

Investor presentation at Bioshares Biotech Summit 2019

SYDNEY, Australia, 26 July 2019: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced its Chief Technology Officer Dr Nick Ede will present a company update at the 15th Bioshares Biotech Summit held in Queenstown New Zealand.

The annual Bioshares Summit attracts biotech CEOs, pharmaceutical licensing executives, fund managers, and retail investors from around the world.

Bioshares published this week a report on Imugene and specifically its license of oncolytic virotherapy CF33 from the City of Hope Cancer Centre in Los Angeles. The report can be accessed at <https://www.imugene.com/analyst-coverage>

The full presentation is available on the Imugene website.

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About Imugene (ASX:IMU)

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumors. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our product pipeline includes multiple

immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies. We are supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets.

Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

AN EMERGING LEADER IN CANCER IMMUNO-ONCOLOGY

Bioshares Presentation

Dr Nick Ede, CTO

July 2019

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- Imugene is a biotech company headquartered in Australia and publicly traded on the Australian Securities Exchange (ASX:IMU)
- B cell vaccine based technology originated from the Medical University of Vienna
- 2017: HER-Vaxx, our anti HER2 B cell cancer vaccine entered the clinic
- 2018-19: HER-Vaxx Phase 1b complete with Phase 2 recruiting
- June 2018: Licensed extensive B cell vaccine 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 new oncolytic virus from City of Hope invented by



Professor Yuman Fong



IMUGENE HAS A DEVELOPING PIPELINE

	Pre-Clinical	Clinical development Phase 1	Clinical development Phase 2	Key Data / Results	Key IP patents
CF33 (Oncolytic Virus)				<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 	Intellectual property patents expiring 2037
CF33 & aPD-L1				<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 	Intellectual property patents expiring 2037
HER-Vaxx (HER-2)				<ul style="list-style-type: none"> 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				<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 	Intellectual property patents expiring March 2037 & February 2038
B-Vaxx (HER-2)				<ul style="list-style-type: none"> 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				<ul style="list-style-type: none"> 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 	

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

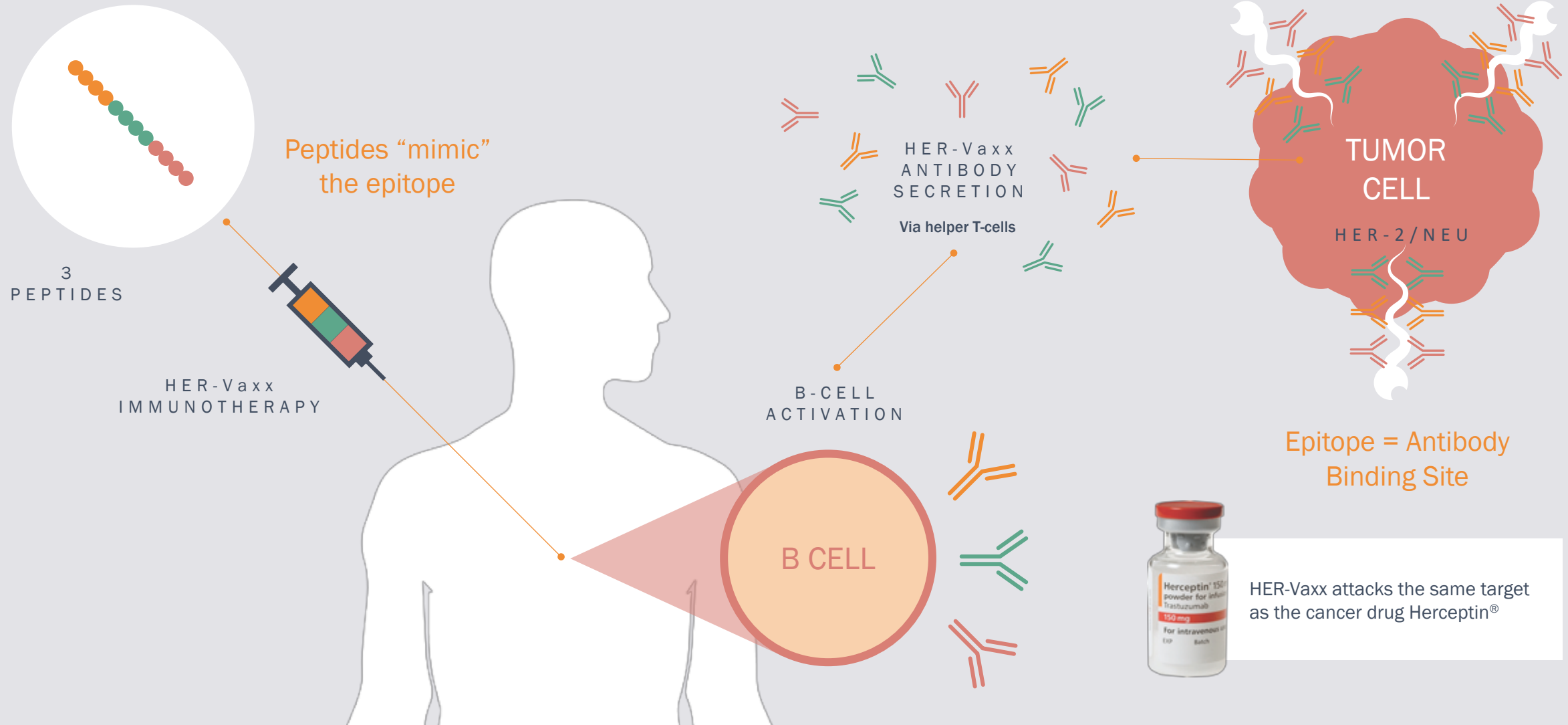
- 25+ years of senior international operational and leadership experience having worked at Amgen, Eli Lilly, Teva, and Cephalon
- Extensive knowledge and experience with novel early drug development

