



**IMUGENE**

Developing Cancer  
Immunotherapies

ASX:IMU

Page 6

FDA clears IND  
for onCARlytics  
Phase 1 Clinical  
Trial

Page 7

Enhanced  
anti-tumour  
activity in  
liver cancer

Page 10

HER-Vaxx induced  
antibodies  
correlated with  
tumour reduction



# ACQUISITION OF AZER-CEL CAR T CELL THERAPY TECHNOLOGY

October 2023

# IMUGENE ACQUIRES AZER-CEL CAR T CELL THERAPY TECHNOLOGY: A LANDMARK MOMENT

Leslie Chong  
Imugene CEO & Managing Director



## CEO UPDATE

I am pleased to share our latest set of exciting developments and achievements from the team at Imugene. Despite some challenging circumstances that we've faced, our commitment to innovation and progress has not wavered, and it's a pleasure to present these noteworthy updates.

### **Imugene Acquires Azer-cel CAR T cell therapy technology: A landmark moment**

In August, Imugene acquired the Azer-cel CAR T cell therapy technology. Azer-cel, with its proven safety and efficacy profile, holds immense potential in the treatment of blood cancers. Additionally, there is the opportunity to combine Azer-cel with our existing onCAR19 therapy for the treatment of solid tumours. This marks an important step in our mission to combat a broader spectrum of cancers.

The acquisition comes with an exclusive worldwide license for Azer-cel, a product that has already demonstrated its effectiveness in a Phase 1 trial with over 84 patients. Furthermore, we have received encouraging guidance from the FDA, suggesting a potential fast-track Phase 2 registration trial, which could make Azer-cel the first FDA-approved allogeneic CAR T cell therapy.

This move is supported by the exceptional team who have joined us, including manufacturing experts, who have diligently worked to ensure the readiness of the drug material and manufacturing process. The fact that no severe side effects were observed in the latest cohort is a testament to the quality of the work and the commitment to patient safety.

### **Revolutionizing cancer treatment with Azer-cel**

Azer-cel has shown positive results to date, especially in patients who have relapsed after receiving approved auto CD19 CAR T therapies. With an 83% overall response rate and a 61% complete response rate in Diffuse Large B Cell Lymphoma (DLBCL) patients, Azer-cel has the potential to significantly improve outcomes in a patient population with substantial unmet needs.

It's worth highlighting that while other CAR T therapies have shown limited efficacy, Azer-cel has shown an ability to maintain a durable response for at least six months. This is a crucial step forward in providing long lasting benefits to patients.

### **Potential FDA accelerated approval**

The potential for securing FDA accelerated approval for the Phase 2 registrational trial within 18 months is an exciting prospect. This could position Azer-cel as the first FDA-approved allogeneic CAR T cell therapy. With this acquisition we receive Azer-cel's extensive clinical data set, fast-to-market development strategy, and the potential to initiate a registrational study as soon as possible.

### **Innovation beyond Azer-cel**

While Azer-cel is potentially a game-changer, Imugene continues to forge ahead in various other areas of cancer research and treatment. Our onCARlytics program progressed with the recent FDA IND clearance for the Phase 1 clinical trial another important milestone.

We are excited about the possibilities that onCARlytics holds for patients with solid tumours, especially in combination with other cutting-edge technologies such as ARTEMIS® T cells. The recent preclinical data presentation at the American Society of Cell & Gene Therapy conference further solidifies our commitment to expanding our portfolio and improving outcomes for cancer patients.

### **Progress in ongoing trials**

Our MAST trial evaluating the CF33-hNIS (VAXINIA) cancer-killing virus is progressing on schedule, progressing through the various cohort milestones in both monotherapy and combination arms. This trial is aimed at meeting an unmet need for patients with metastatic or advanced solid tumours, and we are committed to its success.

Additionally, the upcoming feature of Imugene's CF33 Oncolytic Virus technology and MAST study at the prestigious Society for Immunotherapy of Cancer (SITC) Annual Meeting indicates the recognition of Imugene's science in the immunotherapy community.

