IMUGENE
Developing Cancer Immunotherapies

Proposed Acquisition of Oncolytic Chimeric Poxvirus known as CF33

City of Hope

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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)
- B cell based technology originated from the Medical University of Vienna
- Late 2013: Paul Hopper then built Imugene around this technology
- 2017: HER-Vaxx, our anti HER2 B cell cancer vaccine entered the clinic
- June 2018: Licensed extensive B cell portfolio from OSU and Mayo Clinic comprising of HER1, HER2, HER3, VEGF, IGF-1R, CD28, combinations thereof and the PD-1 cancer vaccine
- July, 2019: License a prolific oncolytic virus from City of Hope invented by

Professor Yuman Fong

International leadership team with extensive commercialisation expertise in the sector

Leslie Chong
SYDNEY, AU

Managing Director & CEO

- 20+ 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 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 BoD 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

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 of director and founder of several biotechnology and venture capital companies.
- Creator of OneStart, the world's largest life science accelerator

Dr Lesley Russell
Philadelphia, PA

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 novel early drug development

Imugene has a team with oncology drug development experience

Experienced management team which have significant clinical development expertise

Dr Mark Marino

SAN DIEGO, USA

Chief Medical Officer

- 28+ years of experience in drug development
- Former CMO of Cytori, Head of Clinical Pharmacology at Eisai and Roche, Head of R&D at Mannkind and VP Clinical Development at Daiichi

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

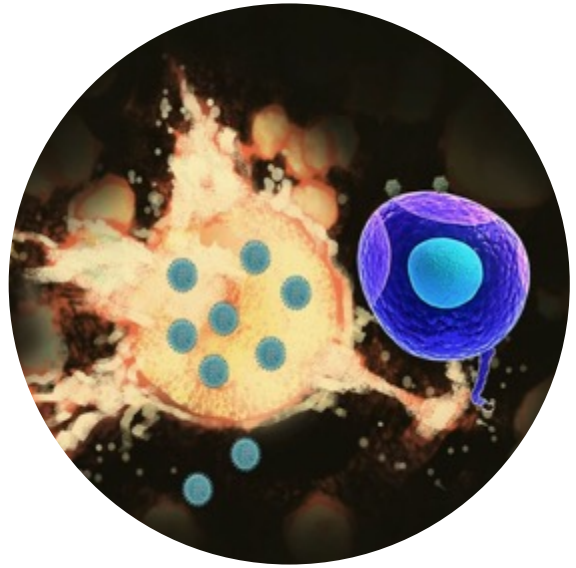
EXECUTIVE SUMMARY

Imugene is acquiring the worldwide exclusive license to a promising **oncolytic virus technology** developed at the City of Hope Cancer Centre in Los Angeles.

The virus, known as CF33, is a chimeric poxvirus, and is poised to enter Phase 1 clinical trials in 2020.

INVESTMENT HIGHLIGHTS

- Novel technology in one of the most sought-after areas of cancer immunotherapy today – oncolytic viruses a.k.a. cancer killing viruses that stimulate immune recognition of cancer
- Poised to enter Phase 1 clinical trials in 2020
- GMP Phase 1 virus material underway, additional GMP Phase 1 virus material with anti-PD-L1 completed.
- Robust intellectual property- long patent life & composition of matter to 2037
- Highly experienced oncolytic virus team to join Imugene, all ex-Viralytics
- Potential applications across many cancers, including combination with CTLA4/PD-1/PD-L1 checkpoint inhibitors or with engineered immune cells
- Outstanding scientific provenance from one of the US leading cancer centres, City of Hope in Los Angeles with Inventor, Professor Yuman Fong, is an internationally recognized oncolytic virus and cancer expert
- Attractive license terms - worldwide exclusive rights to the technology



LANDSCAPE: RECENT ONCOLYTIC VIRUS TRANSACTIONS

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.

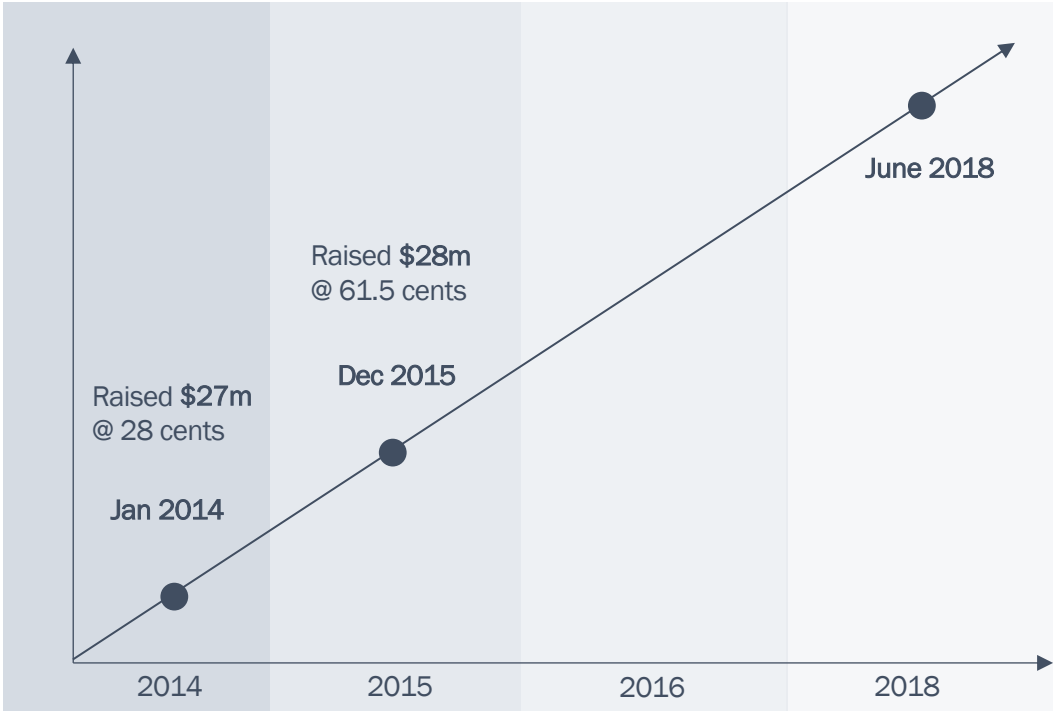
$340m	$200m	$502m
Boehringer Ingelheim	BeneVir	MERCK
ViraTherapeutics	Janssen Pharmaceutical Companies of Johnson & Johnson	Viralytics Developers of Oncolytic Immunotherapies

VIRALYTICS CASE STUDY

ACQUIRED BY MERCK FOR $502M

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

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



THE 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, 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.