Imugene has a team with oncology drug development experience

IMU.ACS.001

**PHASE 1B STUDY
OF IMU-131,
A HER2 TARGETING
B-CELL VACCINE**

HER-Vaxx (IMU-131) IS A THERAPEUTIC B-CELL PEPTIDE VACCINE COMPOSED OF 3 EPITOPES FROM THE EXTRACELLULAR DOMAIN OF HER2/NEU CONJUGATED TO CRM197



IMU.ACS.001 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)



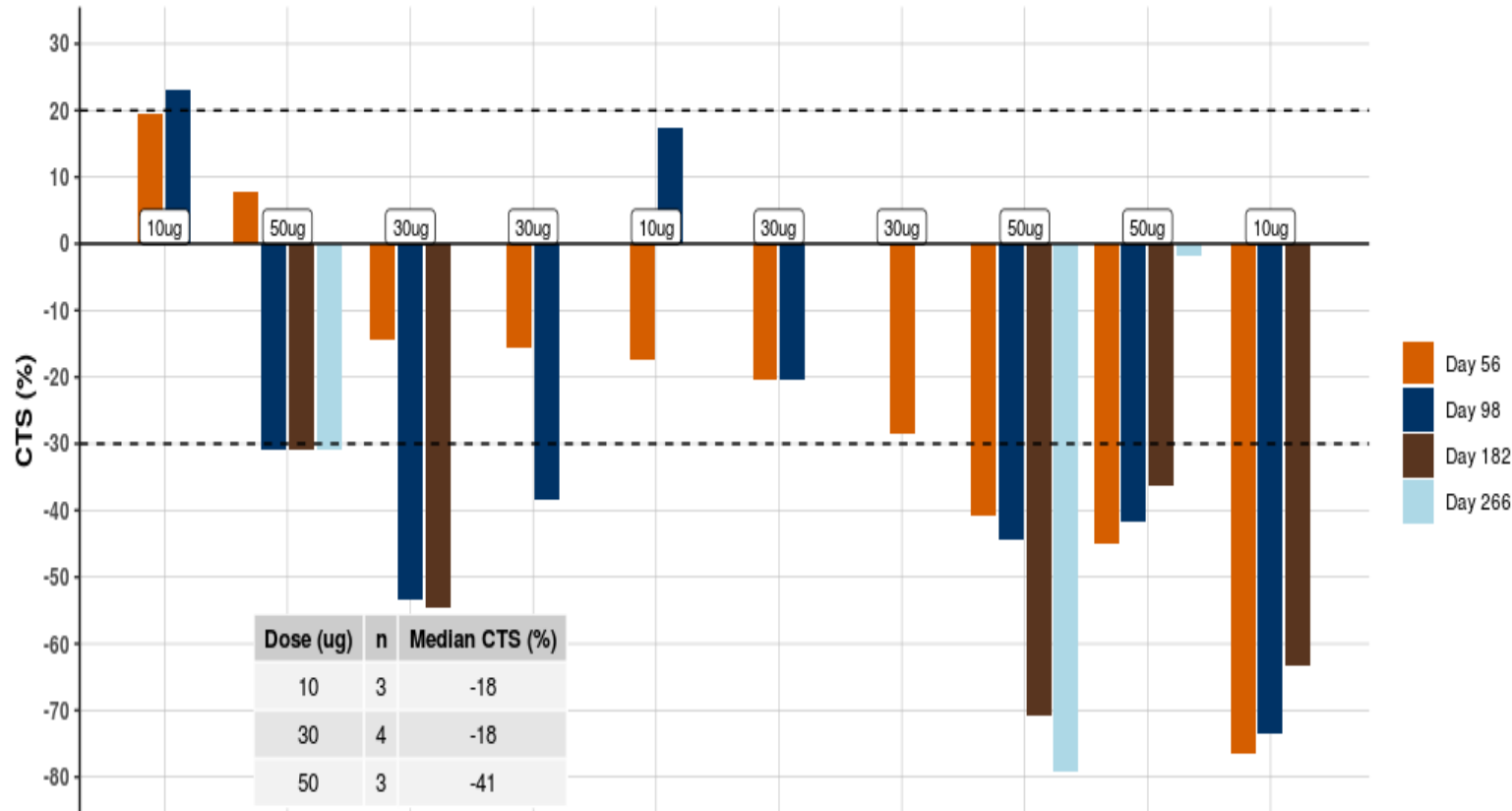
Study Results

- 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 Ph2 dose



IMU.ASC.001 PHASE 1B: CLINICAL RESPONSE & CONCLUSIONS

Change From Baseline (%) in Tumor Size by Evaluation Visit



- 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 μ g of IMU-131 was associated with tumor size reduction.
- The 50 μ g dose of IMU-131 is being used in a phase 2 study.

