IMUGENE
Developing Cancer Immunotherapies

ASX: IMU

CF33 ONCOLYTIC VIRUS ACQUISITION

November 2019

CONFIDENTIAL

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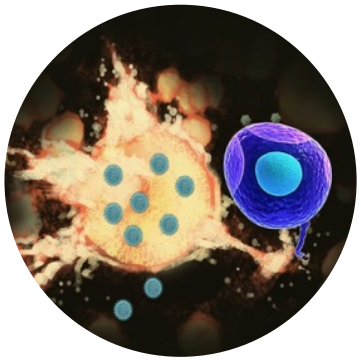
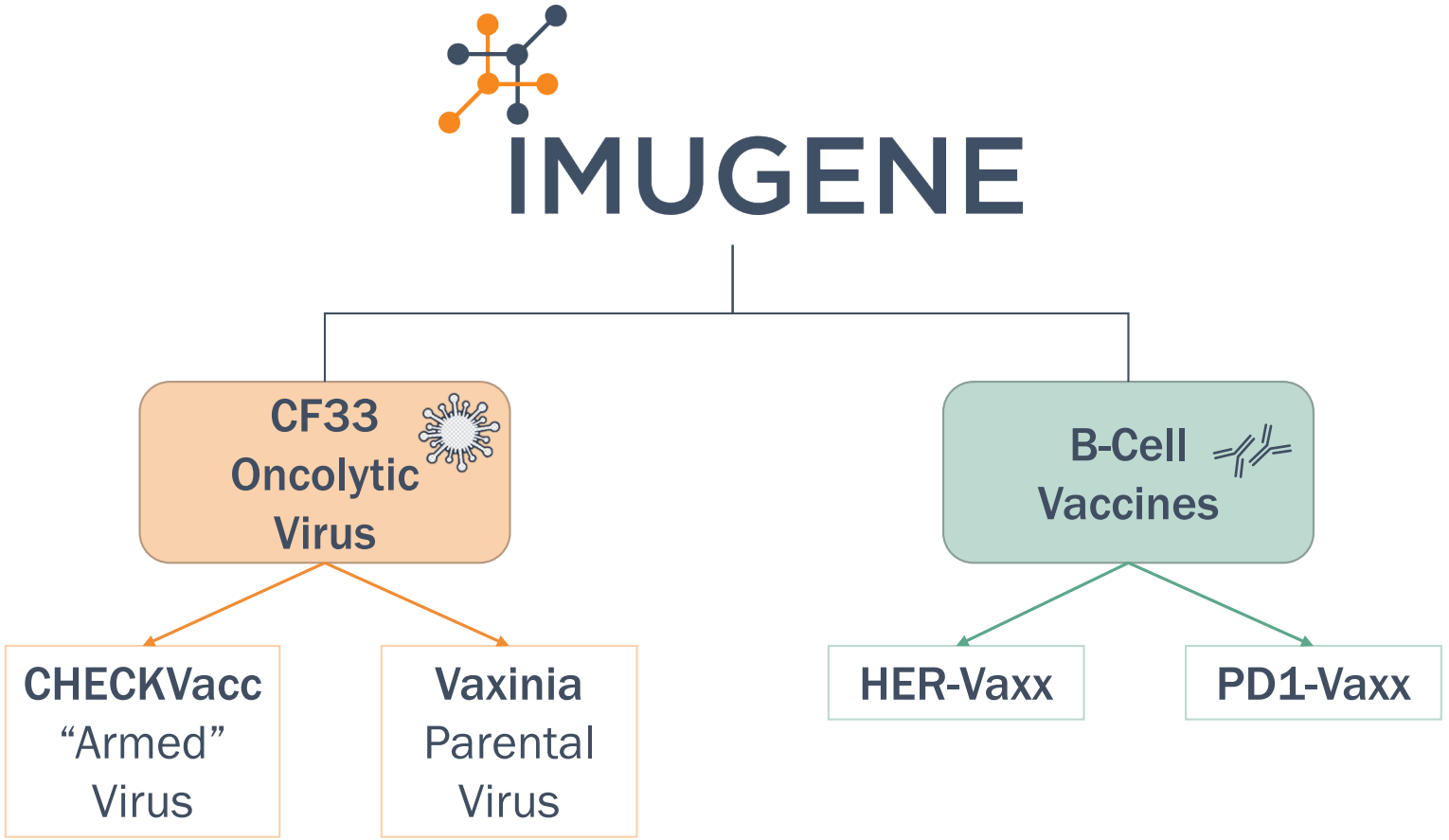
INVESTMENT HIGHLIGHTS



- Two novel technologies: CF33 oncolytic virus; and B-Cell immunotherapy
- CF33 recently acquired from City of Hope Cancer Centre in Los Angeles
- CF33 poised to enter two Phase 1 clinical trials in 2020
- CF33 has demonstrated single agent & combination activity
- Prolific and compelling pre-clinical data
- GMP manufacturing complete for both trials
- Highly experienced CF33 management including ex-Viralytics clinical development team
- B-Cell technology currently recruiting Phase 2 trial in gastric cancer & will initiate Phase 1 immune checkpoint study in 2020
- Robust, long life IP portfolio over both technologies
- Significant news flow with multiple near & medium term valuation inflections