### **Advancing our leadership team**

Imugene has also welcomed key additions to our Board of Directors and senior leadership team. With their wealth of experience and expertise, Ms. Kim Drapkin, Dr Bradley Glover, Dr Paul Woodard, and Dr John Byon are expected to provide significant drive, knowledge and guidance to the Company.

### **Shareholder engagement and webinars**

We value your support and engagement. Alongside new COO Dr Bradley Glover, I hosted an informative investor webinar to discuss the Azer-cel acquisition, and I encourage you to watch the replay if you haven't already. Additionally, we continue to share important updates through various channels, ensuring you stay well-informed about our progress.

### **Looking forward**

As we move forward, Imugene remains dedicated to advancing the field of cancer therapy and making a positive impact on the lives of patients. We are committed to innovation, collaboration, and, most importantly, the well-being of those we aim to serve.

Financially, these are the best and worst of times. Our balance sheet is one of the strongest in the local industry with ~\$186 million in the bank, but at the same time our share price has been slammed and is now at its lowest point in several years. This is despite the Company being in good shape with a diversified technology portfolio, five FDA INDs (the global gold standard for running human clinical trials) for Imugene and another with City of Hope, five clinical trials recruiting across the US and Australia, one soon to begin, and another investigator sponsored trial with City of Hope, as well as a highly qualified senior management team. There are few ASX biotechs with such strength and depth.

Thank you for your support, and we look forward to sharing more exciting developments in the near future. Together, we are making strides toward a brighter and healthier future for all.

# IMUGENE ACQUIRES AZER-CEL CAR T CELL THERAPY TECHNOLOGY

**During August, Imugene licensed the, potential registrational stage, off-the-shelf (allogeneic) CAR T cell therapy drug, azer-cel (azercabtagene zapreleucel).**

To date, the technology has targeted the treatment of blood cancers, however there is the potential to combine Azer-cel with IMU's existing onCAR19 to treat solid tumours.

The transaction includes:



**An exclusive worldwide license for the first-in-class product, Azer-cel, which has treated over 84 patients in a Phase 1 trial, demonstrating safety and compelling efficacy.**

3 additional asset targets.



**Encouraging FDA guidance and feedback on manufacturing for a potential fast-track Phase 2 registration trial.**

The potential to be the first FDA approved allogeneic CAR T.



**Completed drug material and manufacturing process.**



**A manufacturing facility staffed with a highly technically skilled and specialised workforce.**

This provides a unique opportunity to advance the development of this allogeneic (off-the-shelf) CD19 CAR T drug for blood cancers, which has demonstrated enhanced safety and efficacy. The venture complements our existing CD19 onCARlytics program and is supported by compelling data from the ongoing Phase 1b trial of Azer-cel in 84 patients with non-Hodgkin's Lymphoma (NHL) and acute lymphocytic leukemia (ALL). The results indicated a 41% complete response in non-Hodgkin's Lymphoma (NHL) cases and a 61% complete response rate in CAR T relapse patients. 55% of these patients maintained a durable response for at least six months.

It's noteworthy that 60-70% of patients treated with approved auto CD19 CAR T therapies, such as Kymriah®, Yescarta®, or Breyanzi®, unfortunately, experience cancer progression or recurrence. Among the broader set of relapsed/refractory NHL patients, regardless of their prior auto CAR T treatment, Azer-cel reported a 58% ORR and 41% CR rate. Crucially, no severe cytokine release syndrome (CRS), neurotoxicity, infections, or graft versus host disease were observed in the latest cohort following the proper lymphodepletion procedure. Azer-cel's promising results extended to Diffuse Large B Cell Lymphoma (DLBCL) patients relapsing post-CAR T, Azer-cel achieved 83% ORR, 61% CR rate with 55% durable response greater than or equal to six months in this difficult to treat auto CAR T relapse setting (n=18).

**This highlights the potential of Azer-cel to improve outcomes in this patient segment with significant unmet needs.**

There's also potential to secure an FDA accelerated approval for the Phase 2 registrational trial in about 18 months, positioning Azer-cel as a frontrunner to become the first FDA-approved allogeneic CAR T cell therapy.