Phase 2 commenced - First patients dosed March 2019



Trial

- Phase 2
- Open label
- Asia
- Eastern Europe
- India



Patients

- Gastric Cancer
- Up to 70 patients



Study

Randomized

HER-Vaxx in combination with standard of care chemotherapy

Or

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

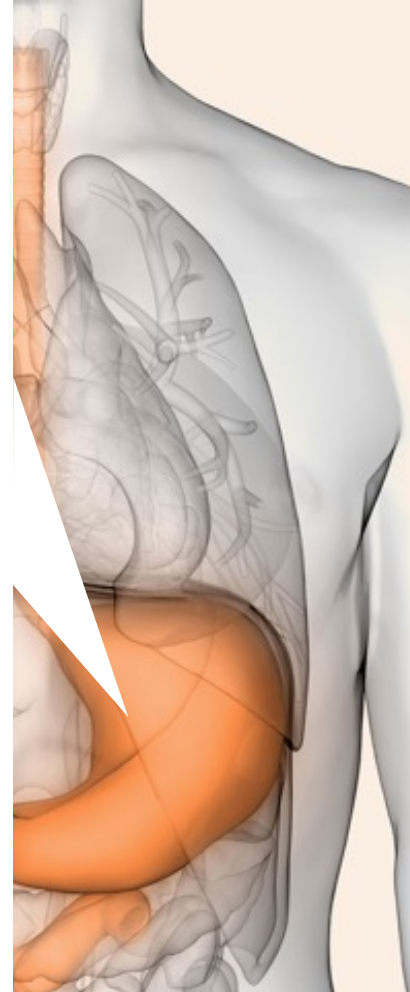


Primary Endpoints

- Overall survival
- Progression-free survival

Secondary Endpoints

- Safety and Tolerability
- Immune response

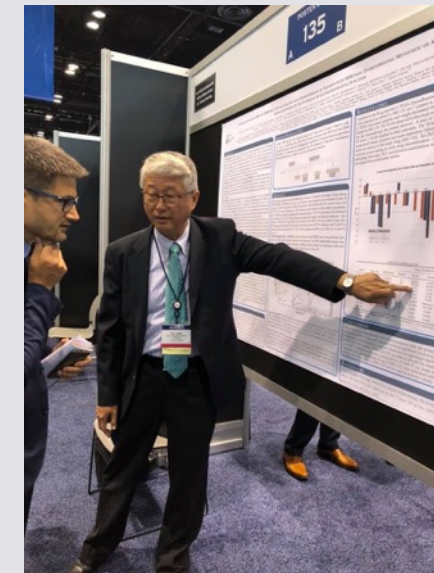


Phase 2 designed to provide definitive data

Imugene announces HER-Vaxx to the world 2019



With a proactive approach to business development and brand awareness through participation in key conferences and acceptance in peer reviewed journals