TWO NOVEL TECHNOLOGY PLATFORMS



FOUR CLINICAL TRIALS IN 2020

ONCOLYTIC VIRUS

CHECKVacc

CF33+hNIS+ PD-L1

Triple Negative Breast Cancer

Phase 1

City of Hope

n=15-20

1H 2020

Vaxinia

CF33+hNIS

Advanced Solid Tumors

Phase 1 / 2

Multi Centre

n=130

1H 2020

B CELL IMMUNOTHERAPIES

HER-Vaxx

Phase 2

Gastric Cancer

Multi Centre

Recruiting

n=68

PD1-Vaxx

Phase 1

Lung Cancer

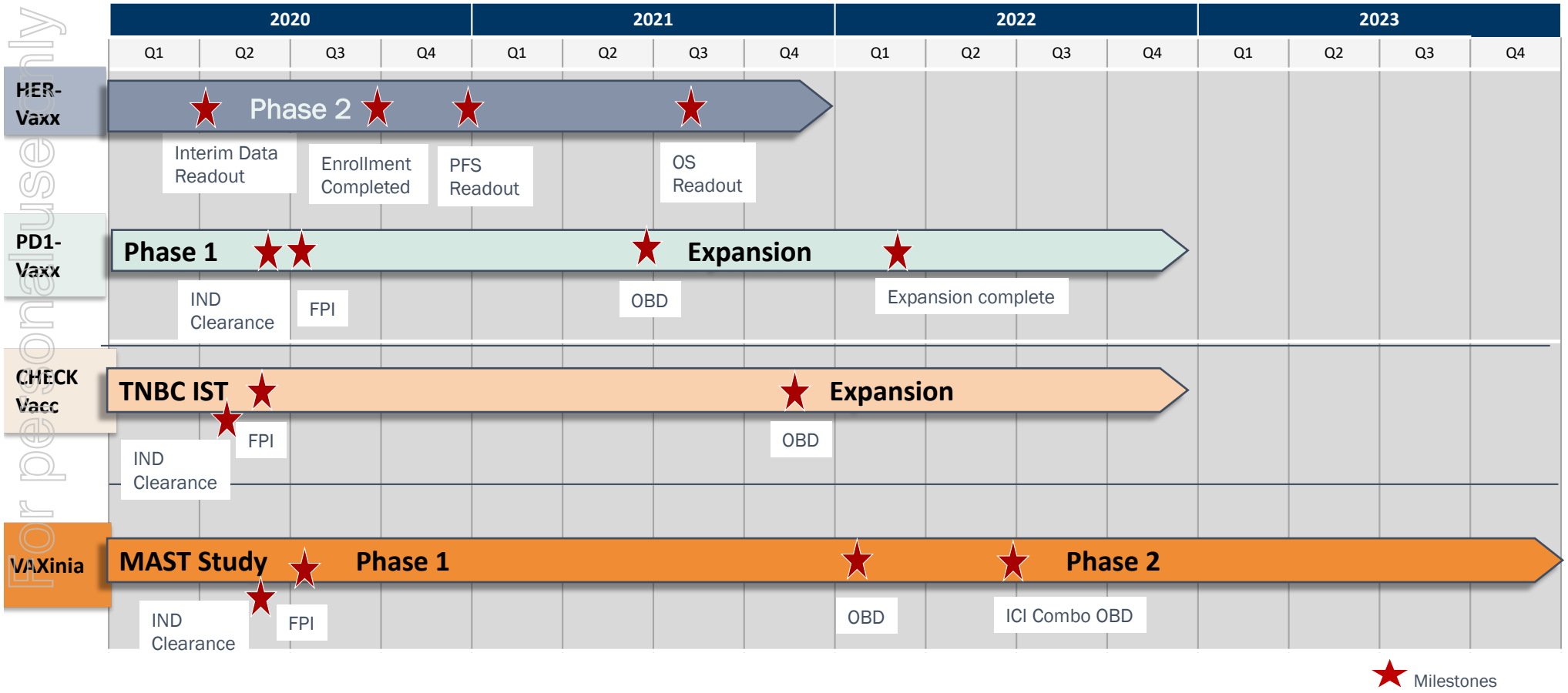
Multi Centre

1H 2020

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		• 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 & PD-L1)		Triple negative breast cancer		• 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	• 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	Expiring 2036
PD1-Vaxx		Lung		• 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

IMUGENE'S ESTIMATED TIMELINE



INTERNATIONAL LEADERSHIP TEAM

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

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

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

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
- 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

THE ONCOLYTIC VIRUS INVENTOR & CITY OF HOPE

Professor Yuman Fong

the MIRACLE of SCIENCE with SOUL
City of Hope

A pioneer, both in the operating room and in the laboratory, Prof Yuman Fong, M.D., 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 has also led research efforts to use genetically modified viruses to destroy cancer cells.

Prof Fong joined City of Hope in 2014 after more than two decades at the renowned Memorial Sloan-Kettering Cancer Center in New York City.

Prof Fong is both an *author and innovator*. He has written and edited over 700 scholarly articles as well as 14 textbooks. He is currently the Editor-in-Chief of *Molecular Therapy Oncolytics* (Cell Press).

Prof 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

ONCOLYTIC VIRUS CLINICAL DEVELOPMENT TEAM – ex VIRALYTICS

Paul Hopper
Chairman of Viralytics

Leslie Chong
MD & CEO

Dr Len Post
Senior Scientific Advisor

- Former Director Biovex
- Former Director Viralytics

Mark Grose
Clinical Trials Manager

- Former Clinical Trials Manager at Viralytics
- Practical Clinical (Lisa Guttman and Leslie Guerreiro)

Dr Seymour Fein
Medical Monitor

- Former Medical Monitor at Viralytics

Dr Evan Siegal
IND Lead on Vaxinia IND Submission

- Former IND Leader on Viralytics IND Submission

Dr Mike White
Biostatistician

- Former Viralytics Biostatistician

Dr Nick Ede

- CMC

Viralytics
Developers of Oncolytic Immunotherapies

LANDSCAPE: RECENT ONCOLYTIC VIRUS TRANSACTIONS

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Oncolytic viruses are attracting the serious attention of big pharma companies such as Merck, Boehringer and Janssen which have made three acquisitions in 2018 alone totalling **over $1.0 billion**, including Viralytics.

$340m	$200m	$502m
Boehringer Ingelheim	BeneVir	MERCK
ViraTherapeutics	Janssen PHARMACEUTICAL COMPANIES OF Johnson&Johnson	Viralytics Developers of Oncolytic Immunotherapies

VIRALYTICS CASE STUDY

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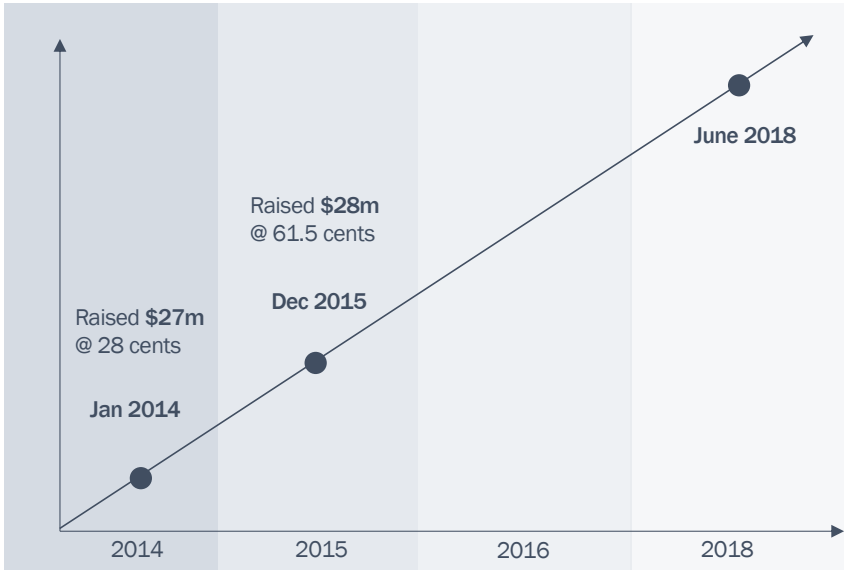
ACQUIRED BY MERCK FOR $502M