This technology is backed by a seasoned CAR T management team and manufacturing experts who were part of the Phase 1 trial. The drug product for the upcoming Phase 2 study will be produced in a cutting-edge cell therapy facility in North Carolina, also acquired by Imugene under the transaction.

Our MD & CEO, Ms Leslie Chong said, "Azer-cel has one of the most extensive clinical data sets for a CD19 directed allogeneic cell therapy, a fast-to-market development strategy and a potential registration-enabling clinical trial in 2024 for patients with 3rd and 4th line DLBCL. We plan to complete the ongoing multi-centre Phase 1b (ClinicalTrials.gov ID NCT03666000) study using the recommended Phase 2 regimen as we prepare for the start of a potential registrational study at the earliest opportunity. We are excited as Azer-cel has the potential to be the first approved allo CAR T.



“By adding Azer-cel to the Imugene pipeline, our onCARlytics program will form the foundation of a novel and broadened approach to cell therapy. CD19 is a well validated clinical target in blood cancers. OnCARlytics can enhance the expression of CD19 on solid tumours. Azer-cel is a supercharged allogeneic T cell designed to identify and kill malignant cells expressing CD19. We are thrilled about the potential benefit for patients from the combination of these two technologies.”

Ms Chong, alongside newly appointed COO Dr Bradley Glover, hosted an investor webinar which discussed the acquisition and provided an overview of the Azer-cel technology.

**A replay of the webinar is available at:**

<https://www.youtube.com/watch?v=p7PrUf16faA>

**Subsequent to the announcement that Imugene had acquired Azer-cel, the Company received positive feedback from the FDA regarding the manufacturing process for its registrational trial and potential commercial production.**

Following the FDA’s positive feedback, the commercial version of Azer-cel will undergo clinical testing and be used in the pivotal trial, with the product to be manufactured at Imugene’s advanced 32,800 sq ft GMP facility in North Carolina.

## Q&A WITH IMUGENE’S COO DR BRADLEY GLOVER



### **Tell us about your experience prior to joining Imugene?**

I began my career as a researcher and postdoctoral fellow but transitioned to industry to help advance programs through the clinic and to commercialisation. I’ve worked across several industries such as diagnostics, venture capital, small/large molecule and the newly emergent cellular therapies.

### **What appealed to you about Imugene?**

Imugene’s technology, people and culture were great selling points. With Azer-cel added to the onCARlytics and oncolytic virus assets, Imugene has positioned itself to deliver on its promise to patients fighting cancer. I believe Imugene’s talented and engaged workforce and collaborative culture provide the necessary capabilities to advance the pipeline successfully.

### **What are you most excited about for your new role as COO at Imugene?**

I am excited to work with the team to develop effective strategies and goals and drive to achieve measurable outcomes and material results.

### **What is your favourite thing to do in your spare time?**

I enjoy spending time with my wife and four children. I’m also an avid outdoor enthusiast and enjoy running, biking and hiking.

### **Where is your favourite travel destination and why?**

There are so many places I’ve travelled in the world and experienced unique cultures and cuisine that it’s hard to pick a favourite. If I have to pick one, it would likely be Switzerland and all the year-round activities you can enjoy indoors and outdoors.

# FDA CLEARS IND FOR ONCARLYTICS PHASE 1 CLINICAL TRIAL

In May we welcomed news that a US Food and Drug Administration (FDA) Investigational New Drug (IND) clearance was received allowing us to initiate a Phase 1 clinical study of our oncolytic virotherapy candidate, onCARlytics (on-CAR-19, CF33-CD19, HOV4).