AACR
American Association
for Cancer Research

ESMO

ASCO
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

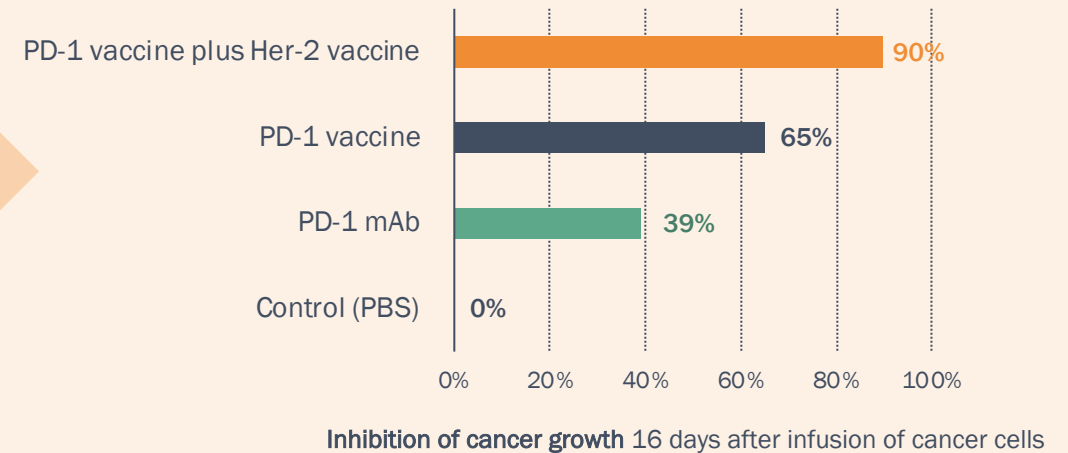
Gastrointestinal
Cancers Symposium

HER-Vaxx Combinations: Potential to increase response rates in HER-2+ cancers

Immuno-oncology combinations driving value

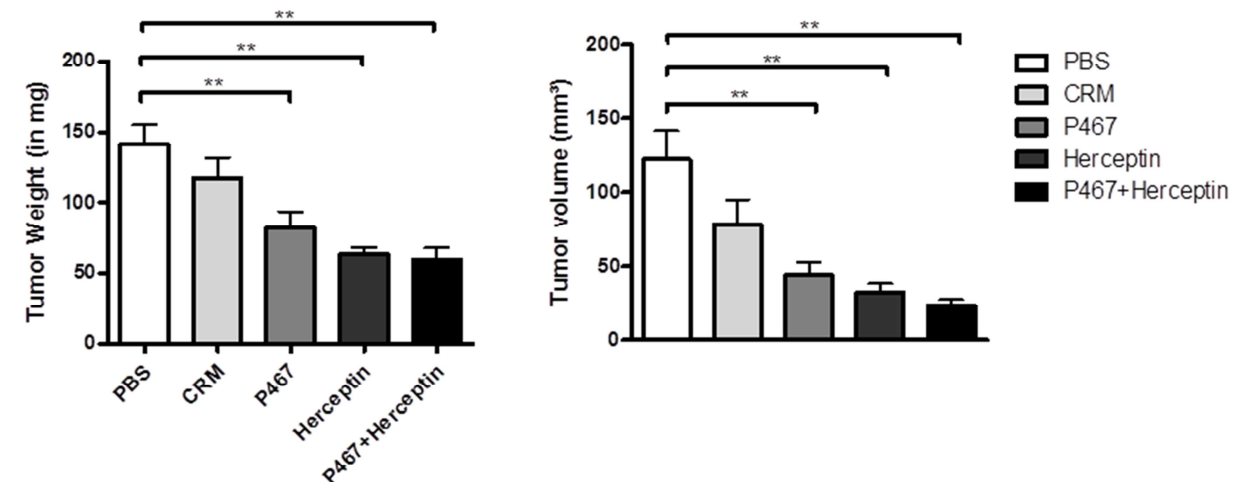
- Combining drugs for **better immuno-oncology outcome** is driving value creation
- Big Pharma are looking for **novel combinations** that
 - ✓ Combine without increasing toxicity
 - ✓ Combine with minimal cost increase
 - ✓ Combine for better response rates and efficacy

% CANCER GROWTH INHIBITION IN COLORECTAL CANCER MODEL (OSU)



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

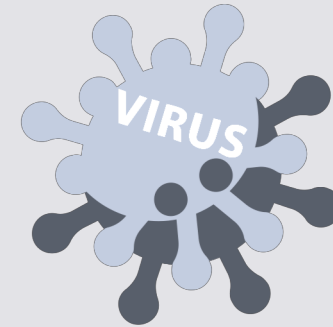
HER-Vaxx / Herceptin Her-2+ breast cancer study (MedUni Vienna)



A NEW HOPE FOR CANCER THERAPY



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.