Virus	Picornovirus/coxsackie
Stage of Development	Phase 2
Disease types	Melanoma, bladder, colorectal, non small cell lung
Industry collaboration	Checkpoint combination trial with Merck
Investors	Orbimed, Abbingworth, Baker Bros, BVF, Quest
Team	Paul Hopper (Chair), McColl, Prof Darren Shafren, Turvey, Post

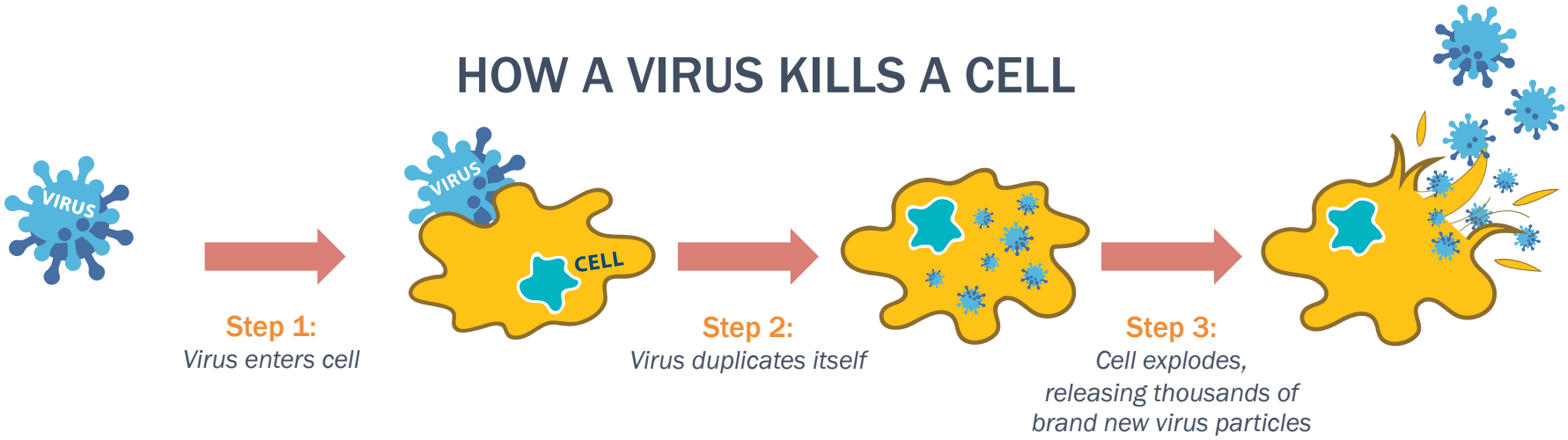
$502M Acquired by **MERCK** @$1.75

MERCK



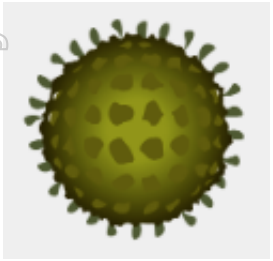
Viralytics
Developers of Oncolytic Immunotherapies

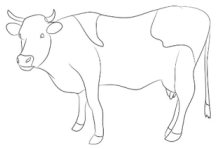
CF33 MECHANISM OF ACTION

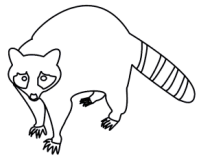


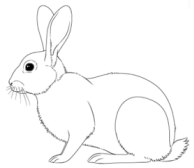
- Direct infection, replication within and cancer cell killing
- Viral infection increases local check point targets (PD-1, PD-L1, CTLA4 etc)
- Cell death is immunogenic [surface expression of calreticulin, release of adenosine triphosphate (ATP) and release of high mobility group box 1 (HMGB1)]
- Local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

HOW WAS THE VIRUS MADE?









- This is a unique “designer virus” which does not exist in nature
- Nine viruses selected: six vaccinia (smallpox); cowpox; rabbit; and racoon
- All inserted in a cancer cell, where they traded DNA
- Hundreds of new virus resulted and were isolated for assessment of cancer killing and safety
- The 33rd virus put through this screening was chosen for clinical development (hence CF33)
- Using high thru-put screening, CF33 was tested against 60 different cancers (NCI60) and had effect on all (killed 97%, retarded growth 3%)

FOUNDATION PATENT (2037)

PCT: US2017/046163

Title: Chimeric poxvirus compositions & use thereof

MAJOR ADVANTAGES OF CF33

Preclinical data has demonstrated that CF33 is more **efficacious** than all parental viruses and some viruses in clinical trials.

Especially impressing is that CF33 can **shrink multiple types** of cancer at an extremely low dose (1000 PFU).

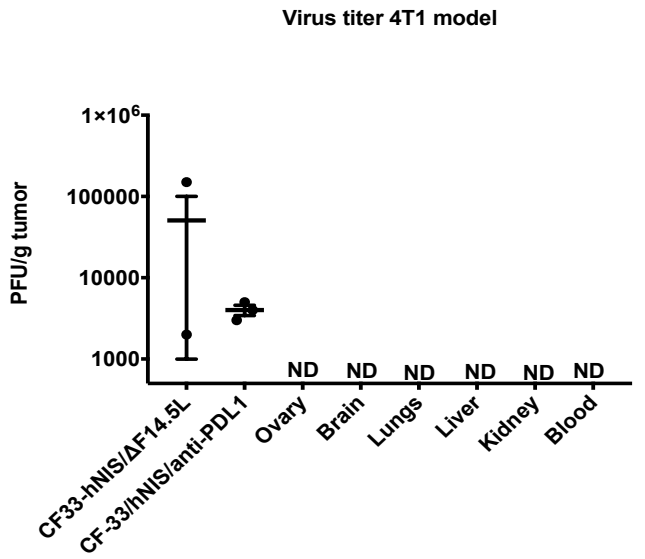
Importantly, CF33 **shrinks** not only injected tumors, but also non-injected **distant tumors** (abscopal effect).

