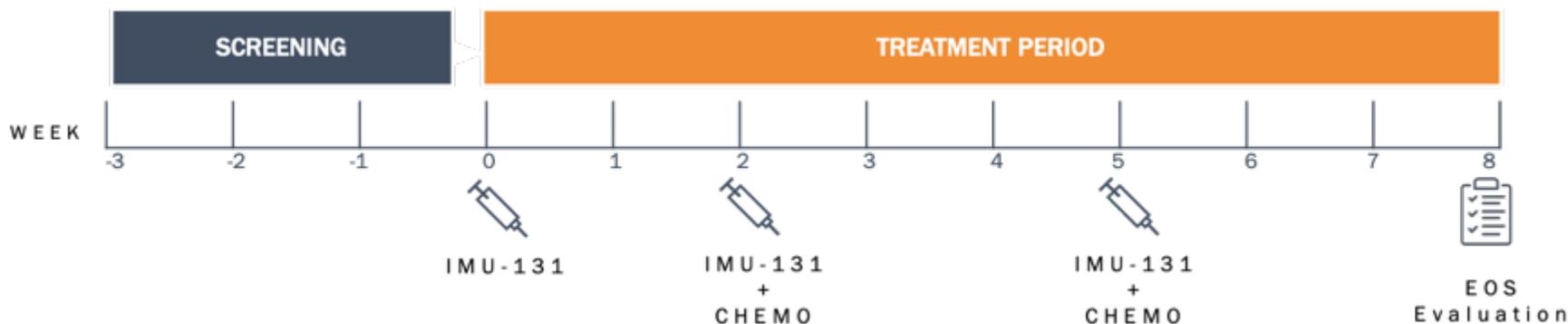
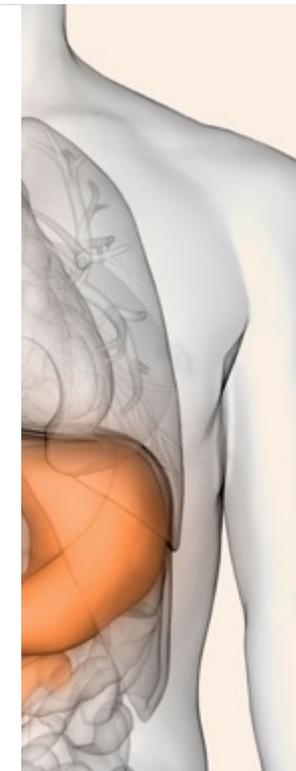
Endpoints

- Recommended Phase 2 Dose of IMU-131
- Safety and Toxicity
- Immunogenicity (anti-peptide (P467) and anti-HER-2 antibody titres)



Study Results

- No safety or toxicity issues
- All patients had increased antibody response
- 1 Complete Response
- 5 Partial Response
- 4 Stable Disease
- 1 Progressive Disease
- 50 µg selected as RP2D



HER-Vaxx PHASE 2: RECRUITING



Trial

- Phase 2
- Open label
- Eastern Europe
- India



Patients

- HER-2+++
- HER-2++ FISH/CISH +ve
- Advance or metastatic Gastric Cancer
- Stage IIIb/IV
- 68 patients in two arms



Study

Randomized

HER-Vaxx in combination with standard of care chemotherapy

Or

Standard of care chemo: Cisplatin and 5FU or capecitabine or oxaliplatin

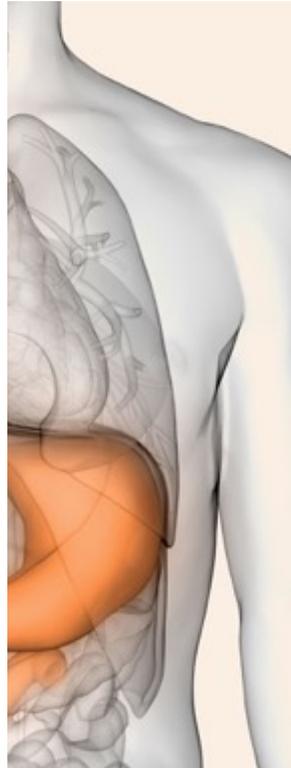


Primary Endpoints

- Overall survival

Secondary Endpoints

- Progression-free survival
- Safety and Tolerability
- Immune response



HER-Vaxx PHASE 2: INTERIM ANALYSIS

Efficacy Outcome Overview

Endpoint	OS ITT * (Primary)	
	Chemo	Chemo+ HER-Vaxx
Treatment		
All Patients n=27 (at data cut off)	13	14
Events**	8	4
Hazard Ratio (HR)	0.418	
2-sided 80%CI	(0.186,0.942)	
Log-rank Test (1-sided p-value)***	.083 ⁺	

*Overall Survival Intent to Treat

**Death

***Pre-specified alpha at 0.10

⁺ Statistically Significant

HER-Vaxx PHASE 2: INTERIM ANALYSIS

Safety Overview - Patients with at least one TEAE*

Total at data cut off	Chemo + HER-Vaxx %	Chemo alone %
Grade 3	42.9%	30.8%
Grade 4	0%	15.4%
Grade 5	0%	7.7%

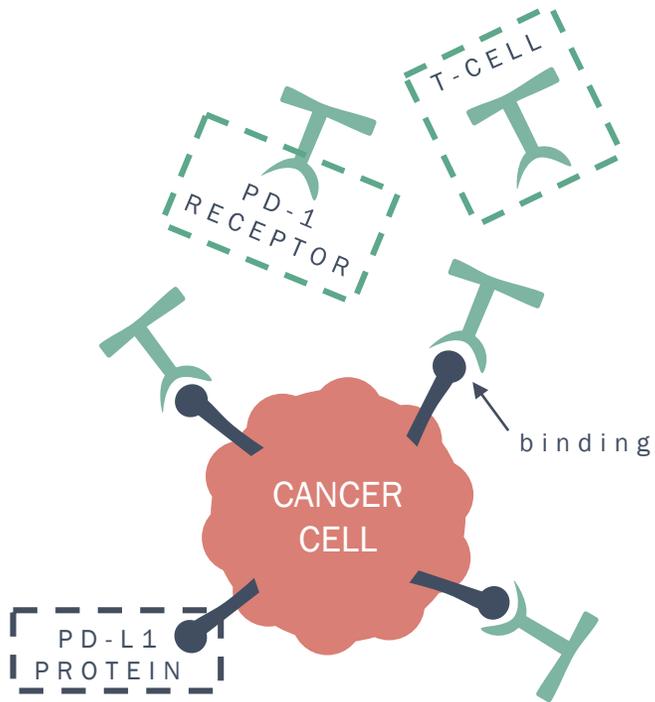
*Treatment Emergent Adverse Events showed **no added Toxicity to HER-Vaxx and Chemo arm** independent of causality