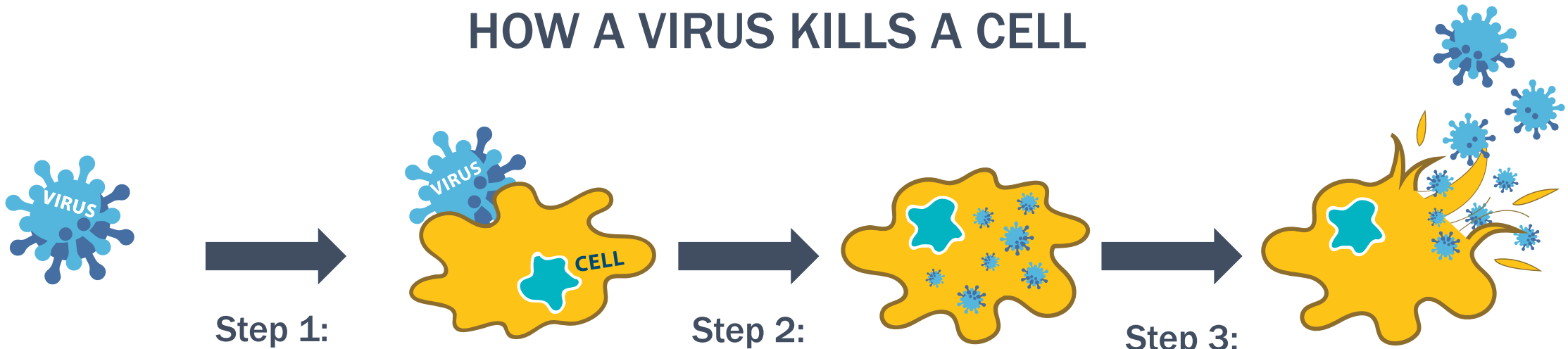
Prof. Fong is both an *author and innovator*. He has written and edited over 700 scholarly articles as well as 14 textbooks. He is currently the Editor-in-Chief of ***Molecular Therapy Oncolytics*** (Cell Press).

Prof. Fong has had leadership roles in regulatory aspects of gene therapy, including serving as Chair of 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

CF33 MECHANISM OF ACTION

HOW A VIRUS KILLS A CELL



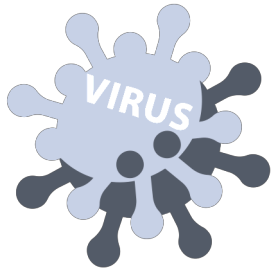
Step 1:
Virus enters cell

Step 2:
Virus duplicates itself

Step 3:
Cell explodes, releasing thousands of brand new virus particles

- **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)]
- **Human sodium** iodine symporter (hNIS) expression allows additional use of ^{131}Iodine or ^{188}Rhenium killing of infected cells and adjacent cells

MAJOR ADVANTAGES OF CF33



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

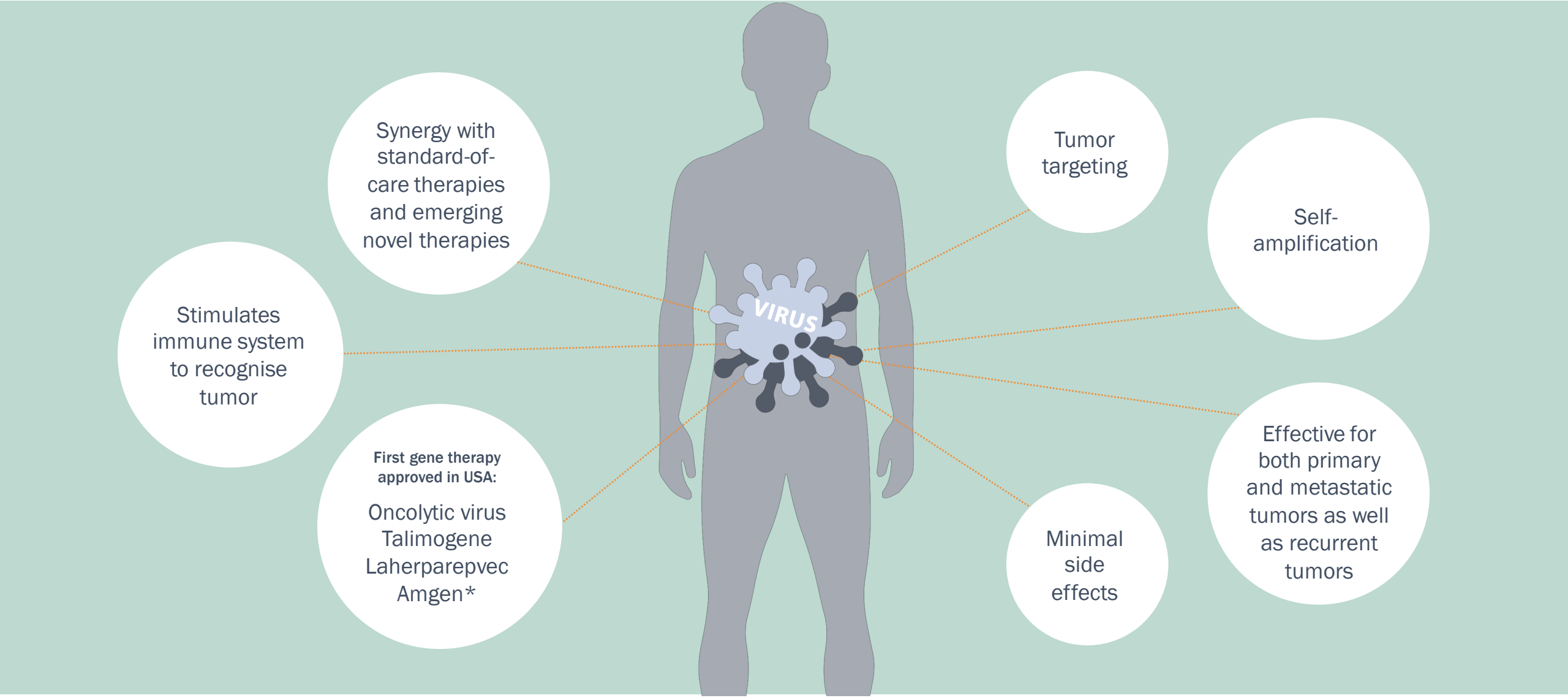
Especially impressing is that CF33 can **shrink multiple types** of cancer at an extremely low dose (1000 PFU).