KEY DIFFERENTIATION

1. **DNA virus -** Much easier to manipulate and vectorize to carry foreign gene as therapeutic payloads
2. **CF33 -** more potent in terms of;
   a) Range of cancer cell types infectible,
   b) Low doses necessary for cancer killing in vitro and in vivo, and
   c) Therapeutic window (dose for toxicity minus dose for efficacy)
3. **CF33** can be made in high titres
4. **CF33** can be used in multiple doses without complete neutralization by host immune system

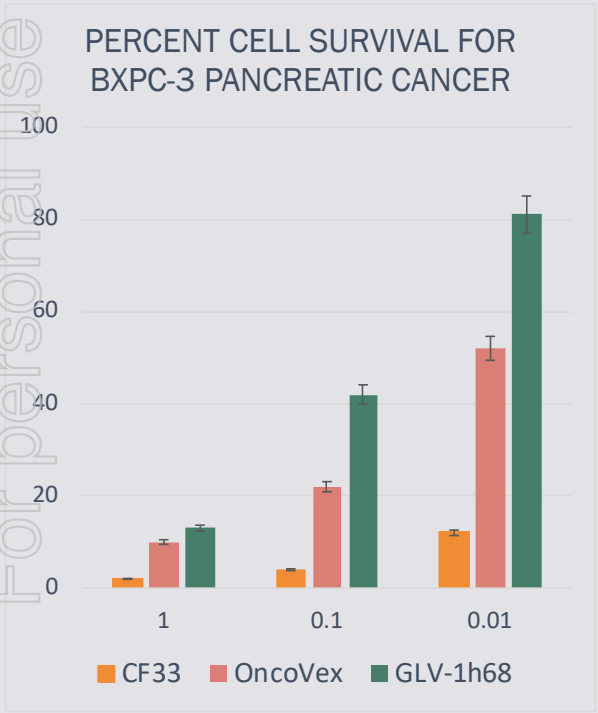
CF33 SAFETY

Figure 1. Day 7 biodistribution of the virus in Immune-competent mice: Immune-competent BALB/c mice bearing a single tumor in mammary fat-pad were injected with the the indicated HOVs (10e7 pfu, i.t.).

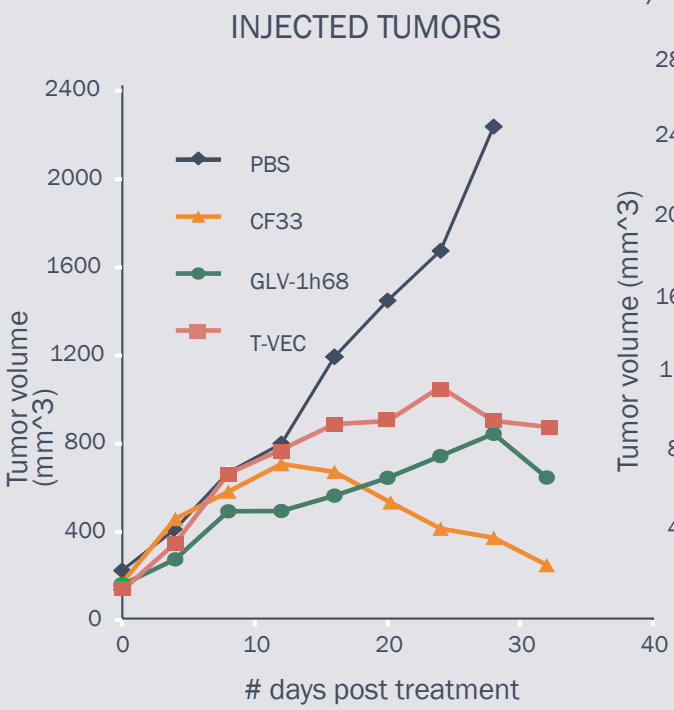


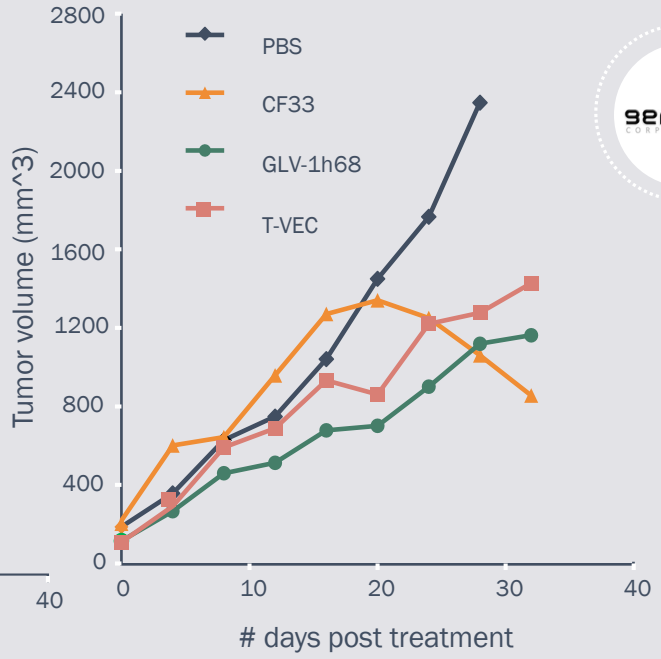
- A number of studies have been completed with CF33 as well as some of the derivatives. It has proven very safe in nude mice and in immunocompetent mice.
- In data published in Journal Translational Research, no viral shedding in blood and urine was found. No signs of illness were found and animals ate well and gained weight.
- In total, more than 900 mice have been treated with derivatives from this back bone. More than 50 mice have been treated with doses up to 10E7 IV and IT without signs of toxicity.
- In BALB-C mice, no virus can be detected by PCR at day 7 in any other organ (limit of detection approx. 200 copies), while it was detected in tumor (figure 1).

CF33 OUTPERFORMS AMGEN & GENELUX VIRUSES



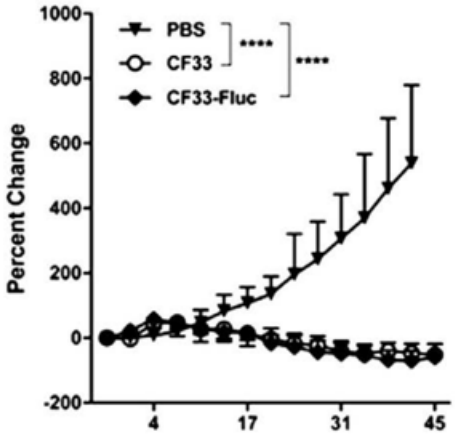
MICE BEARING THE A549 XENOGRAFTS WERE TREATED WITH INDICATED VIRUSES AT A DOSE OF 10^3 PFU/MOUSE