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

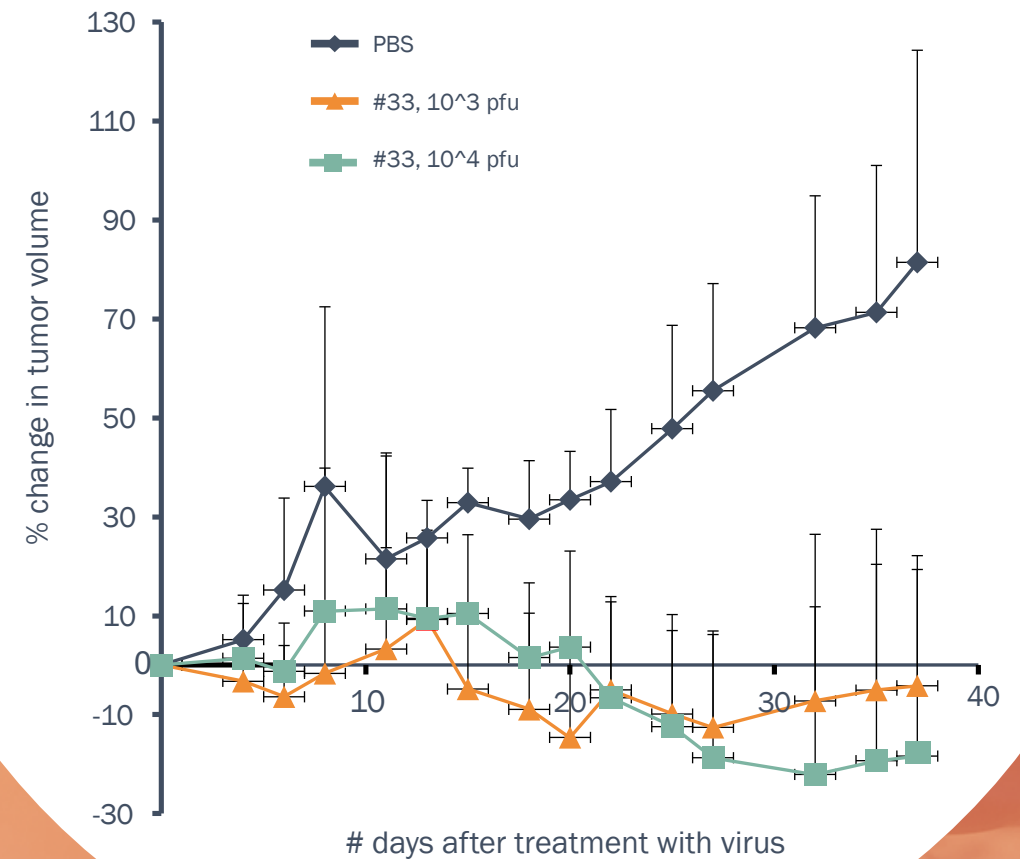


CF33 SHRINKS TRIPLE-NEGATIVE BREAST CANCER

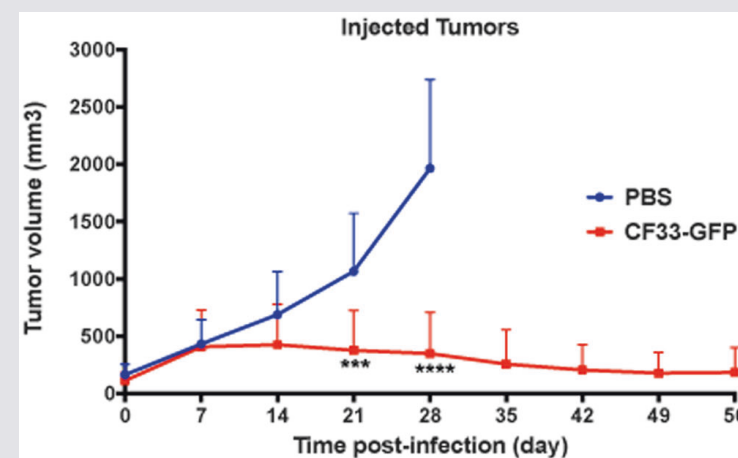