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

ADVANTAGES OF ONCOLYTIC VIRUSES

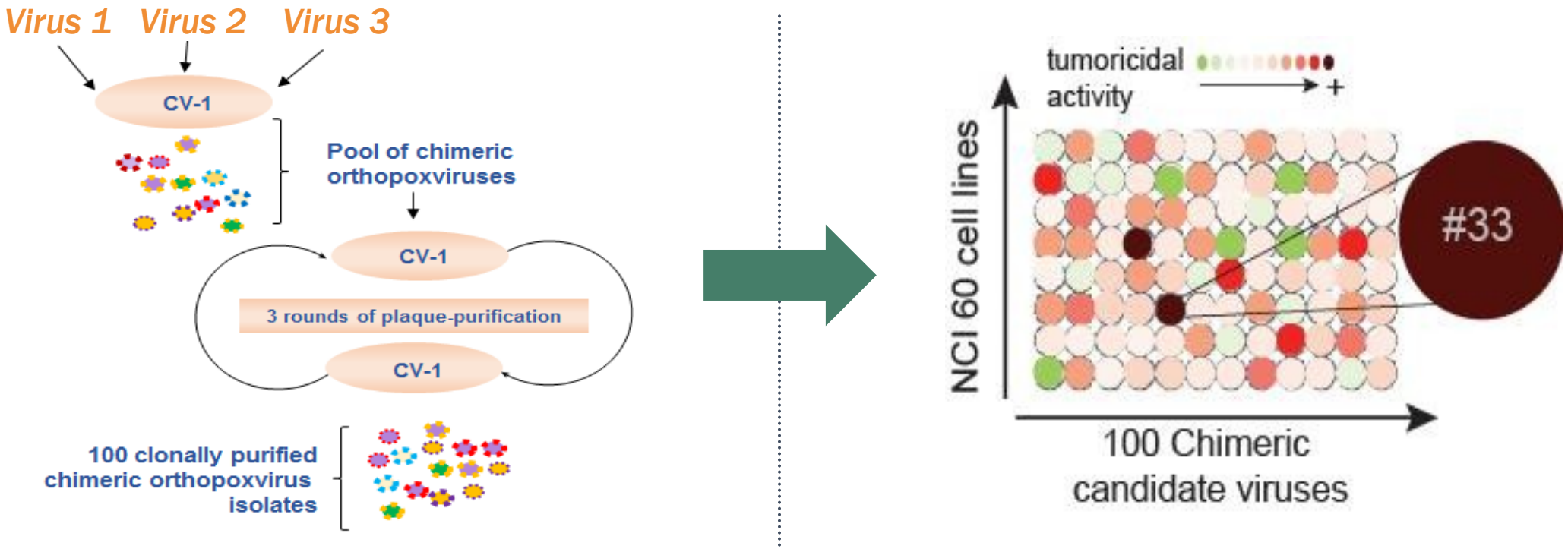


*Approved by FDA on Oct. 27, 2015 (acquired for $1.0 billion in 2011)

WHY A VACCINIA VIRUS?

1. Belongs to the genus Orthopoxvirus in the family Poxviridae
2. A large virus that contains a double stranded DNA genome & genetically very stable
3. Famous for use as a vaccine to eradicate the human deadly disease, smallpox.
4. The first oncolytic virus demonstrating viral oncolysis in the laboratory in 1922.
5. Short, well characterized life cycle and spreads very rapidly from cell to cell.
6. Highly cytolytic for a broad range of tumor cell types.
7. Has a large insertion capacity (> 25 kb) for the expression of exogenous genes.
8. Amenable to large scale production of high levels of infectious virus.
9. Does not integrate into the host genome.
10. May be administered via intratumoral and intravenous routes.

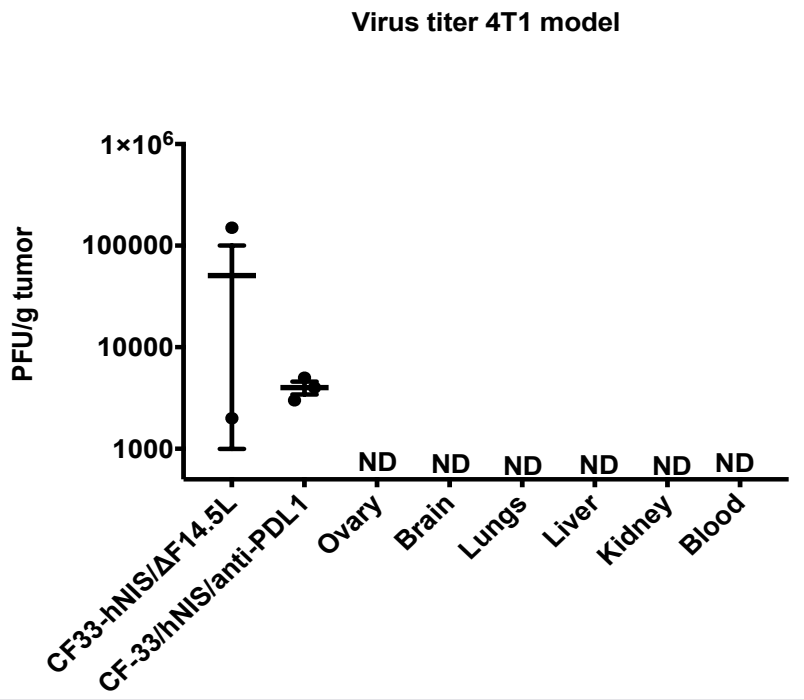
HOW WAS CF33 DERIVED?



1. 100 chimeric orthpoxviruses and 100 chimeric parapoxviruses were generated
2. Several orthopoxvirus and parapoxvirus chimeras showed superior cancer cell killing in the NCI-60 cell lines
3. CF33 is the chimeric orthopoxvirus chosen for further evaluation *in vivo* and clinical development

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.).



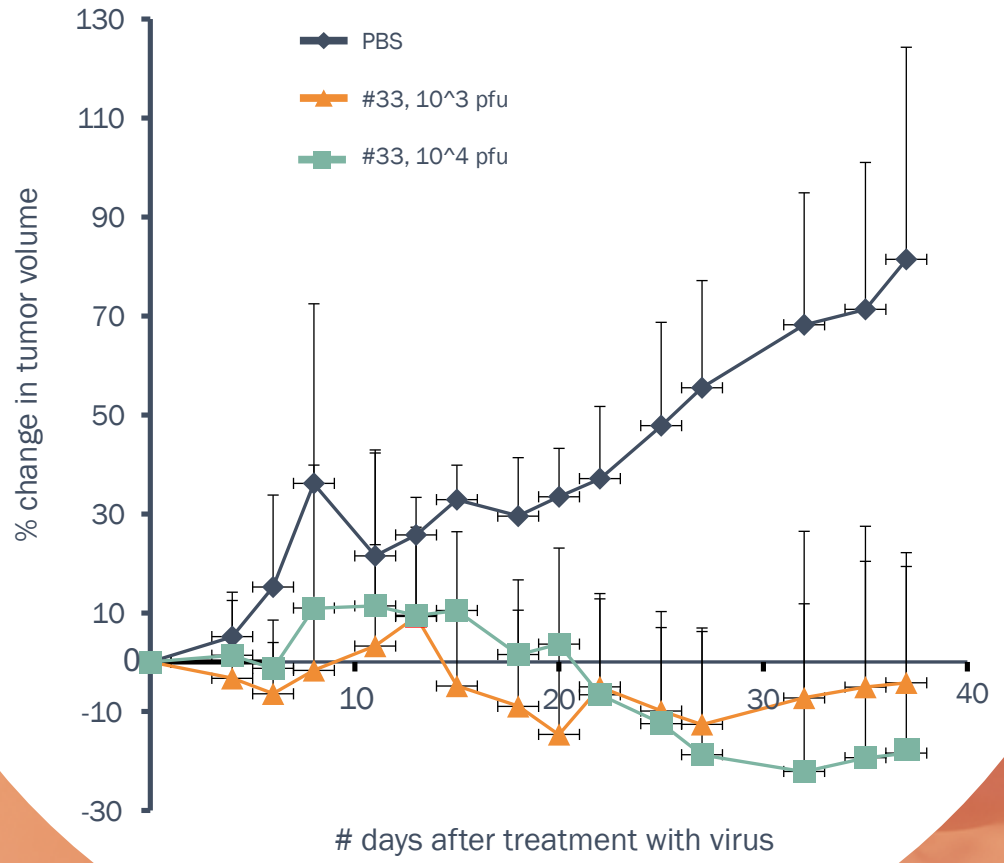
- A number of studies have been completed with CF33 as well as some of the derivatives. It has proven very safe in nude mice and in immunocompetent mice.
- In data published in Journal Translational Research, no viral shedding in blood and urine was found. No signs of illness were found and animals ate well and gained weight.
- In total, more than 500 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 SHRINKS TRIPLE-NEGATIVE BREAST CANCER