HER-Vaxx PHASE 2: INTERIM ANALYSIS

- ✓ Interim analysis showed statistically significant overall survival Hazard Ratio (HR) of **0.418** (80% 2-sided CI: 0.186, 0.942); HER-Vaxx showed a reduced risk of death of **58.2%** in the HER-Vaxx plus chemotherapy group as compared to chemotherapy alone.
- ✓ The median overall survival (OS) for patients receiving HER-Vaxx plus chemotherapy was **14.2 months**, compared to **8.8 months** in patients treated with chemotherapy alone.
- ✓ The Independent Data Monitoring Committee (**IDMC**) confirms a favourable survival outcome with no added toxicity for HER-Vaxx combined with SOC chemotherapy over chemotherapy alone and advised to **reduce the overall number of patients to ~34** and number of required events **given the strong signal** that it would be considered unethical to enroll 68 as originally planned.
- ✓ The IDMC agreed, that the safety of the study is favorable with **no added toxicity** for the combination of HER-Vaxx and SOC chemotherapy versus SOC chemotherapy alone.
- ✓ The IDMC agreed that the presented data is strongly encouraging to conclude that the combination of **HER-Vaxx and SOC Chemotherapy is safe**.
- ✓ The Phase 2 data represent a **clinical proof-of-concept signal for HER-Vaxx** when added to chemotherapy and indicate that B-cell activating immunotherapy vaccines can induce clinically active antibody responses.

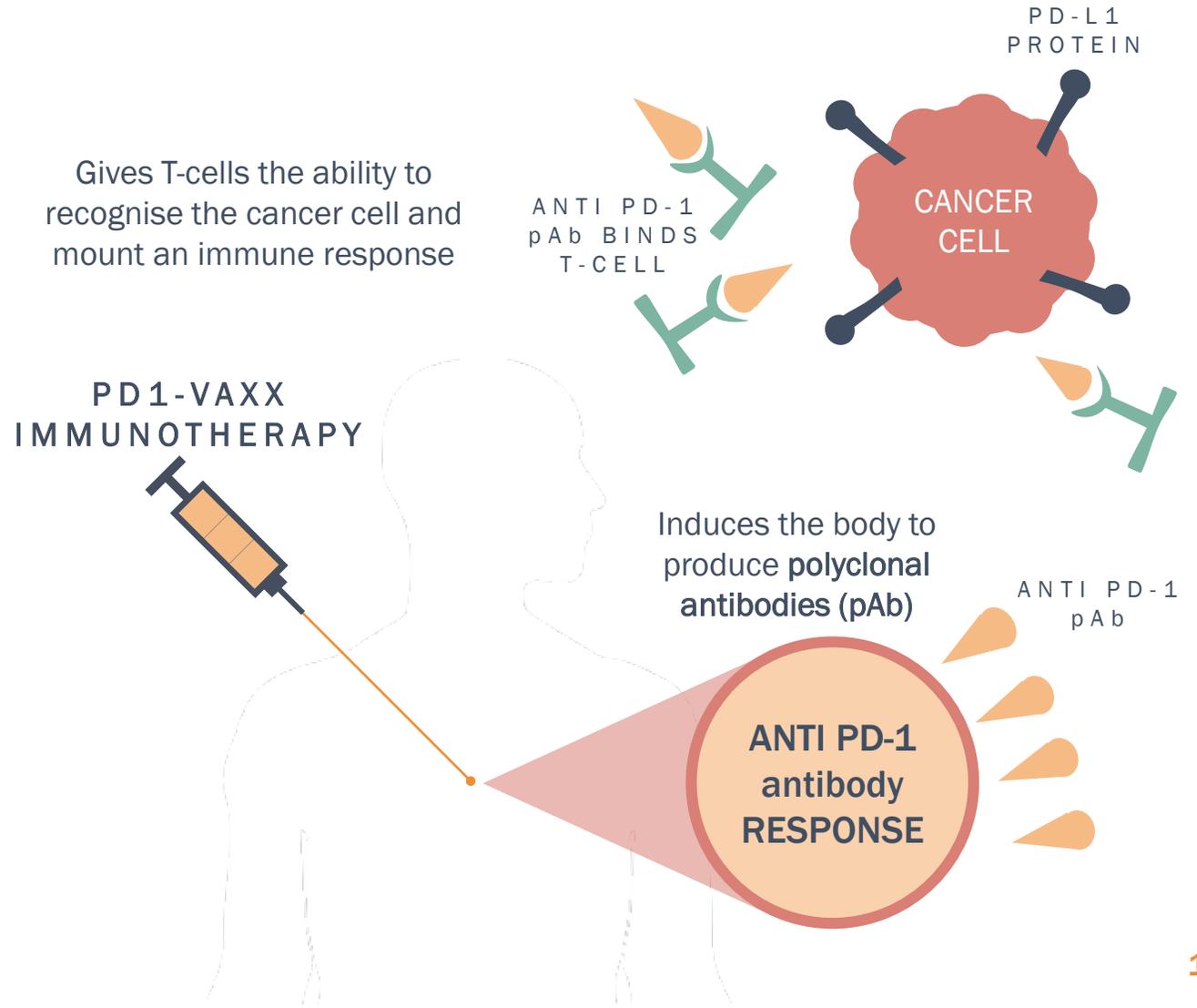
HOW DOES PD1-Vaxx WORK?