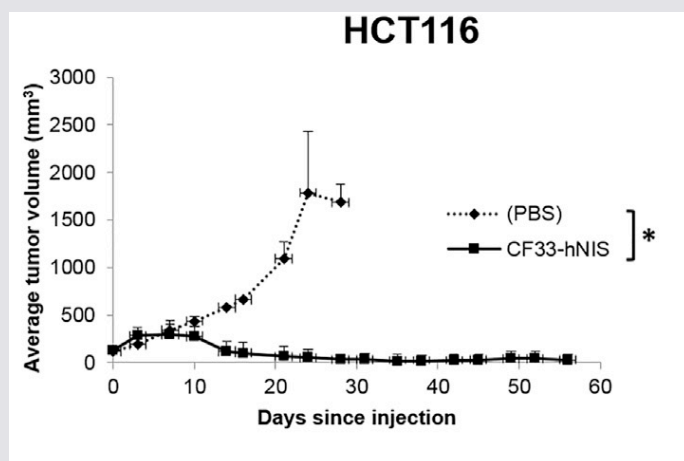
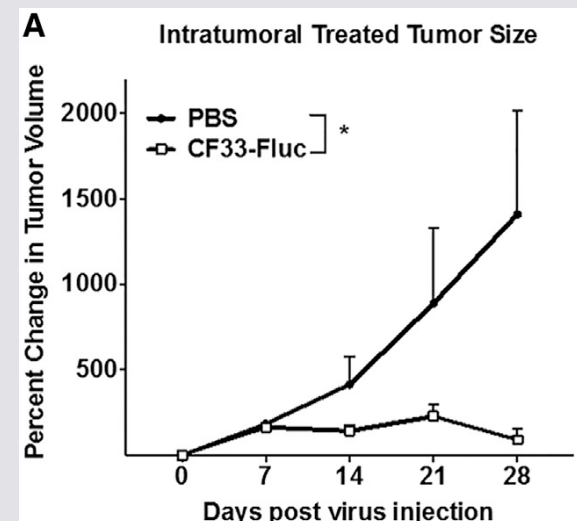
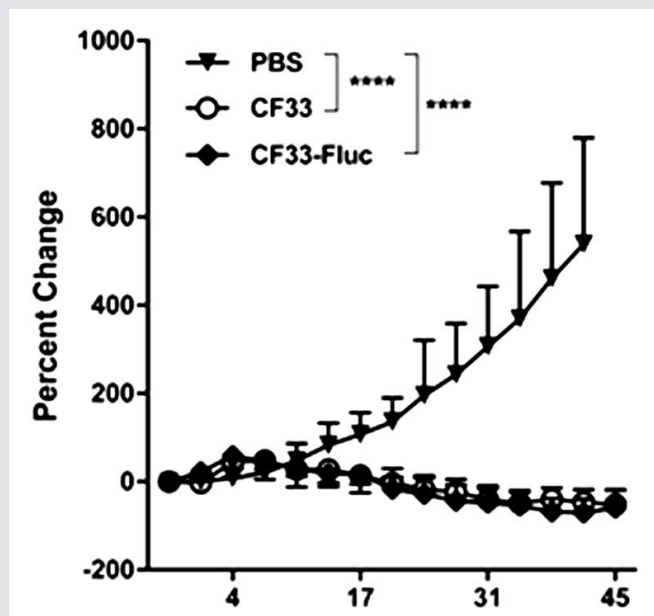
Mice treated with both intratumoral virus and IV