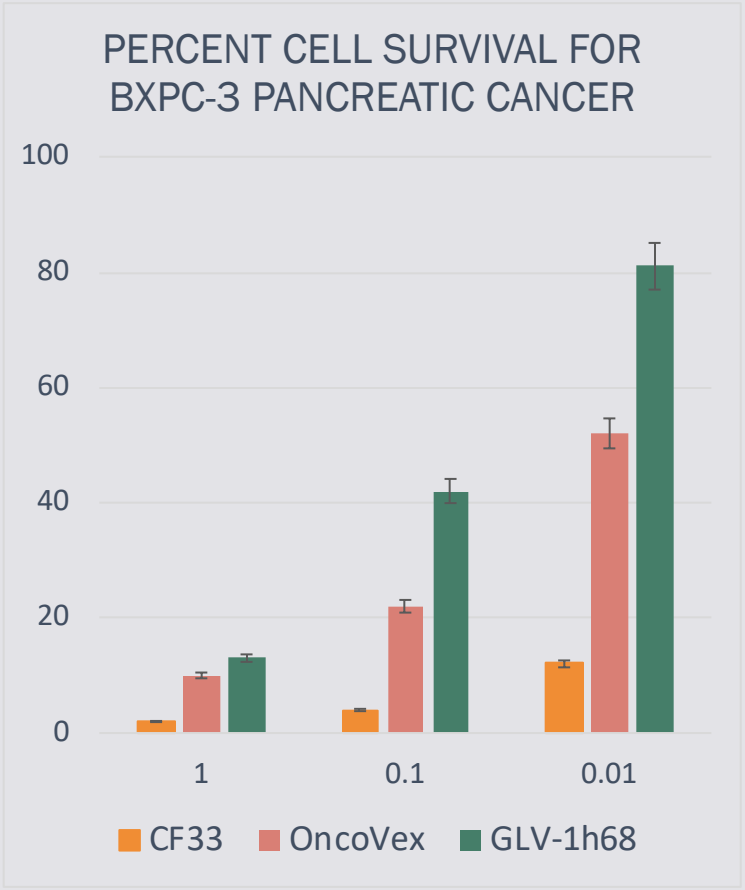
Mice treated with both intratumoral virus and IV