HOW CANCER STAYS UNDETECTED BY THE IMMUNE SYSTEM



The PD-L1 protein binds to the PD-1 receptor and stops the T-Cell from recognising the cancer cell, allowing the cancer cell to survive and spread

PD1-VAXX STOPS THE CANCER CELL FROM AVOIDING T-CELL RECOGNITION AND KILLING

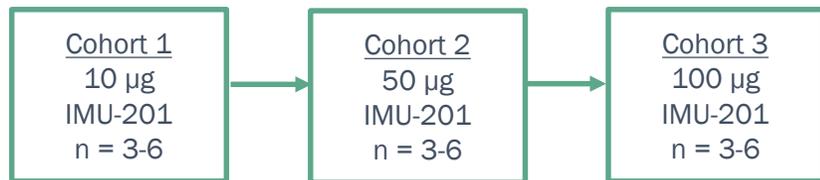


PD1-Vaxx PHASE 1: STUDY DESIGN

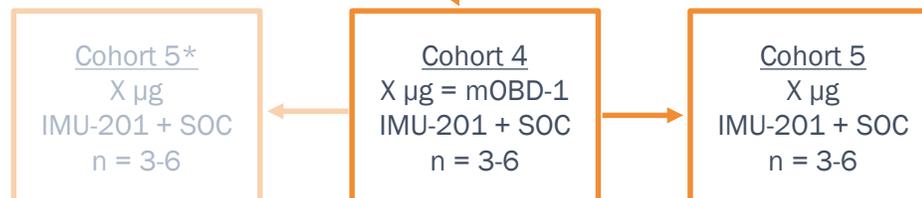
Part 1: Monotherapy Dose Escalation

Part 2: Combination Escalation & Dose Expansion (Planned)

PD1-Vaxx Monotherapy (MTD/OBD evaluation)



PD1-Vaxx + SOC Combination (MTD/OBD evaluation)



Combination OBD

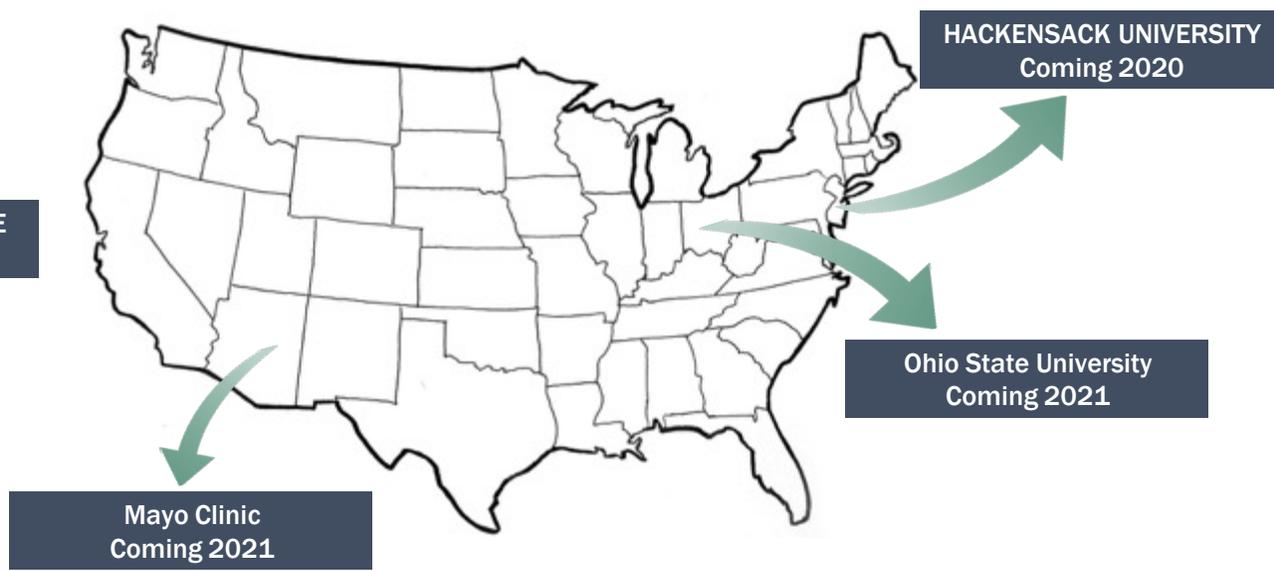
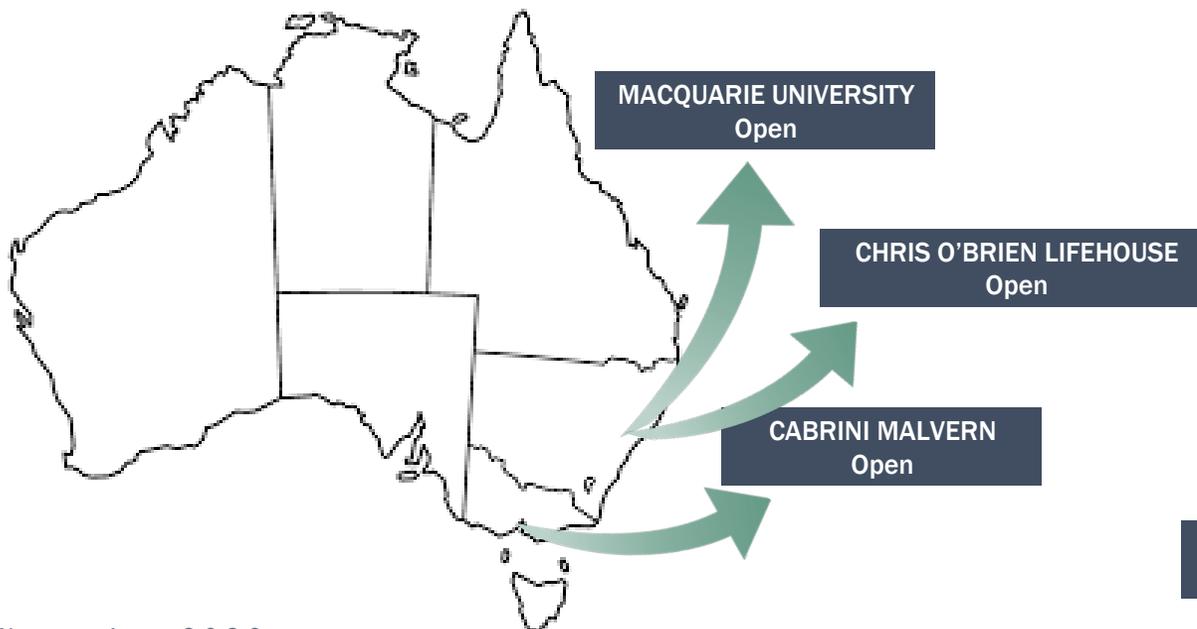