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



Compelling tumour inhibition in multiple cancers



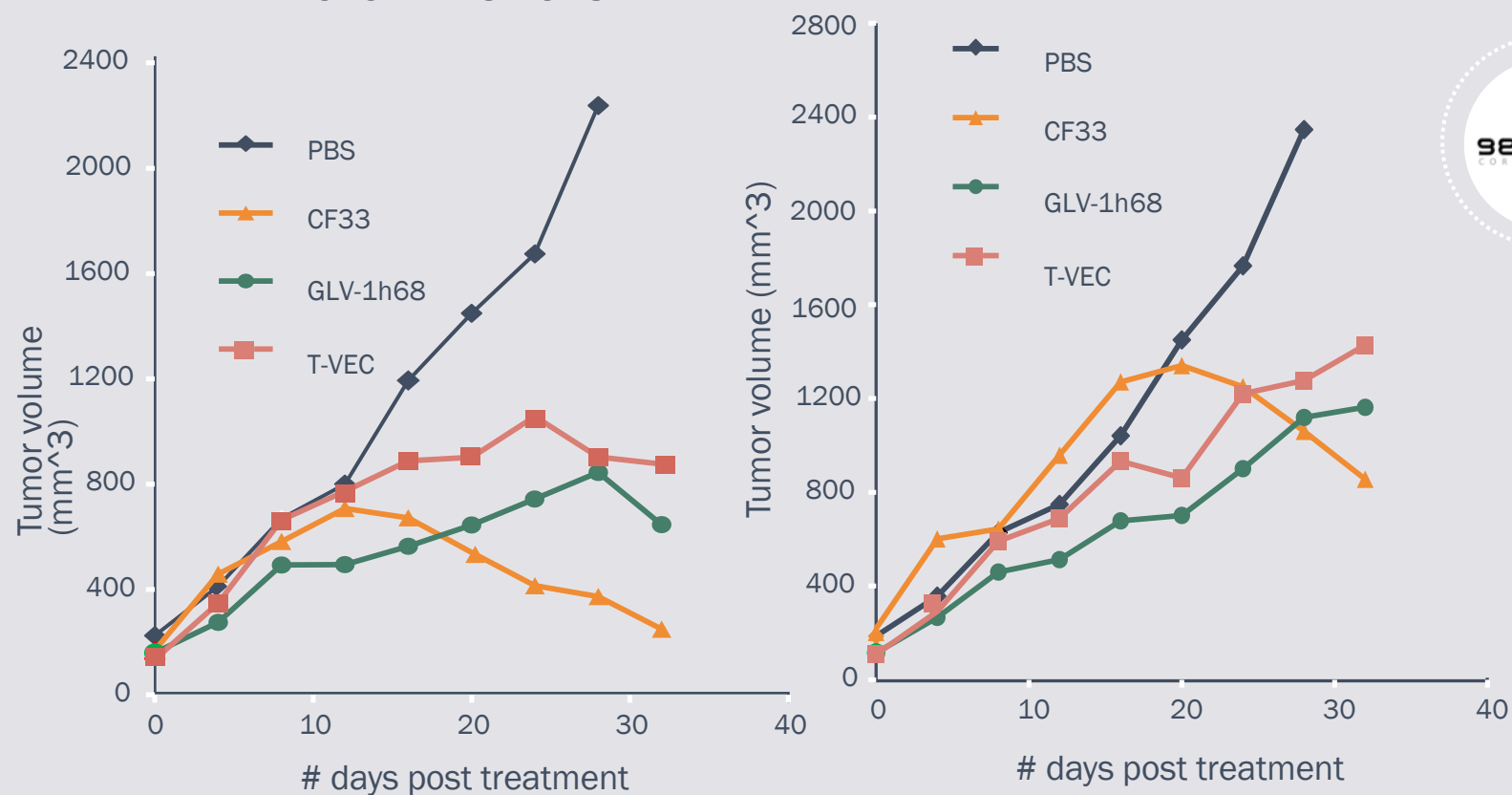
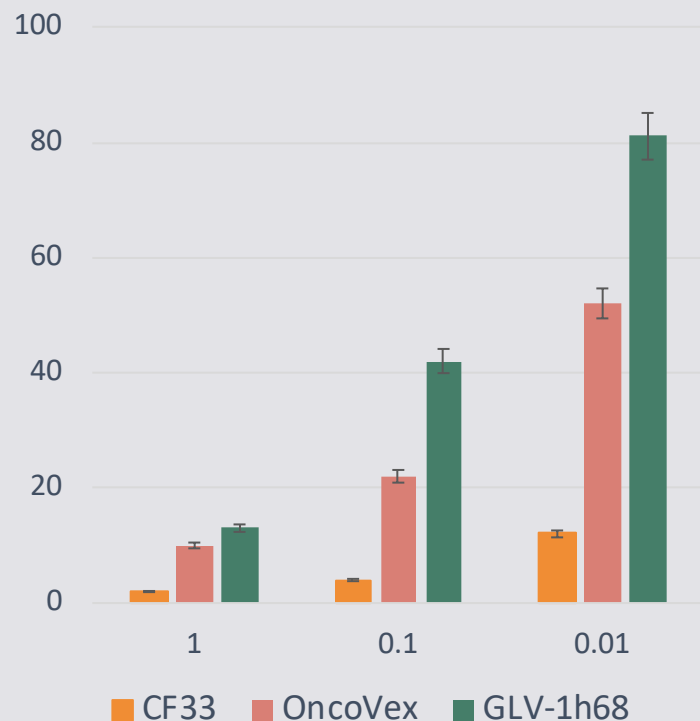
CF33 OUTPERFORMS AMGEN & GENELUX VIRUSES