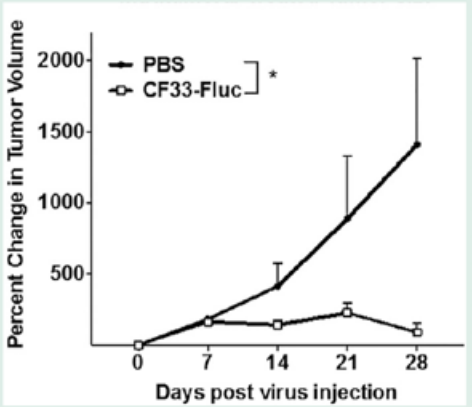
COMPELLING SINGLE AGENT TUMOUR INHIBITION IN MULTIPLE CANCERS

PANCREATIC



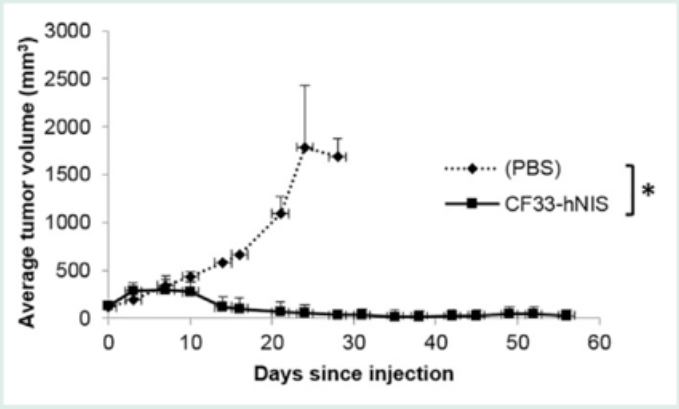
J Transl Med. 2018, 16, 110

COLORECTAL



Mol Ther Oncolytics. 2018, 9, 13

COLON



Mol Ther Oncolytics. 2019, 13, 82

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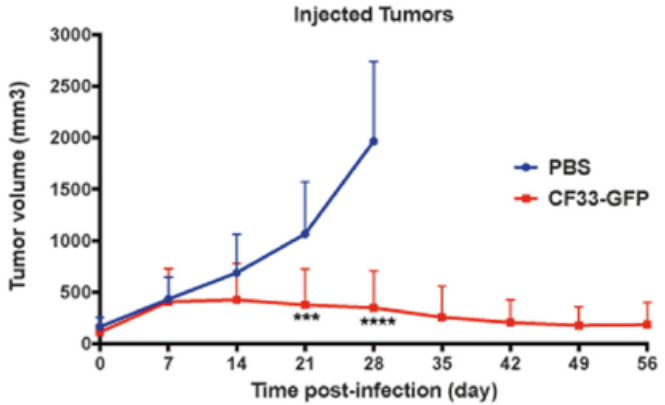
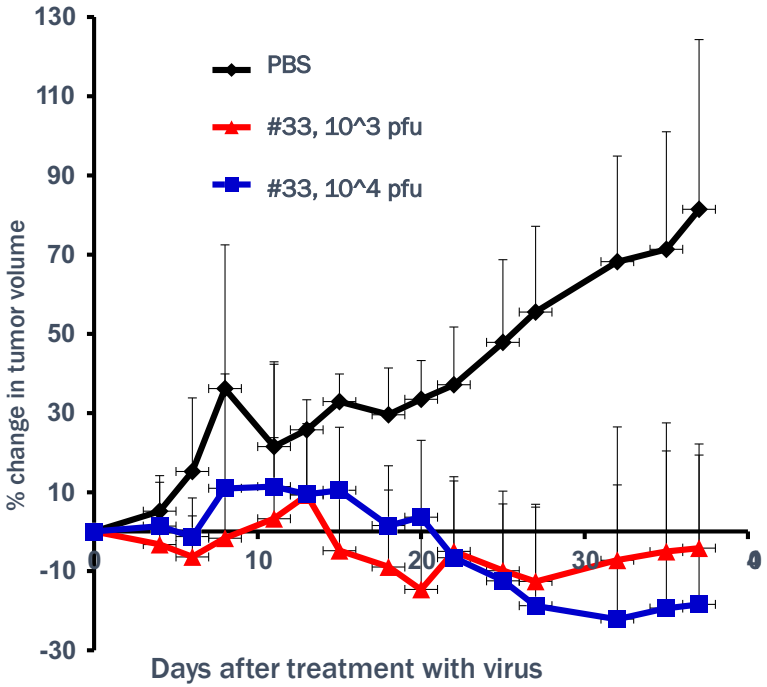


Cancer Gene Ther. 2019

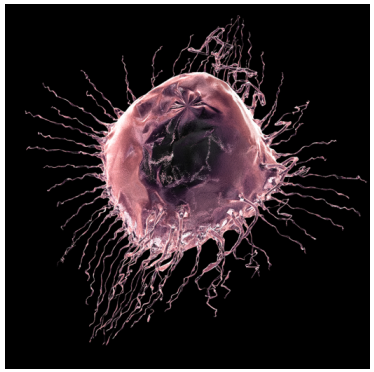
CF33 SHRINKS TRIPLE-NEGATIVE BREAST CANCER



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

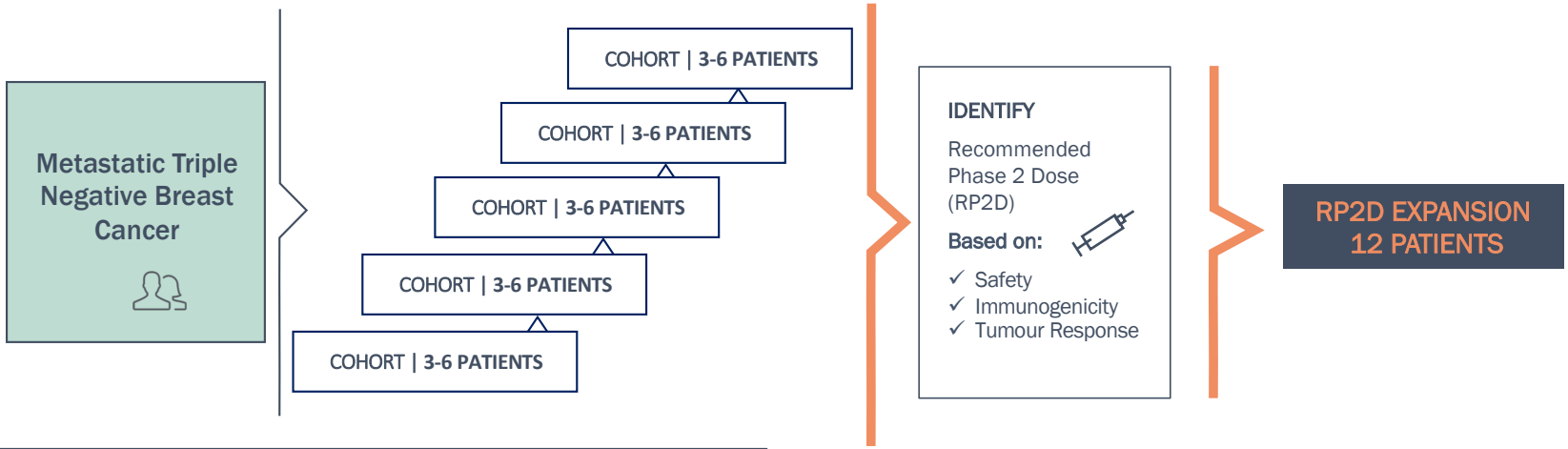
Mol Ther Oncolytics. 2018 Jun 29;9



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

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

Qtr 2 2020 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)