IMU-201+SOC Expansion
n = 12

Phase	Part 1 Monotherapy Dose Escalation	Part 2 Combination Escalation & Expansion (Planned)
Indication	Non-small cell lung cancer expressing PD-L1	
Objectives	Safety & Tolerability, Immunogenicity, OBD Monotherapy	
No. of Patients	Approx. 12-22	Approx. 12-30
Site Location	Australia & USA	

PD1-Vaxx PHASE 1: RECRUITING

Current status

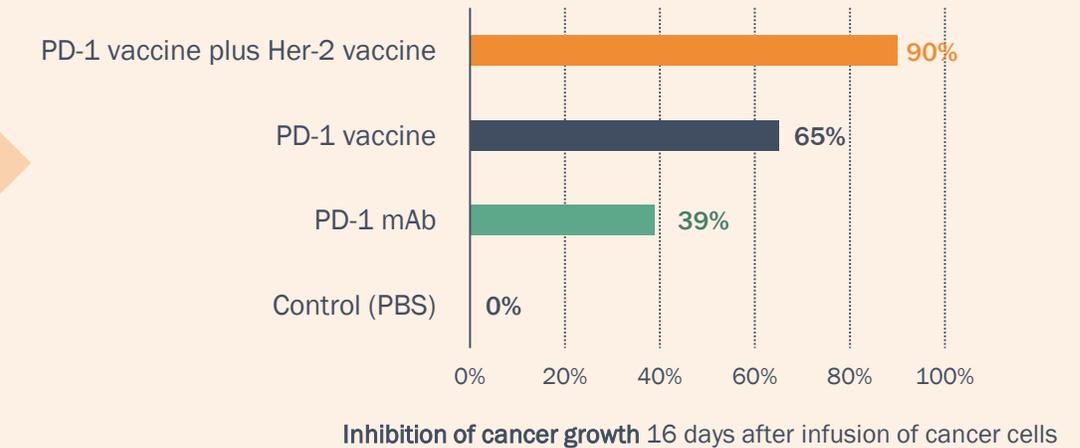


PD-1/HER-2 COMBINATION: POTENTIAL TO INCREASE RESPONSE RATES IN HER-2+ CANCERS

Immuno-oncology combinations are driving value

- Combining drugs for **better immuno-oncology outcome** is driving value creation
- Big Pharma are looking for **novel combinations** that
 - ✓ Combine without increasing toxicity
 - ✓ Combine with minimal cost increase
 - ✓ Combine for better response rates and efficacy

% CANCER GROWTH INHIBITION IN COLORECTAL CANCER MODEL



Imugene's novel therapies have the potential to tick all three boxes

Opdivo / Yervoy Case Study

In 2018, the FDA approved the Opdivo and Yervoy combination for a subset of patients with metastatic colorectal cancer

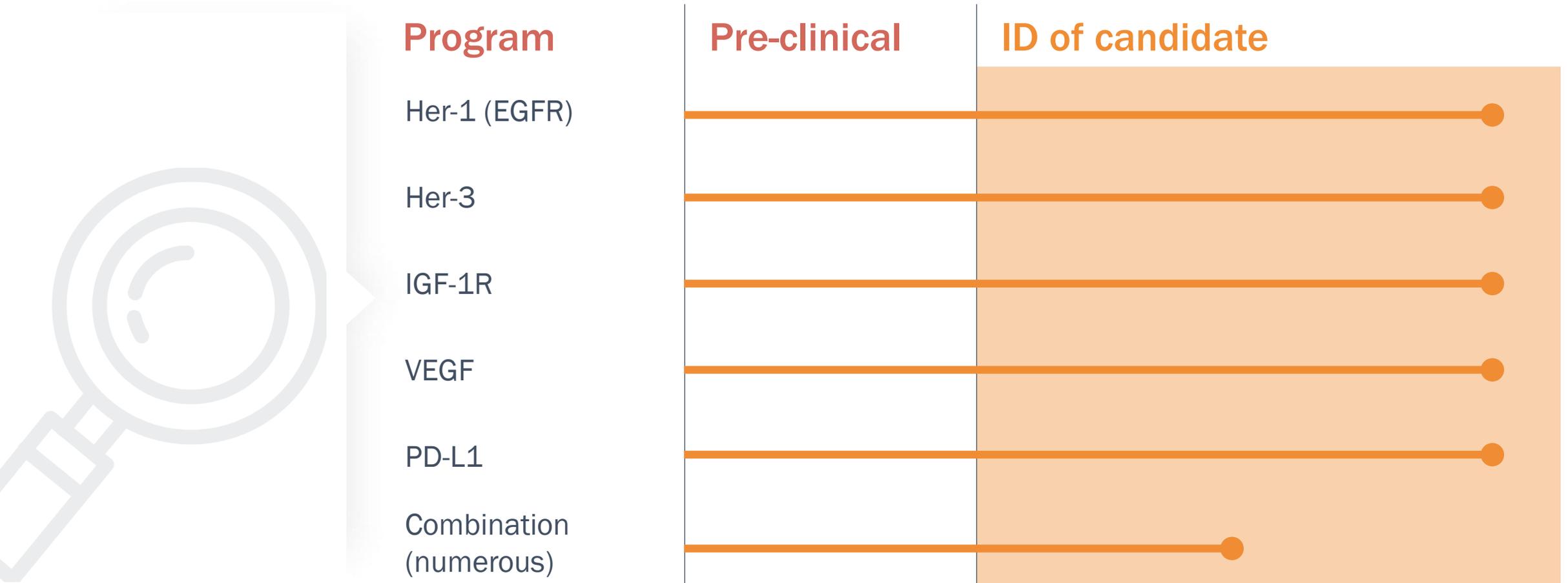
Provides a novel therapeutic option with a higher response rate than that from monotherapy immunotherapy