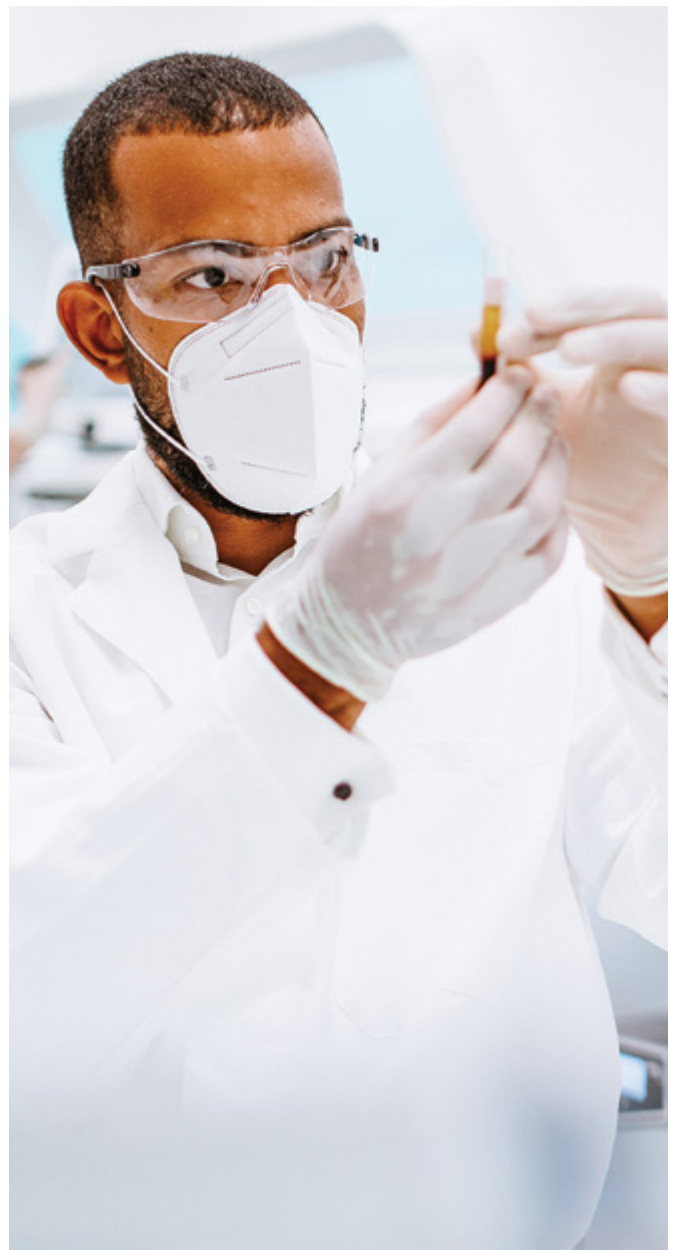
This allows for the commencement of patient recruitment and dosing in a first-in-class Phase 1 clinical study for the onCARlytics platform in patients with solid tumours: “A Phase I, Dose Escalation and Dose Expansion, Safety and Tolerability Study of onCARlytics (CF33-CD19), Administered Intravenously or Intratumorally in Combination with Blinatumomab in Adults with Advanced or Metastatic Solid Tumors (OASIS)”.

Imugene’s CF33-CD19 oncolytic virus, when combined with the CD19 targeting bispecific monoclonal antibody blinatumomab (Blinicyto®), has the potential to target and eradicate solid tumours that otherwise cannot be treated with Blincyto® therapy alone.

Our Managing Director and CEO Leslie Chong, alongside Scientific Advisory Board member and onCARlytics co-inventor Dr Saul Priceman, held an investor webinar to discuss the FDA IND clearance.

**It can be viewed at:**

<https://youtu.be/bkcmDym8Qic>





# ONCARLYTICS + ARTEMIS<sup>®</sup> T CELLS COMBINATION SHOWS ENHANCED ANTI-TUMOUR ACTIVITY IN LIVER CANCER

Our onCARlytics technology, in combination with Eureka Therapeutics, Inc.'s ARTEMIS<sup>®</sup> cell receptor platform, had preclinical data presented at the American Society of Gene and Cell Therapy's Annual Meeting (ASGCT). The data demonstrated enhanced anti-tumour activity in vivo against hepatocellular carcinoma (liver cancer) tumours.

Presented as a poster presentation at the ASGCT conference held in Los Angeles, titled 'Effective combination immunotherapy using onCARlytics and ARTEMIS<sup>®</sup> CD19 T cells against hepatocellular carcinoma', the data investigated the combination in the most common type of primary liver cancer and sixth most common cancer worldwide.