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

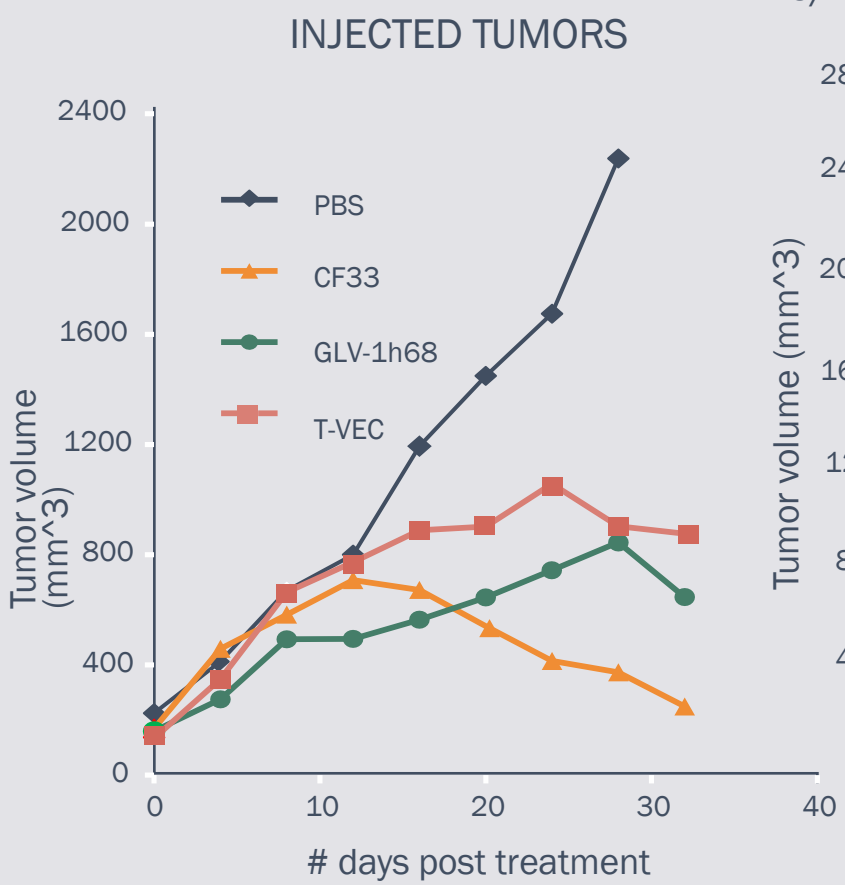
Mol Ther Oncolytics. 2018 Jun 29;9

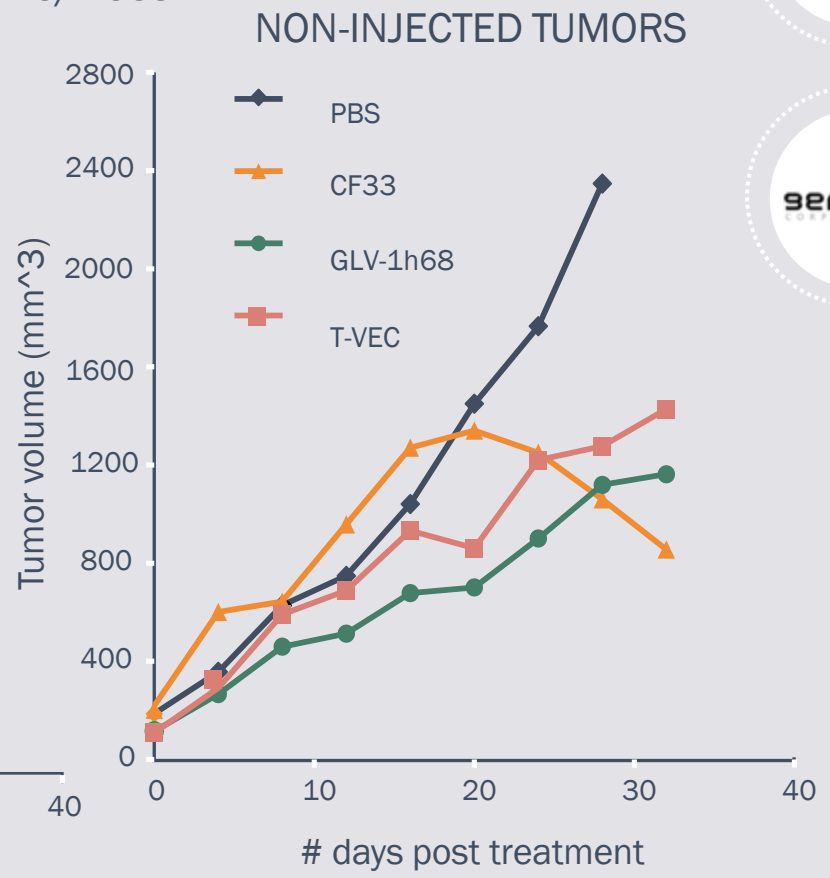


CF33 OUTPERFORMS AMGEN & GENELUX VIRUSES



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

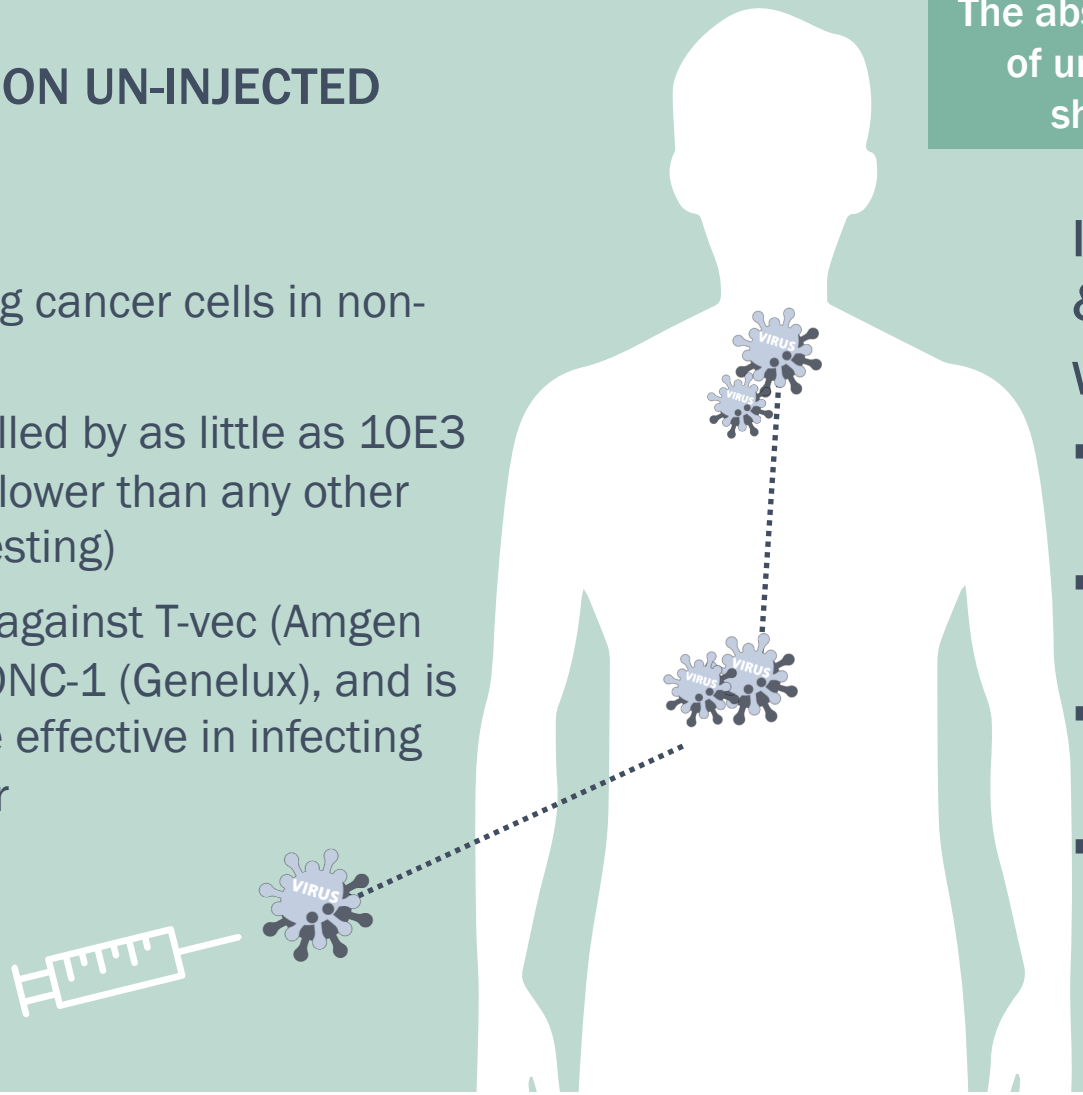




CF33 ABSCOPAL EFFECTS

IMPACT OF CF33 ON UN-INJECTED TUMORS

- Effective for killing cancer cells in non-injected tumors
- Tumors can be killed by as little as 10E3 viruses (2-3 logs lower than any other virus in human testing)
- Virus was tested against T-vec (Amgen product) and GLONC-1 (Genelux), and is many times more effective in infecting and killing cancer



The abscopal effect describes a situation whereby shrinkage of untreated or distant tumors occurs concurrently with shrinkage of tumors directly treated with the drug.

Inhibition of un-injected tumors by both CF33 & immune effects

We have data showing:

- Spread of virus to and killing non-injected tumors
- Regression of tumor that did not have viral spread
- Increased infiltration of tumors by CD8+ cells and other immune cells
- Infiltration of CD8 T cells are enhanced in both injected and uninjected tumors in virus-treated mice compared to PBS-treated mice.

PHASE 1 GMP-MANUFACTURING AT CITY OF HOPE

Center for biomedicine and genetics (CBG)

The Center for Biomedicine & Genetics (CBG) is a California-licensed, 20,000 square foot, multi-product biologics manufacturing facility within City of Hope. With twelve ISO 7 production rooms in three product type “zones”, a dedicated aseptic fill suite and a staff with extensive biopharmaceutical experience, the CBG is capable of producing virtually any type of biologic at scales suitable for Phase I through Phase II clinical trials.

- ✓ GMP Phase 1 virus material underway
- ✓ Additional GMP Phase 1 virus material with anti-PD-L1 completed.
- ✓ If third party to manufacture cost would be approx. $3.0m

CF33 PROPOSED PHASE 1/2 CLINICAL DEVELOPMENT PLAN

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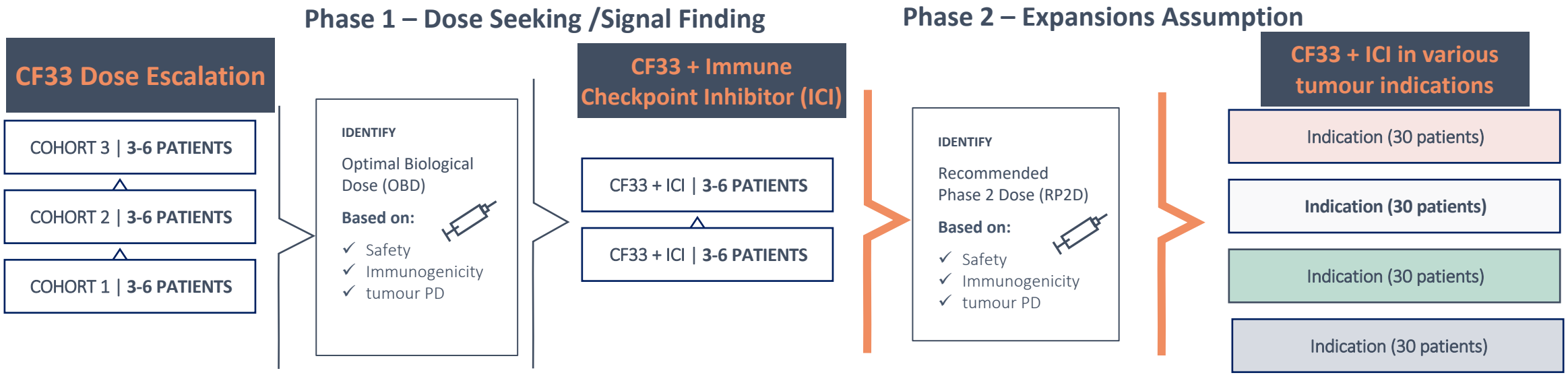
	MAST Study Phase 1 "Mixed Advanced Solid Tumors"		MAST Study Phase 1/2 "Mixed Advanced Solid Tumors"	
	**Indication**	Lung, TNBC, melanoma, bladder, GI	**Indication**	Select tumors from Phase 1 cohorts
	FDA IND	15 – Single Agent CF33 15 – Combo with ICI to be selected	**FDA IND**	Combination with ICI (Keytruda? Or Atezolizumab)
	**N=30**	6+6+6+6+6	**N=100-120**	4 cohorts of 30 patients each
	Location	Multi Centre, COH + 3 other sites	**Location**	Multi Centre, COH + 3 other sites
	**Admin Route**	IT or IV	**Admin Route**	IT or IV
	PI	TBD	**PI**	TBD
	**Study Cost/patient**	$150K	**Study Cost/patient**	$150K
	Drug Supply	COH	**Drug Supply**	COH
	**Recruitment time**	18 Months	**Recruitment time**	18 Months