BUT more significant toxicity is noted with the combination, and immune-mediated side effects need to be monitored

Although early in development, Imugene's PD-1 and Her-2 cancer vaccines potentially provide efficacy and response rate with minimal toxicity

IMUGENE'S DISCOVERY PIPELINE

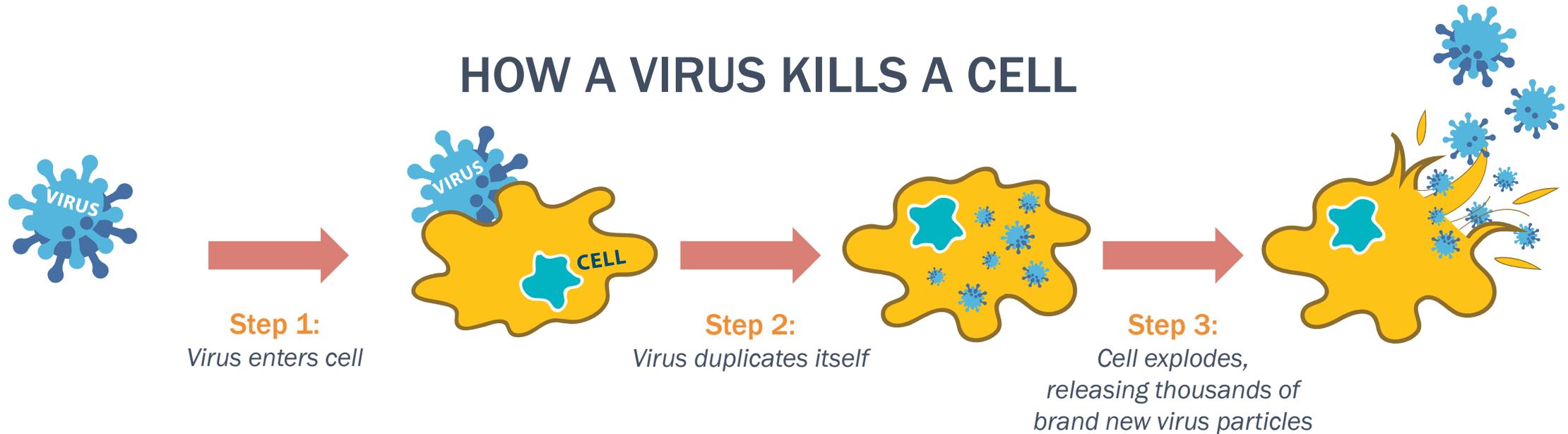
Imugene has the ability to advance these programs at any point





CF33: Oncolytic Virus

HOW A VIRUS KILLS A CELL



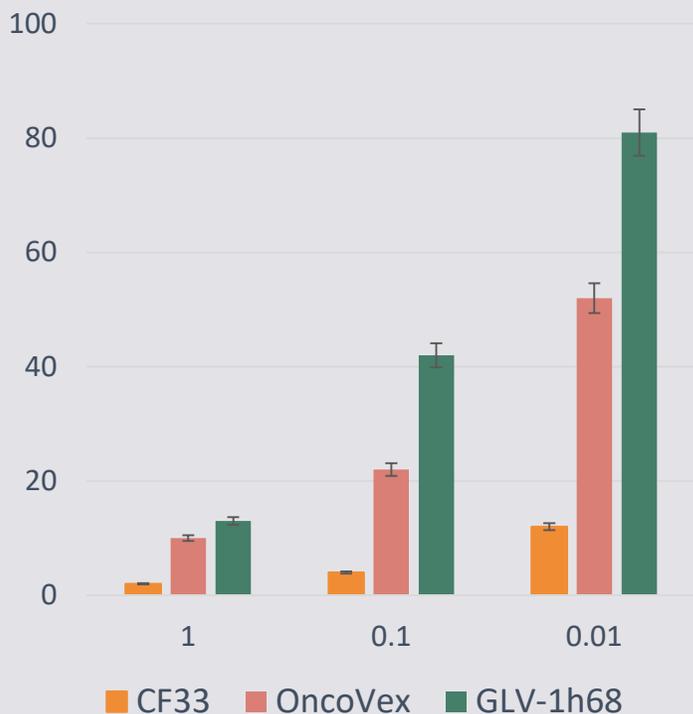
- Direct infection, replication within and cancer cell killing
- Viral infection increases local check point targets (PD-1, PD-L1, CTLA4 etc)
- Cell death is immunogenic [surface expression of calreticulin, release of adenosine triphosphate (ATP) and release of high mobility group box 1 (HMGB1)]
- Local anti-PD-L1 expression may allow enhancement of anti-cancer immunotherapy
- Human sodium iodine symporter (hNIS) expression allows additional use of ^{131}I Iodine or ^{188}Re Rhenium killing of infected cells and adjacent cells