PHASE 1/2 VAXINIA MAST STUDY
(Mixed Advanced Solid Tumours

Advanced Melanoma TNBC, Urothelial IT Administration

NSCLC, TNBC, Urothelial, Gastric IV Administration

GMP manufacturing complete

PHASE 1 STUDY: DOSE SEEKING/SIGNAL FINDING

PHASE 2 – DOSE EXPANSION

Part 1

Vaxinia Monotherapy Dose Escalation

IT or IV

COHORT | 3-6 PATIENTS

COHORT | 3-6 PATIENTS

COHORT | 3-6 PATIENTS

COHORT | 3-6 PATIENTS

IDENTIFY

Maximum Feasible Does (MFD)

Select ICI Combo

Based on:

✓ Safety
✓ Immunogenicity
✓ Tumour PD

Part 2

Vaxinia + ICI Combination in Selected Indications

CF33 + ICI | 3-6 PATIENTS

CF33 + ICI | 3-6 PATIENTS

CF33 + ICI | 3-6 PATIENTS

CF33 + ICI | 3-6 PATIENTS

IDENTIFY

Recommended Phase 2 Dose (RP2D)

Based on:

✓ Safety
✓ Immunogenicity
✓ Tumour PD

Vaxinia + ICI in various tumour indications

Phase 2

n=approximately 100

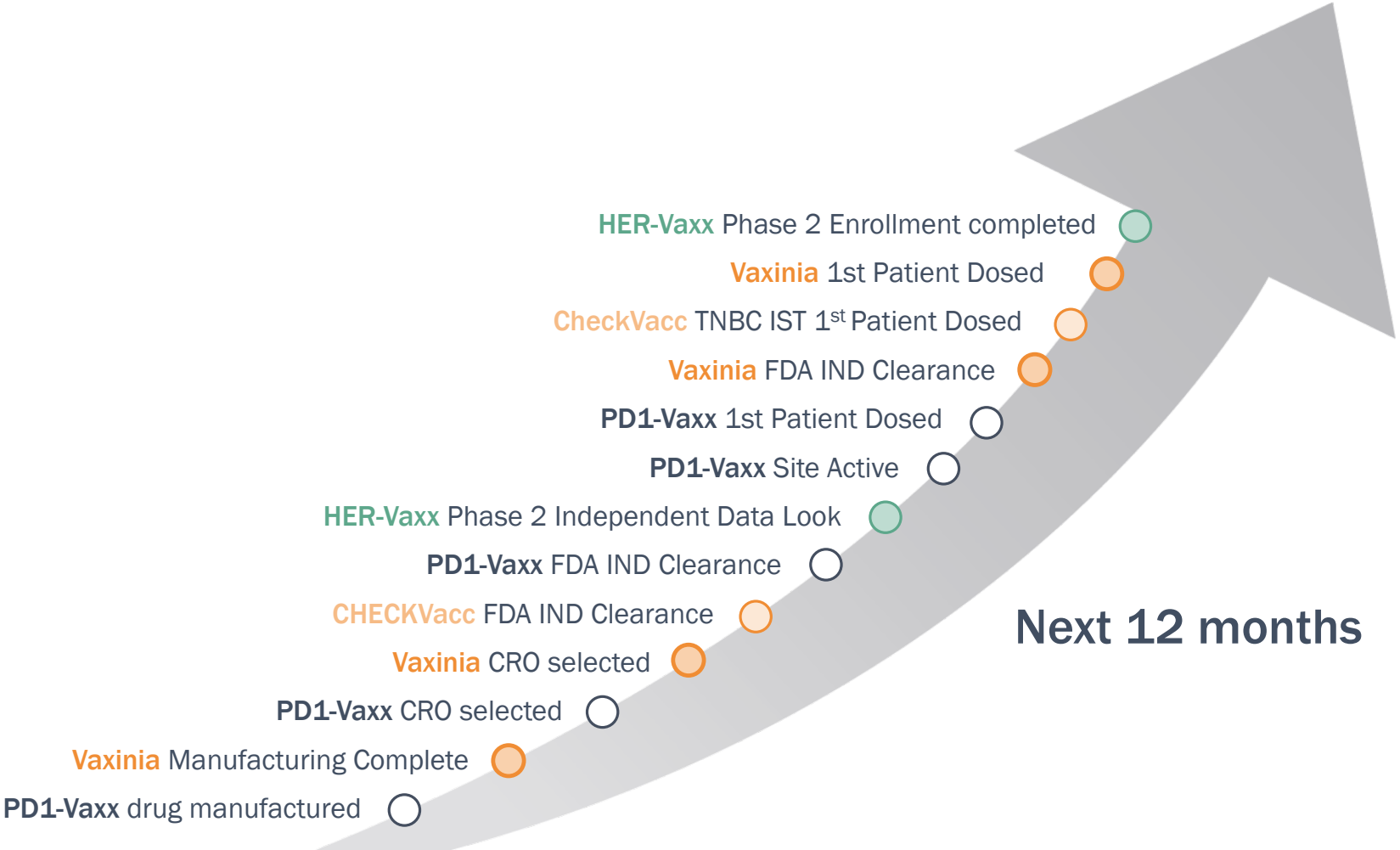
**ICI: Immune Checkpoint Inhibitor*

Vaxinia: CF33 + hNIS (Parental Virus)

Proposed Phase 1 & 2 MAST STUDY

	MAST Study Phase 1 Dose Seeking/Signal Finding		MAST Study Phase 2 Vaxinia + ICI	
	Indication	Lung, TNBC, Melanoma, Bladder, Gastric, Colorectal	**Indication**	Select tumors from Phase 1
	FDA IND Study Design	1.Vaxinia: CF33-hNIS monotherapy 2.Vaxinia + Immune Checkpoint Inhibitor (ICI) Combination	**FDA IND**	Vaxinia + Immune Checkpoint Inhibitor (ICI) Combination
	N	Monotherapy: 6 cohorts of 3-6 patients Combination: 2 cohorts of 3-6 patients **Total ~30**	**N**	Depends on the number of Indications and combination **Total ~120**
$	**Estimated per patient Cost**	$150 / 4.5m	**Estimated per patient cost**	$150 / 18m
	Location	Multi Centre	**Location**	Multi Centre
	Admin Route	IT or IV	**Admin Route**	IT or IV
	Estimated Timelines	18 months for Recommended Phase 2 Dose (Q2, 2020)	**Estimated Timelines**	24 months (start Q1, 2022)

