

ASX: IMU

IMUGENE

Wholesale Investor Emergence February 2020

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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
- CF33 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 & initiate Phase 1 for PD1-Vaxx 1H, 2020
- Robust, long life IP portfolio over both technologies
- Significant news flow with multiple near & medium term valuation inflections









IMUGENE'S ESTIMATED TIMELINE



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International Leadership Team with Extensive Commercialization **Expertise in the Sector**





Leslie Chong SYDNEY, AU Managing Director & CEO

- 21+ vears 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

- · Former Chairman of Viralvtics
- Prescient
- · Chairman of SUDA Pharmaceutical
- Extensive international & experience particularly in immuno-oncology & vaccines



Executive Chairman

- Founder of Imugene
- Founder & Director of
- ASX biotech capital markets



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 immunooncology treatment to improve survival in melanoma
- 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

Imugene has a team with oncology drug development experience

Experienced Management Team with Significant Clinical Development Expertise



Dr Mark Marino

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 Seymour Fein NEW YORK, USA

Medical Director

- 30+ years of drug development experience across numerous therapeutic areas with 20 FDA drug approvals
- Managing partner of CNF Pharma, LLC
- Co-founder and CMO of Serenity Pharmaceuticals, LLC
- Co-founder of ChiRhoClin, Inc.



Lisa Guttman TORONTO, CAN

Director of Clinical Operations

- 30+ years experience of pharmaceutical and biotechnology industry experience across a wide variety of therapeutic areas & functions
- Founder/owner of Practical Clinical
- Ex VP Global Clinical Operations at Abraxis BioScience (now Celgene), Ex Director North American Development Operations at Amgen



Dr Nick Ede Melbourne, Aus

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



Bonnie Nixon SYDNEY, AUS

Project Manager

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



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[®], Lipitor[®], and Somavert[®]
- Ex Pfizer Global Research and Development, Ex Covance Clinical Services



THE ONCOLYTIC VIRUS INVENTOR & CITY OF HOPE





Professor Yuman Fong

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 SCIENTIFIC ADVISORS

and cell engineering) and oncolytic

genetically engineered viruses).

viral therapy (killing cancer cells using





Imugene has a world renowned advisory board of scientists and oncologists

Cancer Research Ottawa Hospital.

Principal Investigator in the approved TENCENTRIQ[®] study for Roche

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with oncolytic viruses began at Onyx

on the oncolvtic adenovirus program.

He was later on the boards of

directors of BioVex and then

Viralytics.

LANDSCAPE: RECENT ONCOLYTIC VIRUS TRANSACTIONS



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

In **2019** the attention continued with big pharma making more deals even with companies only in early development.





\$125m USD in upfront payment\$900m in milestone payments+ co-development and commercialization

Total + \$1billion USD

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	





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ONCOLYTIC VIRUS CLINICAL DEVELOPMENT TEAM – ex VIRALYTICS







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 ¹³¹Iodine or ¹⁸⁸Rhenium killing of infected cells and adjacent cells

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



JGENE

CF33 SHRINKS TRIPLE NEGATIVE BREAST CANCER

Mice treated with both intratumoral 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



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



Q2 2020 Phase 1 Triple Negative Breast Cancer Study – GMP Manufacturing Complete



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VAXinia PHASE 1/2 MAST STUDY (Mixed Advanced Solid Tumours)



*IO: Cancer Immuno-therapy

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B-Cell Immunotherapy

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 wellvalidated 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
Endpoint	Safety & Tolerability, Impurogenicity, RP2D	Primary: OS, Secondary: PFS, Safety & Tolerability, Immune Response
No of Patients		68
Site location	Asia, Eastern Europe, India	Eastern Europe, India

HER-Vaxx PHASE 1B: CLINICAL RESPONSE





- The preliminary immunology and clinical response data are promising.
- Safety data indicates 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

First patient dosed March 2019



Primary Endpoints

Overall survival

Secondary Endpoints

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



HOW DOES PD1-Vaxx WORK?





PD1-Vaxx: VACCINE IN PHASE 1 DEVELOPMENT PATH





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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

Opdivo / Yervoy Case Study

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

% CANCER GROWTH INHIBITION IN COLORECTAL CANCER MODEL



Inhibition of cancer growth 16 days after infusion of cancer cells

MULTIPLE NEAR & MEDIUM TERM VALUE INFLECTION POINTS



Next 12 months

FINANCIAL SUMMARY



Public Market Overview

Share Price ¹	A\$0.035	
Market Capitalisation ²	A\$150M	
52 week high/low	6.3c / 1.3c	
Cash equivalents (Dec 2019)	A\$36.8M	
Enterprise Value	A\$84.7M	
Top 5 Shareholders (as at February 2020)		
Paul Hopper		
Private Portfolio Manager (PPM)		
Private Holder		
Citicorp Nominees Pty		
Private Holder		

Share Price Performance (last 6 months)



Note:

1. As of 21 February 2020

2. Market capitalization calculations based on ordinary shares (4.43b) only

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