CF33 OUTPERFORMS AMGEN & GENELUX VIRUSES

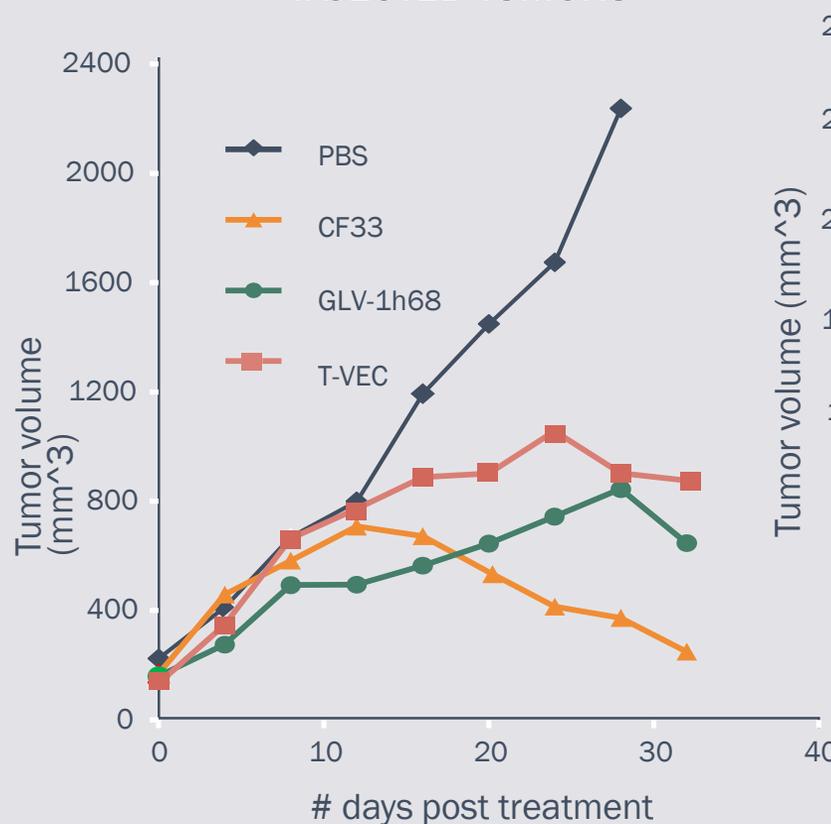
MICE BEARING THE **A549 XENOGRAPTS** WERE TREATED WITH INDICATED VIRUSES AT A DOSE OF 10^3 PFU/MOUSE