MULTIPLE NEAR & MEDIUM TERM VALUE INFLECTION POINTS



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B-Cell Immunotherapy

B CELL BASED ANTIBODIES HAVE DISTINCT ADVANTAGES TO EXISTING TREATMENTS

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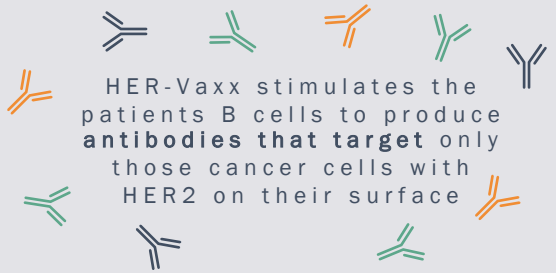
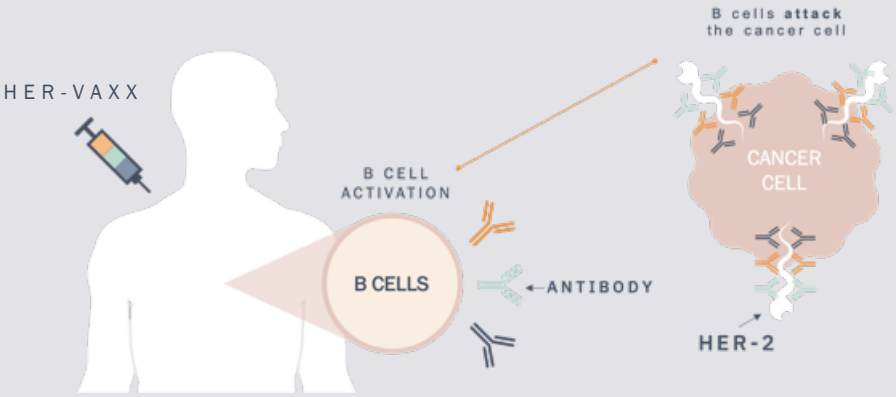
B cell Vaccines offer a unique opportunity to intervene at multiple points in the immune system and create immune memory which enhances durability of response.

	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, 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: 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

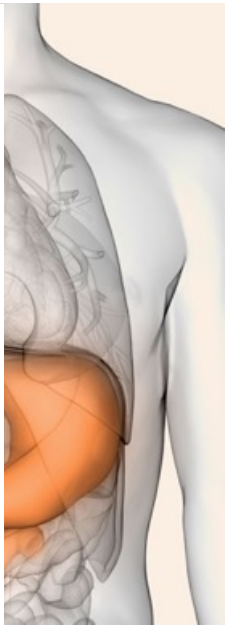
- 14 patients in 3 cohorts (10µg (3), 30µg (6) and 50µg (5))
- Dosed on D0, D14, D35
- IMU-131 in combination with chemo: cisplatin and 5FU or capecitabine