CF33 MAST (MIXED ADVANCED SOLID TUMOURS) STUDY

CF33 Proposed Phase 1 / 2 Clinical Development Plan



INTELLECTUAL PROPERTY

FOUNDATION PATENT (2037)

PCT	**US2017/046163**
Title	Chimeric poxvirus compositions & use thereof
Inventor	Yuman Fong
Assignee	City of Hope
Primary Date	9 August 2016
International Publication	18 February 2018

PCT application filing date was 8/9/2017, and estimated expiration date is in late 2037. The patent application includes both composition of matter and method of use. It is currently pending with the opportunity to secure worldwide rights. International search report was favorable.

(43) International Publication Date
15 February 2018 (15.02.2018)

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WO 2018/031694 Al

(51) International Patent Classification:
C12N 7/01 (2006.01) *C07K 16/28* (2006.01)
C12N 15/863 (2006.01) *A61K 31/7088* (2006.01)
C07K 14/47 (2006.01) *A61K 35/76* (2015.01)

(21) International Application Number:
PCT/US20 17/046 163

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(30) Priority Data:
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62/5 19,010 13 June 2017 (13.06.2017) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available):* AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV

CORE SCIENCE PUBLISHED IN LEADING PEER PUBLICATIONS

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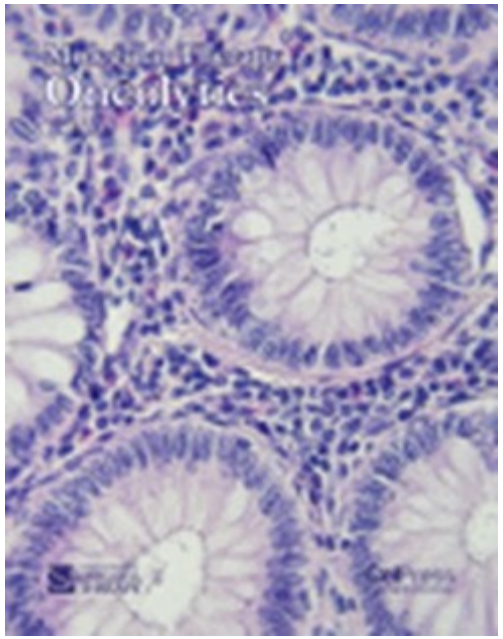
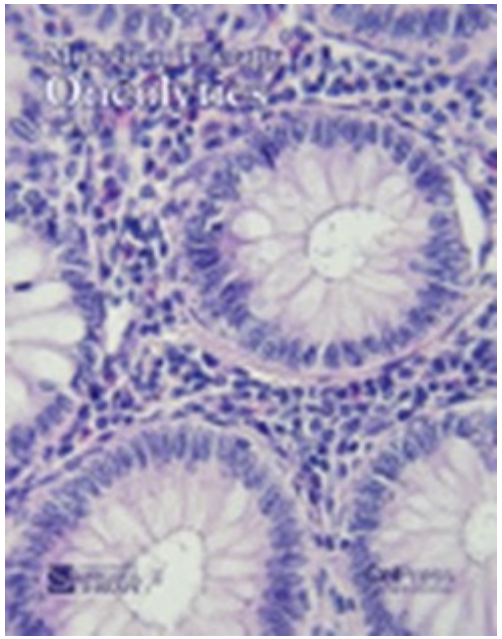
2018



Mol Ther Oncolytics. 2018 Jun 29;9

A Novel Oncolytic Chimeric Orthopoxvirus Encoding Luciferase Enables Real-Time View of Colorectal Cancer Cell Infection

2018



Mol Ther Oncolytics. 2018 Jun 29;9

Endogenous AKT Activity Promotes Virus Entry and Predicts Efficacy of Novel Chimeric Orthopoxvirus in Triple-Negative Breast Cancer

2018

J Transl Med. 2018 Apr 26;16:110

Novel Oncolytic Chimeric Orthopoxvirus Causes Regression of Pancreatic Cancer Xenografts and Exhibits Abscopal Effect at a Single Low Dose

2018

Surgery. 2018 Feb;163(2)

Novel Chimeric Parapoxvirus CF189 as an Oncolytic Immunotherapy in Triple-Negative Breast Cancer