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

INJECTED TUMORS

NON-INJECTED TUMORS

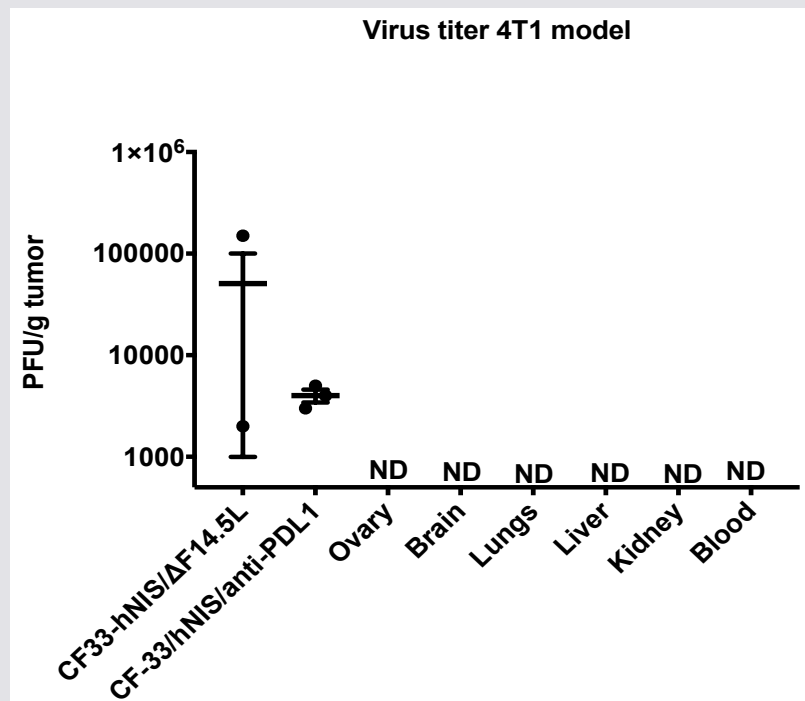
PERCENT CELL SURVIVAL FOR BXPC-3 PANCREATIC CANCER



AMGEN



genelux
CORPORATION

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 PROPOSED PHASE 1/2 CLINICAL DEVELOPMENT PLAN

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

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)



WO 2018/031694 A1

(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)

(74) Agent: HETZER-EGGER, Claudia et al; Minitz Levin Cohn Ferris Glovsky And Popeo, P.C., One Financial Center, Boston, MA 02111 (US).

(21) International Application Number:

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(22) International Filing Date:

09 August 2017 (09.08.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

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 62/519,010 13 June 2017 (13.06.2017) US

(71) Applicant: CITY OF HOPE [US/US]; 1500 E. Duarte Road, Duarte, CA 91010 (US).

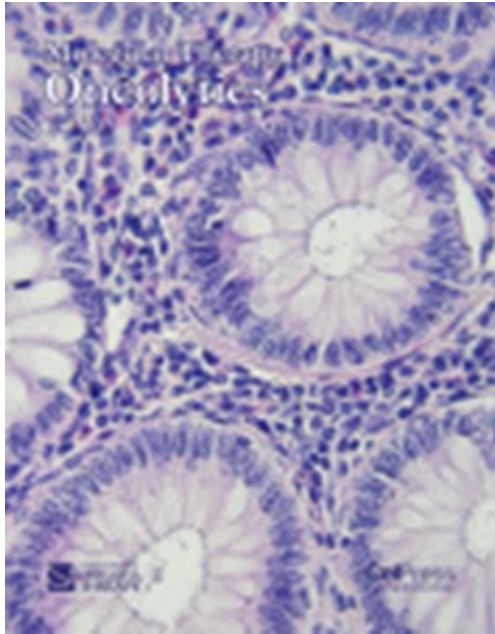
(72) Inventors: FONG, Yuman; 5219 La Canada Boulevard, La Canada, CA 91011 (US). CHEN, Nanhai; 9167 Buck-

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CORE SCIENCE PUBLISHED IN LEADING PEER PUBLICATIONS

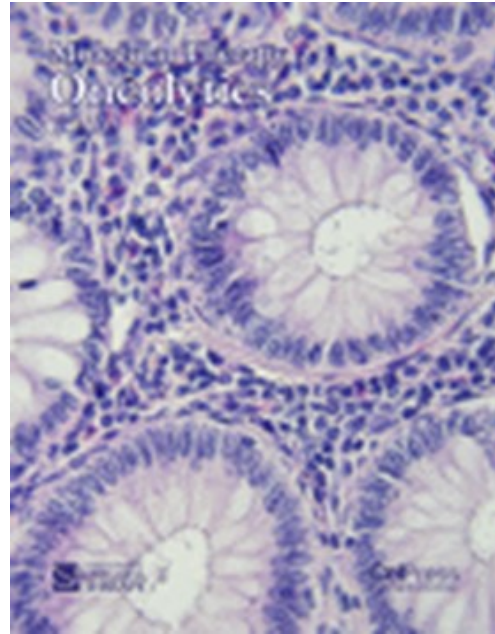
2018



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

2019



Cancer Gene Ther. 2019 17 June

A chimeric poxvirus with J2R (thymidine kinase) deletion shows safety and anti-tumor activity in **lung cancer** models

- **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+)

WHY CF33?





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