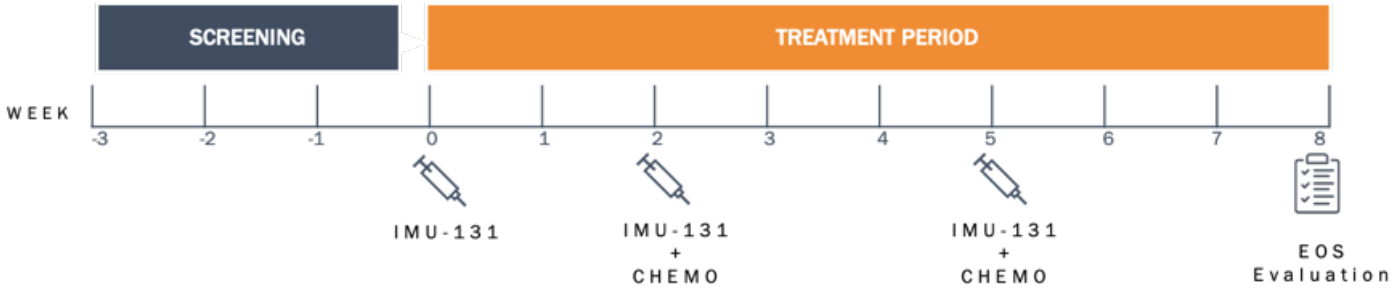
Endpoints

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

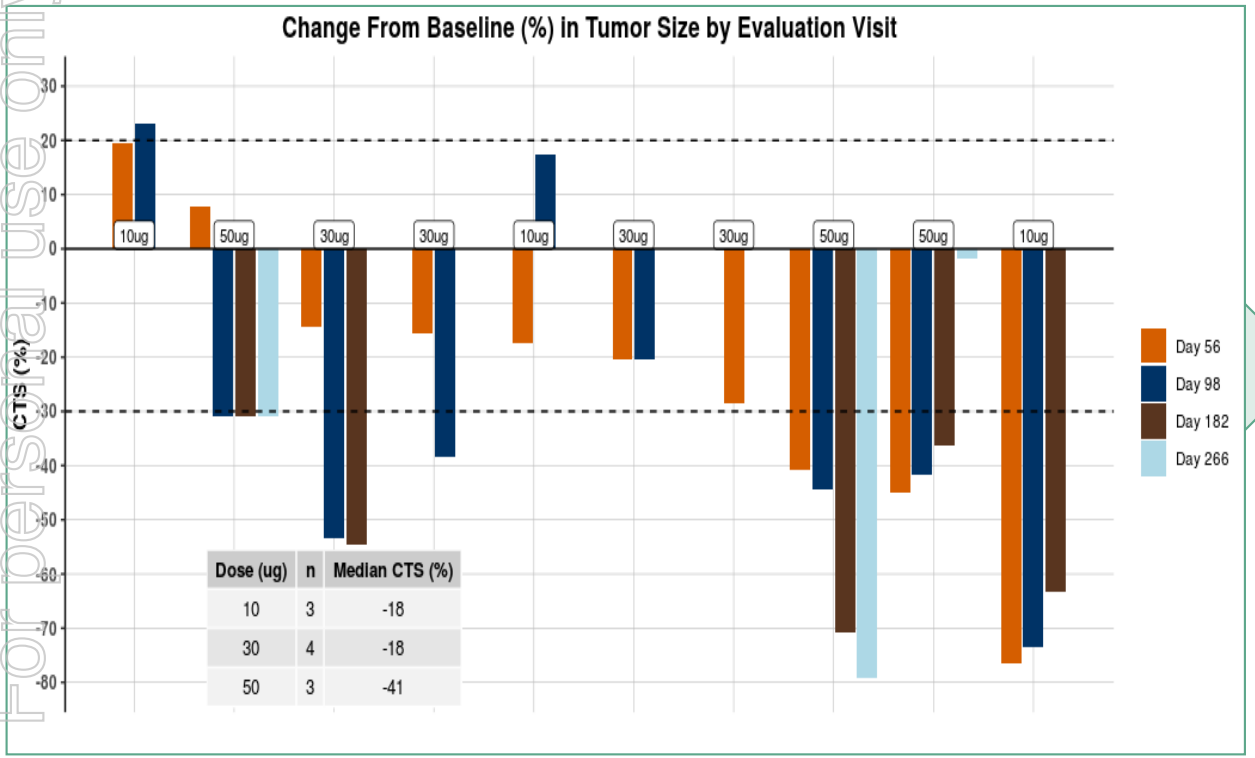
Study Results

- 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 1B: CLINICAL RESPONSE



- The preliminary immunology and clinical response data are promising.
- Safety data indicate that IMU-131 is well-tolerated with no significant local or systemic reactions.
- There were no dose-limiting toxicities observed, no significant injection site reactions and no IMU-131 related SAEs.
- Preliminary response data demonstrates 50 µg of IMU-131 was associated with tumor size reduction.
- The 50 µg dose of IMU-131 is being used in a phase 2 study.

GOING FORWARD: HER-Vaxx PHASE 2 RECRUITING

Trial

- Phase 2
- Open label
- Asia
- 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

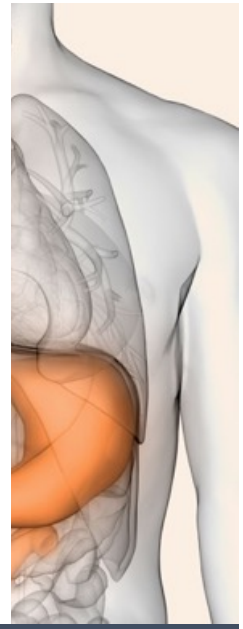
Or
Standard of care chemo: Cisplatin and 5FU or capecitabine or oxaliplatin

Primary Endpoints

- Overall survival

Secondary Endpoints

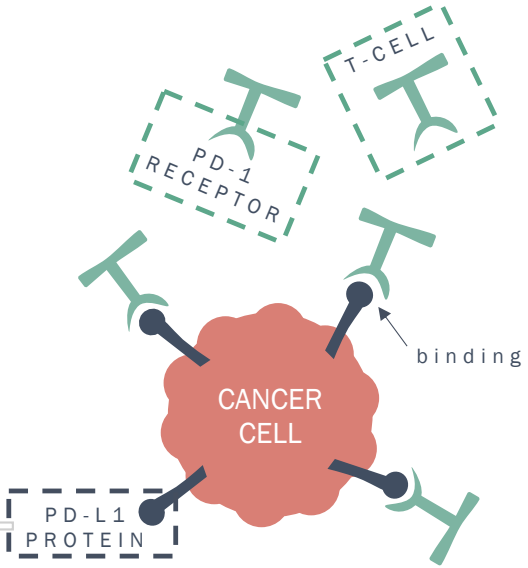
- Progression-free survival
- Safety and Tolerability
- Immune response



First patients dosed March 2019

HOW DOES PD1-Vaxx WORK?

HOW CANCER STAYS UNDETECTED BY THE IMMUNE SYSTEM



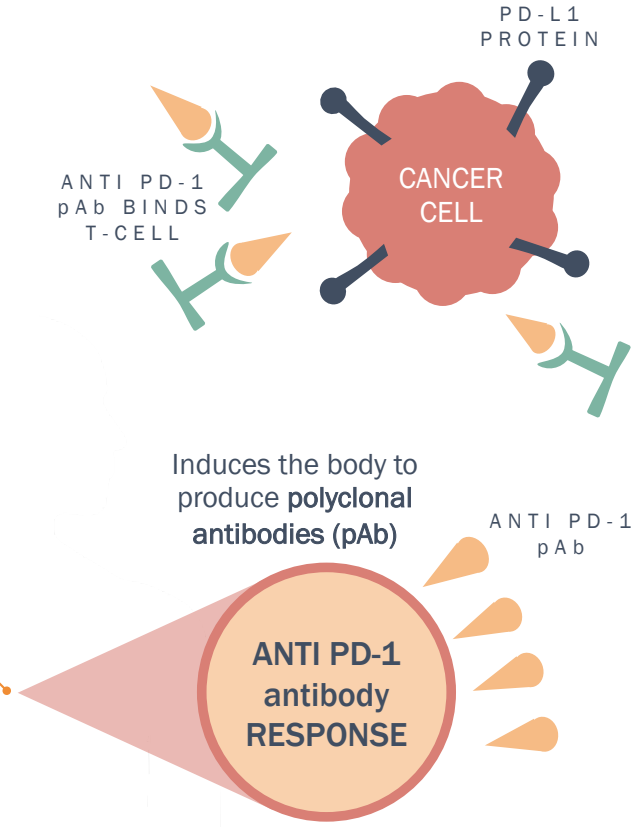
The PD-L1 protein binds to the PD-1 receptor and stops the T-Cell from recognising the cancer cell, allowing the cancer cell to survive and spread

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

Gives T-cells the ability to recognise the cancer cell and mount an immune response

PD1-VAXX IMMUNOTHERAPY

Induces the body to produce **polyclonal antibodies (pAb)**

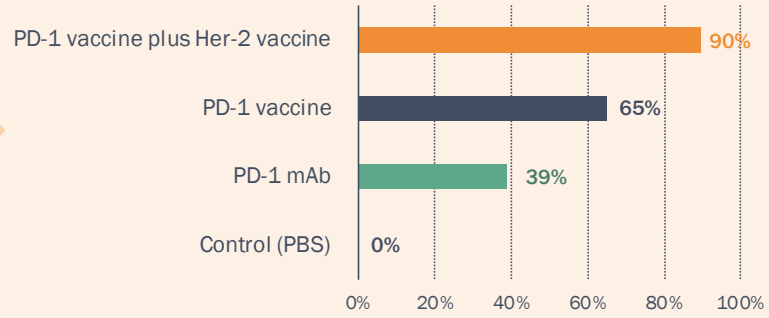


PD-1/HER-2 COMBINATION: POTENTIAL TO INCREASE RESPONSE RATES IN HER-2+ CANCERS

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



Inhibition of cancer growth 16 days after infusion of cancer cells

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