M&A FRENZY FOR ONCOLYTIC VIRUSES

M&A FRENZY FOR ONCOLYTIC VIRUSES... CONTINUED

SELECTED ONCOLYTIC VIRUS DEALS

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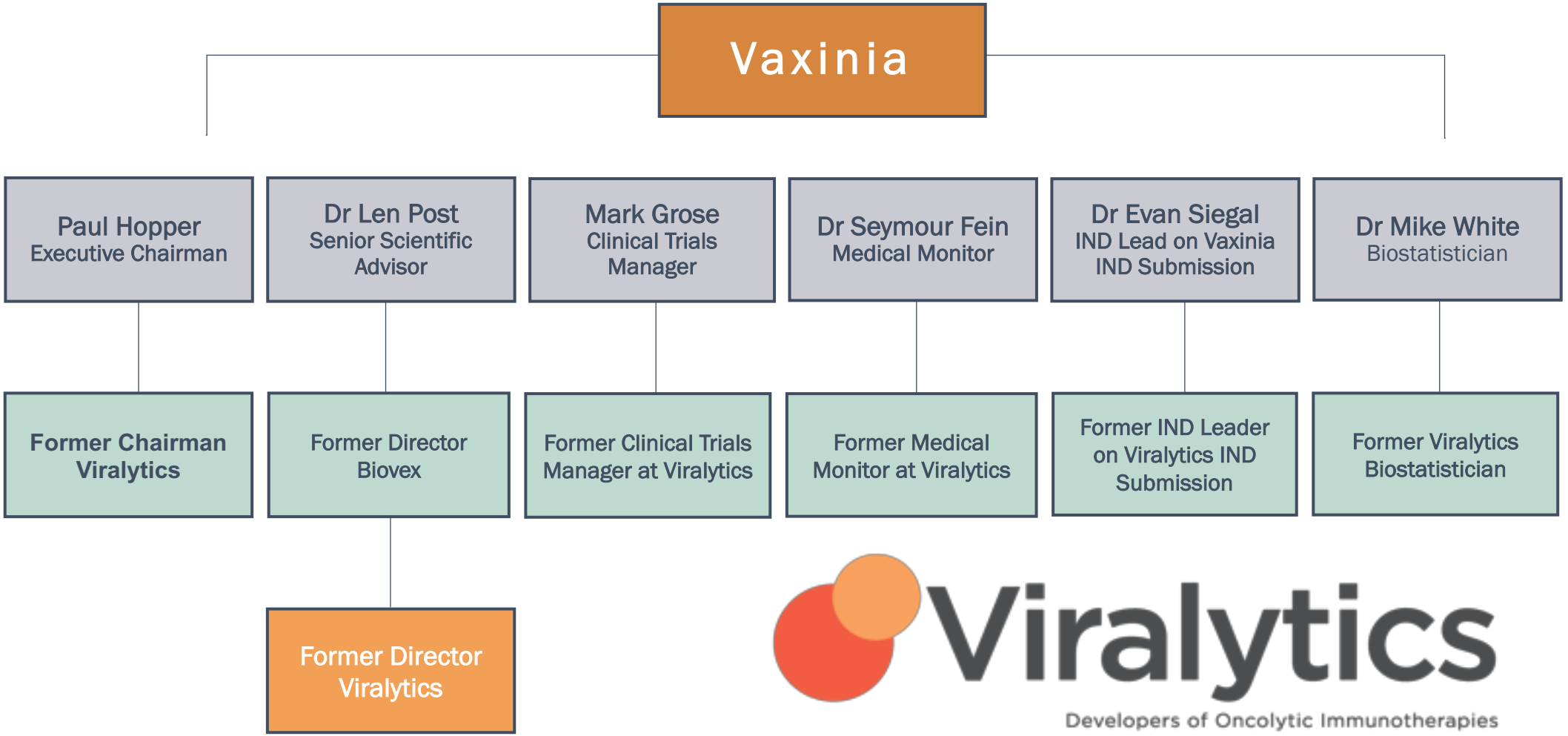
Date	Source	Buyer	Deal type	Up-front (US$m)	Note
May 2019	Transgene	Astrazeneca	Licensing	10	Five research candidates
Sep 2018	Viratherapeutics	Boehringer Ingelheim	Acquisition	245	VSV-GP project, preclinical
Feb 2018	**Viralytics**	**Merck & Co**	**Acquisition**	**394**	**Cavatak, phase II asset**
Nov 2017	Oncolytics	Adlai Norte	Licensing	5	Far East development of Reolysin
Oct 2017	Turnstone Biologics	Abbvie	Licensing	Undisclosed	Ad-MG1-MAGEA3, phase I/II asset
Dec 2016	Ignite Immunotherapy	Pfizer	Acquisition	Undisclosed	50% stake
Dec 2016	Psioxus	Bristol-Myers Squib	Licensing	Undisclosed	NG-348, preclinical asset
Dec 2016	Takara Bio	Otsuka	Licensing	Undisclosed	Japan rights to HF10
Nov 2016	Virttu Biologics	Sorrento	Acquisition	25 (equity)	Seprehvir, phase II asset
Jun 2016	Psioxus	Bristol-Myers Squib	Licensing	10	Enadenotucirev, phase I collaboration
Jun 2015	Oncos	Targovax	Acquisition	Undisclosed	Structured as a 50/50 merger
Jan 2015	Omnis	Astrazeneca	Licensing	Undisclosed	VSV project, phase II
Nov 2013	Jennerex	Sillajen	Acquisition	Undisclosed	$150m biodollar value
Jan 2011	Biovex	Amgen	Acquisition	424	Imlygic, approved for melanoma in 2015

Source: https://www.evaluate.com/vantage/articles/news/snippets/astrazeneca-doubles-down-oncolytic-viruses *Company statements.*

THE VAXINIA TEAM: PLUG & PLAY

DEEP ONCOLYTIC VIRUS EXPERIENCE



ONCOLYTIC VIRUS SCIENTIFIC ADVISORS

Professor Ulrich Lauer

Head of Virotherapy Research bei University of Tuebingen Germany. Prof. Lauer is also Head of the German Oncolysis Consortium (GOC). From 2012-2014 Prof. Lauer carried out the first German clinical virotherapy trial employing a recombinant oncolytic virus.

Prasad S. Adusumilli

Deputy Chief, Thoracic Service; Co-Director, Mesothelioma Program; Head, Solid Tumors Cell Therapy, Cellular Therapeutics Center. Memorial Sloan Kettering Cancer Centre. These therapies include immunotherapy (enhancing patients' own immune systems using genetic and cell engineering) and oncolytic viral therapy (killing cancer cells using genetically engineered viruses).

Dr. Rebecca Auer

Associate Scientist Cancer Therapeutics Program, The Ottawa Hospital Research Institute and Cross-Appointed Member, Associate Professor Department of Surgery and Department Biochemistry, Microbiology and Immunology University of Ottawa. Director of Cancer Research Ottawa Hospital.

Professor James Market

James Garber Galbraith Endowed Chair of Neurosurgery, University of Alabama at Birmingham. His major interest remains the use of herpes simplex virus and other viruses as oncolytic and gene therapy vectors for the treatment of malignant brain tumors and other cancers

MULTIPLE VALUE REALISATION PATHWAYS

SALE OF COMPANY

OR

PARTNER WITH BIG PHARMA

OR

LICENSE A TARGET DISEASE

OR

DEVELOP INDEPENDENTLY

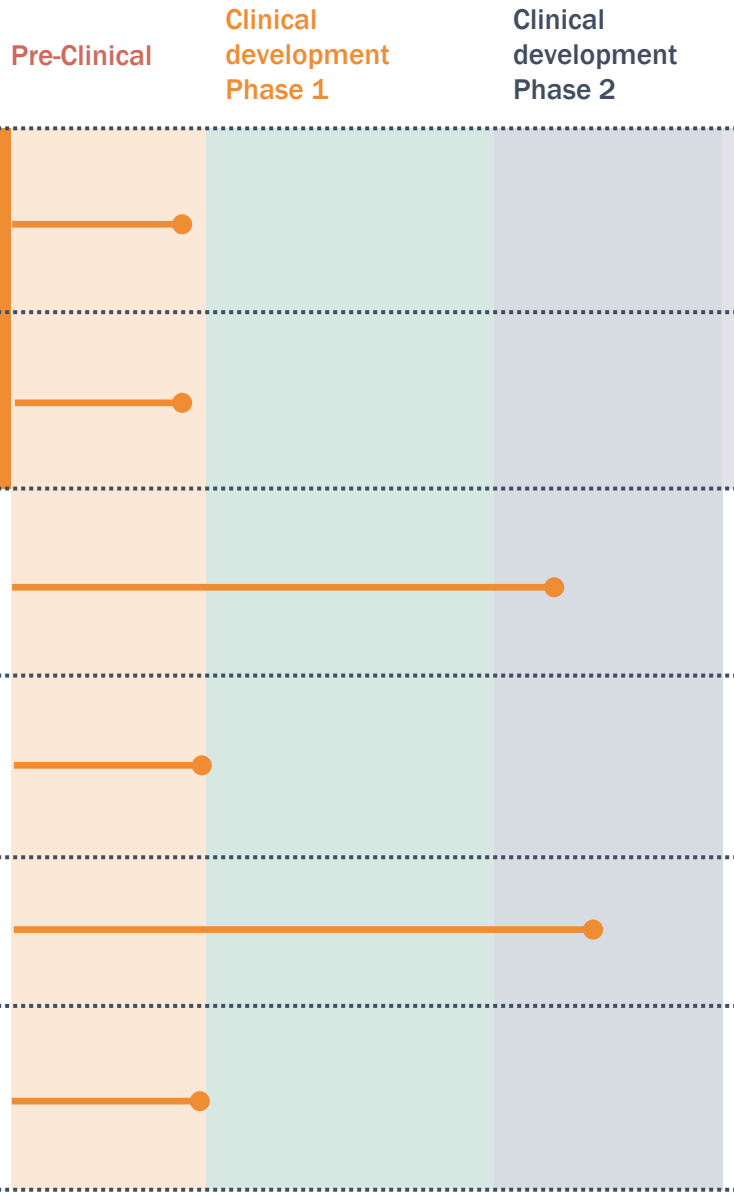
WHY CF33?