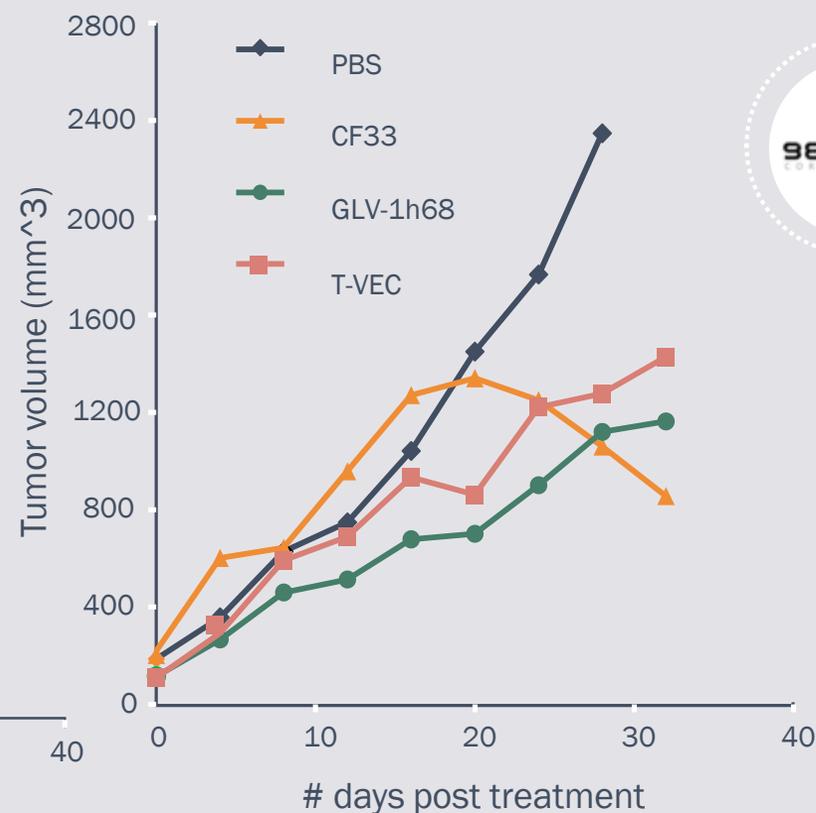
PERCENT CELL SURVIVAL FOR BXPC-3 PANCREATIC CANCER



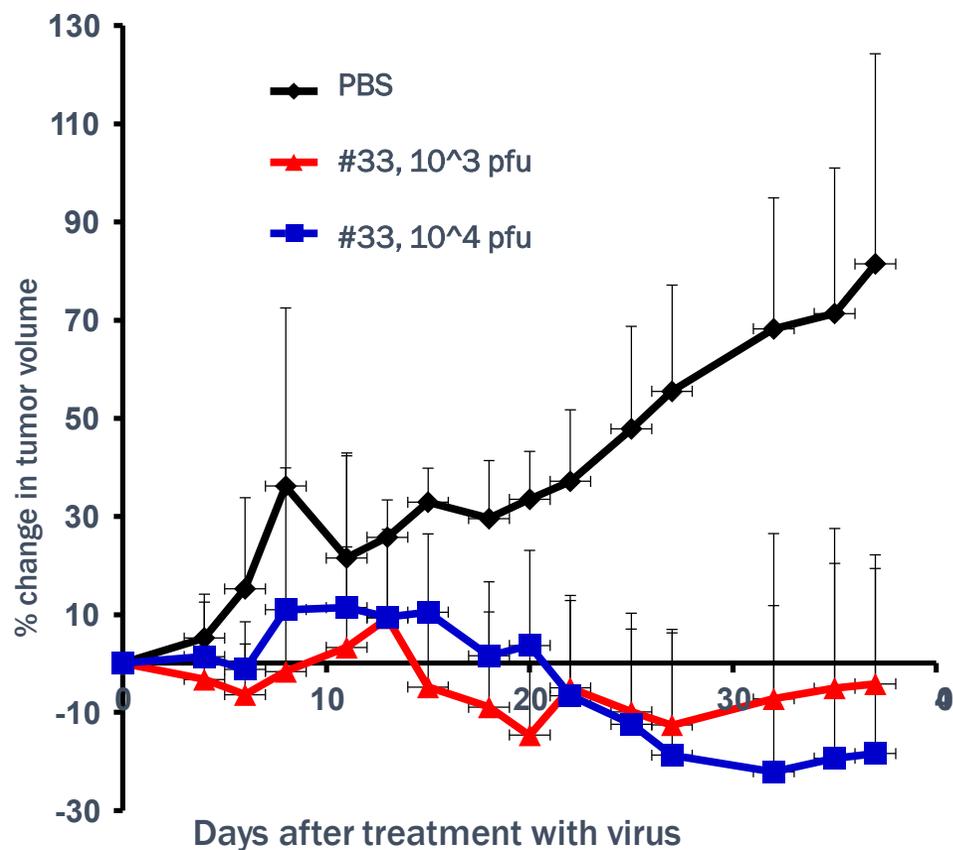
INJECTED TUMORS



NON-INJECTED TUMORS



CF33 SHRINKS TRIPLE-NEGATIVE BREAST CANCER



Mice treated with both intratumoral virus and IV

The viral dose used was **2-5 orders of magnitude** lower than doses used for oncolytic viruses under clinical testing

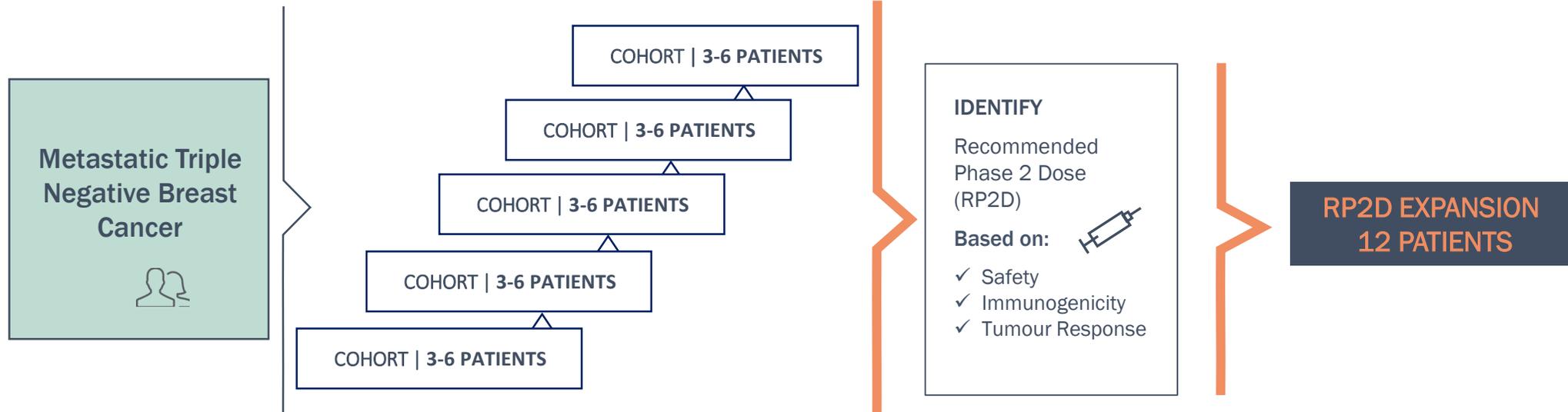
Mol Ther Oncolytics.
2018 Jun 29;9



The viral dose used was **2-5 orders of magnitude** lower than doses used for oncolytic viruses under clinical testing

CHECKvacc: CF33+hNIS+aPD-L1 (“Armed” Virus)

Phase 1 Triple Negative Breast Cancer Study – GMP Manufacturing Complete

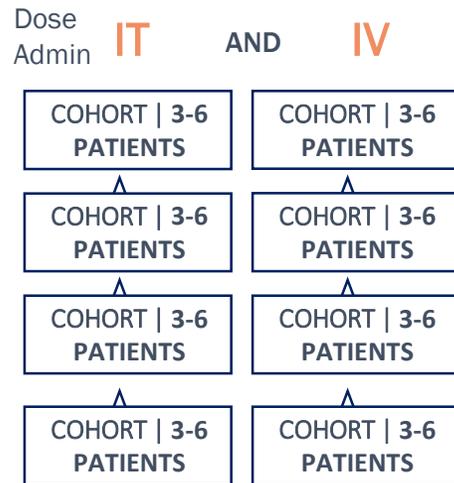


- ❑ Disease of need
 - 8-13 month survival for metastatic disease with few treatments
- ❑ Potential target for immunotherapy
 - Expresses PD1, PD-L1
- ❑ Treatment responses to Atezolizumab (JAMA Oncology, 5:74, 2019)
 - 1st line: 24%; 2nd line: 6%
 - Approved by FDA 8-March, 2019
- ❑ Potential for registration in well-designed, randomized P2 study

	Indication	TNBC
	FDA IND	CHECKvacc: CF33-hNIS-aPDL1
	N	Part 1=18-24 ; Part 2=12
	Location	Single Center: COH
	Admin Route	Intratumoral (IT)

VAXINIA PHASE 1 MAST STUDY (Metastatic Advanced Solid Tumours)

Part 1: VAXINIA Monotherapy Dose Escalation



IT Administration
Head & Neck, Advanced Melanoma, TNBC

IV Administration
Head & Neck, Advanced Melanoma, TNBC, NSCLC, Bladder, Gastric, Colorectal, RCC

IDENTIFY MONOTHERAPY

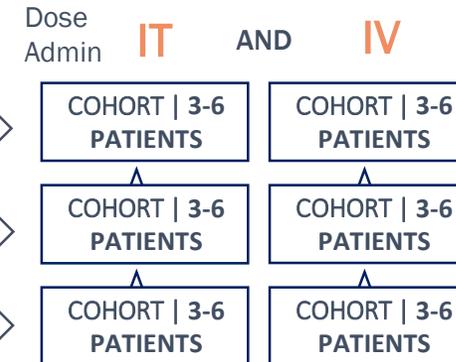
Maximum Feasible Does (MFD)