- **Novel technology** in one of the most sought-after areas of cancer immunotherapy today – oncolytic viruses a.k.a. cancer killing viruses
- **Compelling** pre-clinical data & safety
- **GMP** manufacturing has commenced
- **Poised** to enter Phase 1 clinical trials in 2020
- **Potential** applications across many cancers, including combination with immune checkpoint inhibitors
- **Outstanding** scientific provenance from one of the US leading cancer centres, City of Hope in Los Angeles with Inventor, Professor Yuman Fong, is an internationally recognized oncolytic virus and oncology expert
- **Robust** intellectual property – long patent life & composition of matter to 2037
- **Vaxinia** brings one of the most experienced oncolytic virus teams globally (associated with the sale of two oncolytic virus companies for USD$1.0 billion+)

ESTIMATED TIMETABLE

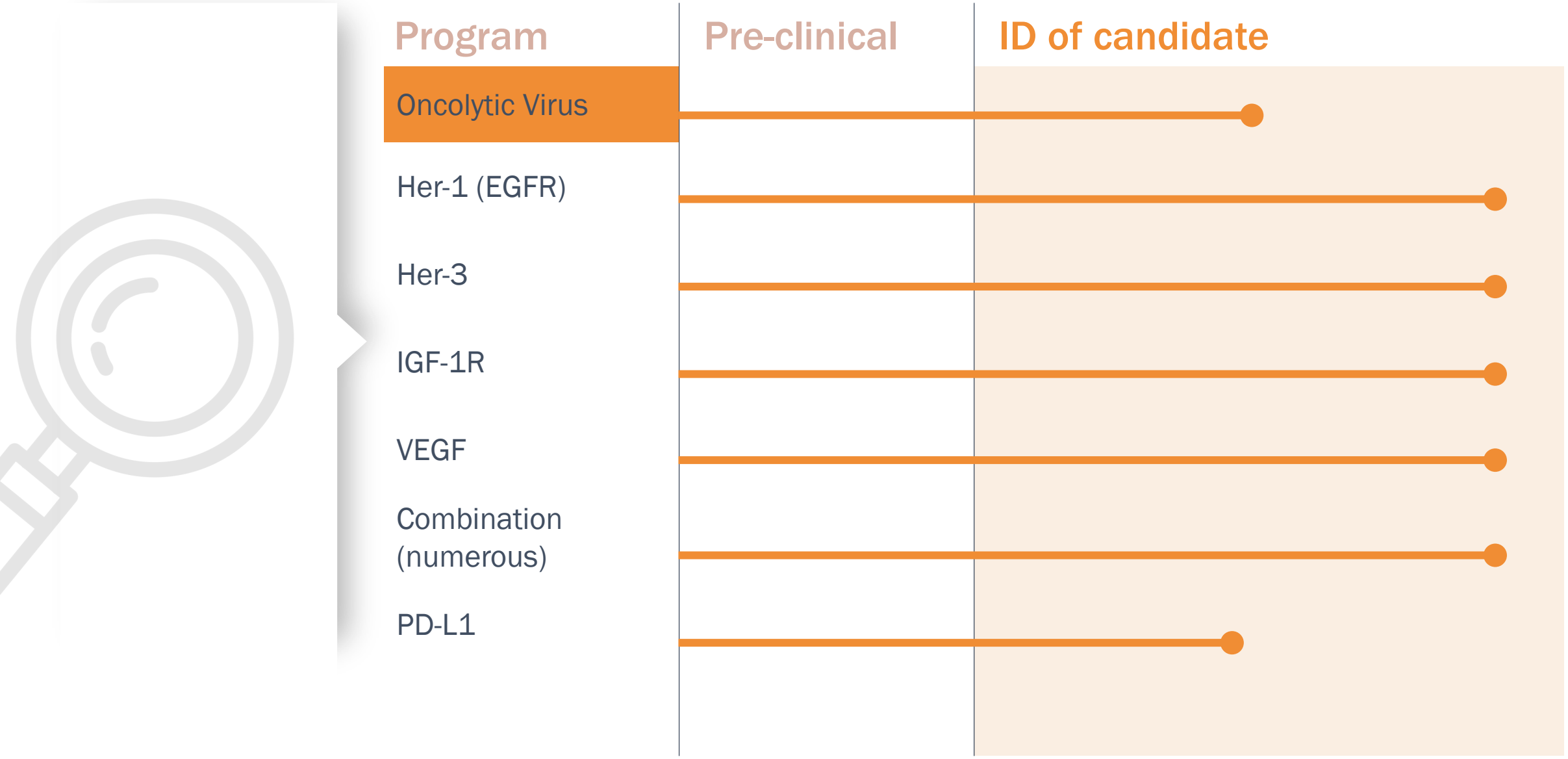
- **15th July:** Announce transaction to ASX
- **7th of August:** Dispatch Notice of Meeting to Shareholders
- **9th September:** Extraordinary General Meeting of Imugene shareholders

IMUGENE HAS A DEVELOPING PIPELINE



	Key Data / Results	Key IP patents
CF33 (Oncolytic Virus)	• 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	Intellectual property patents expiring 2037
CF33 & aPD-L1	• 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	Intellectual property patents expiring 2037
HER-Vaxx (HER-2)	• Successful completion of Phase 1b trials • Strong trial results with no safety or toxicity issues • All patients had increased antibody response • 11/14 evaluable patients with encouraging clinical responses	Intellectual property patents expiring April 2027, August 2030 & April 2036
PD1-Vaxx	• 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	Intellectual property patents expiring March 2037 & February 2038
B-Vaxx (HER-2)	• Positive Phase 1 results and now currently in phase 2 • B-Vaxx is fully funded by OSU grant • 14/24 evaluable late stage patients with encouraging clinical response	Intellectual property patents expiring April 2027 & August 2030
HER-2 & PD-1 Vaccine Combination	• Pre-clinical studies showed 90% cancer growth inhibition in colorectal cancer model with the combination • Potentially solves the industry problem of additive toxicity of combined checkpoint inhibitors if safety of vaccines maintained in combination	

IMUGENE DISCOVERY PIPELINE



IMUGENE
Developing Cancer Immunotherapies

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