Based on:

- ✓ Safety
- ✓ Immunogenicity
- ✓ Tumour Response



Part 2: VAXINIA + SOC IO* Combination Dose Escalation



IDENTIFY COMBINATION

DLT* cleared VAXINIA monotherapy dose combined with IO* in dose escalation cohorts. Select IO* Combination for recommended phase 2 dose (RP2D) based on:

- ✓ Safety
- ✓ Immunogenicity
- ✓ Tumour PD and target Signals

Phase

Phase 1

Indication



IT: Head & Neck, Advanced Melanoma, TNBC
IV: Head & Neck, Advanced Melanoma, TNBC, NSCLC, Bladder, Gastric, Colorectal, RCC

Objectives

Safety & MFD

No. of Patients



Approx. 60-120

Site Location

USA

*IO: Immunotherapy

*DLT: Dose Limiting Toxicity

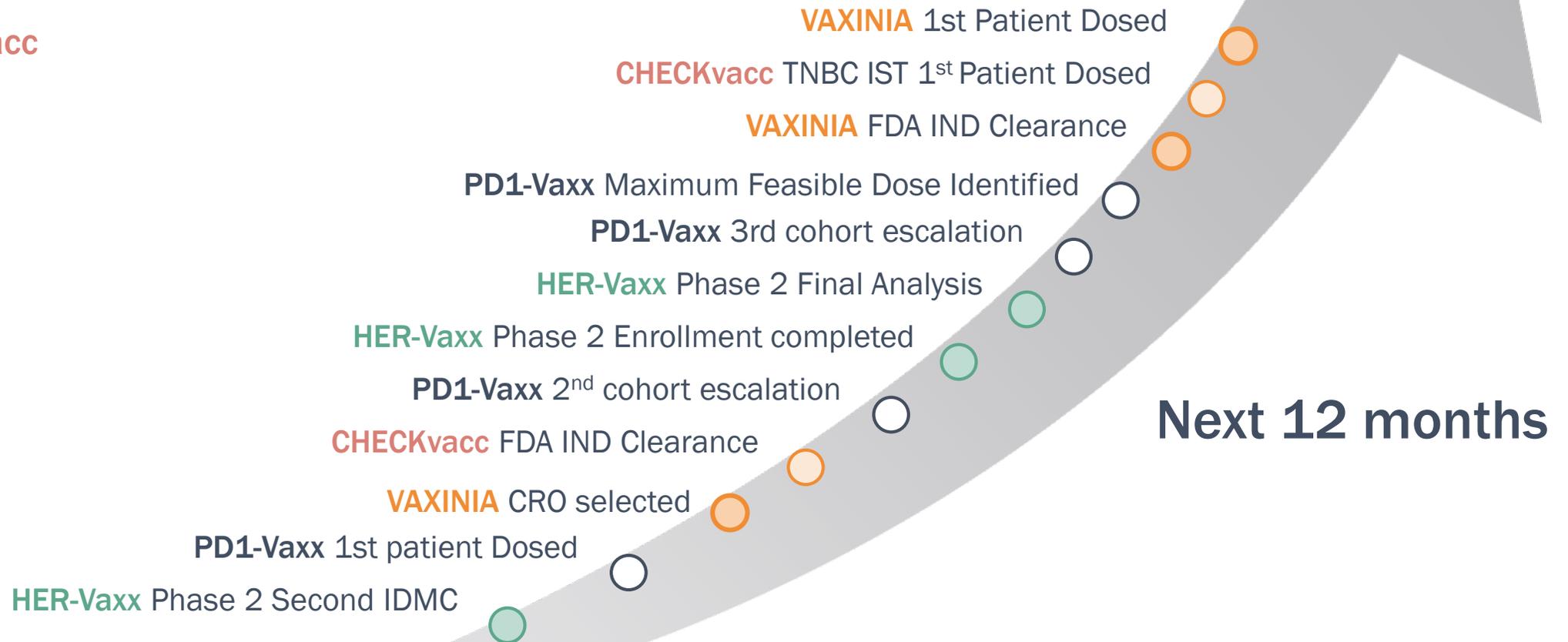
LANDSCAPE: RECENT ONCOLYTIC VIRUS TRANSACTIONS

Date	January 2011	February 2018	May 2018	September 2018	December 2019
Oncolytic Virus Company					
Focused virus technology	Onco-vex (herpes)	Coxsackie virus A21	Herpes virus	VSV (vesicular stomatitis virus)	Vaccinia Virus
Partnership Company			 <small>PHARMACEUTICAL COMPANIES OF</small> 		
Phase of Development	Approved 2015 IMLYGIC™ <small>(talimogene laherparepvec)</small>	Phase 1	Pre-clinical	Pre-clinical	Pre-clinical
Upfront	\$425 million	\$394 million	\$140 million	\$245 million	\$120 million
Potential milestones	\$575 million	-	\$900 million	-	\$900 million
Total Deal Value	\$1 billion	\$394 million	\$1.04 billion	\$245 million	\$1.2 billion

~\$3.7 billion USD in total value) with 3 Deals Done in Preclinical Stage

MULTIPLE NEAR & MEDIUM TERM VALUE INFLECTION POINTS

- PD1-Vaxx
- VAXINIA
- HER-Vaxx
- CHECKvacc



FINANCIAL SUMMARY

Public Market Overview

Share Price ¹	A\$0.115
Market Capitalisation ²	A\$528.4M
Cash equivalents (30 Sep 20)	A\$26.6M
Enterprise Value	A\$501.8M

Top 5 Shareholders (as at November 2020)

Richard Mann and Assoc.	5.66%
Paul Hopper	3.86%
National Nominees Limited	2.77%
Dr Nicholas Smith	2.57%
HSBC Custody Nominees (Australia)	1.82%

Note:

1. As of 23 November 2020
2. Market capitalization calculations based on ordinary shares (4.59bn) only and excludes the dilutive impact of options outstanding (842m)

Share Price Performance (last 6 months)





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