Hepatocellular carcinoma (HCC) occurs most often in people with chronic liver diseases, such as cirrhosis caused by hepatitis B or hepatitis C infection. Currently, there are few systemic therapies available for patients with advanced disease in addition to the traditional treatments including ablation, surgical resection, and liver transplantation.

onCARlytics in combination with ARTEMIS<sup>®</sup> T cells potentially provide a solution. ARTEMIS<sup>®</sup> T cells differentiate from CAR T cells with lower CRS risks, better tumour infiltration, and higher T cell persistence in preclinical studies, making them ideal cell therapy candidates for solid tumours.

**The full poster presentation can be viewed [on our website](#).**

# MAST MARCHES ON WITH VAXINIA TRIAL CONTINUING POSITIVE MOMENTUM



**Our Phase 1 MAST (metastatic advanced solid tumours) trial evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA) continues to progress on schedule.**

**The trial has now reached dosing for:**



The fourth cohort of both the intratumoral (IT) and intravenous (IV) arms of the monotherapy dose escalation study



The second cohort of both the IT and IV arms of the combination study (with pembrolizumab)

The multicenter Phase 1 MAST trial commenced by delivering a low dose of VAXINIA to patients with metastatic or advanced solid tumours who have had at least two prior lines of standard of care treatment.

The City of Hope-developed oncolytic virus has been shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumours in preclinical laboratory and animal models.

Overall, the study aims to recruit up to 100 patients across approximately 10 trial sites in the United States and Australia.

## **MAST to feature at SITC**

The CF33 Oncolytic Virus technology and MAST study will be featured at the renowned Annual Meeting for the Society for Immunotherapy of Cancer (SITC), to be held in San Diego, USA on 1-5 November 2023.

SITC is a prestigious immunotherapy event featuring cutting-edge research presentations by various experts, oral, and poster abstract presentations and various opportunities for networking and discussion with members of the oncology community.

CF33 and MAST will be showcased in a Trial-in-Progress Poster titled: A Phase I Safety and Tolerability Study of VAXINIA (CF33-hNIS), a Novel Chimeric Oncolytic Poxvirus, Administered Intratumorally or Intravenously in Adults with Metastatic or Advanced Solid Tumors.

## **Abstract #: 730**

More details from this abstract will be provided closer to the time of the event.

## **CF33 Patent Allowed in US**

In other news related to CF33, we received a Notice of Allowance from the US Patent and Trademark Office (USPTO) for patent application number 16/324,541 which protects the oncolytic virotherapy, including VAXINIA (CF33-hNIS) and CHECKVacc (CF33-hNIS-antiPDL1).

The patent titled "CHIMERIC POXVIRUS COMPOSITION AND USES THEREOF" (inventors Yuman Fong and Nanhai Chen from the City of Hope) protects the method of composition and method of use of Imugene's licensed oncolytic virotherapy to 2037.



## COLLABORATION WITH RENOVORX FOR CF33 VIROTHERAPY DELIVERY

**We entered into a collaboration agreement with RenovoRx (Nasdaq: RNXT), to optimize the delivery of our oncolytic virus therapy with RenovoRx's TAMP (Trans-Arterial Micro-Perfusion) therapy platform for the treatment of difficult-to-access tumours.**

Under the collaboration, the companies will investigate the ability to administer Imugene's CF33 oncolytic virus technology with RenovoRx's TAMP therapy platform, and thereby analyse the ability of the combination to treat difficult-to-access tumours, such as pancreatic and liver cancers. This will be done by delivering CF33 trans-arterially, which may be valuable to cancer patients compared to traditional administration methods where dense fibrous tissue and lack of blood vessels supplying the tumours have been shown to limit therapy uptake.

RenovoRx's TAMP platform is designed to ensure precise therapeutic delivery to a target tissue, and the platform won the Drug Delivery Technology category of the Fierce Innovation Awards – Life Sciences Edition 2020.

## FOURTH DOSE COHORT REACHED FOR PHASE I CHECKVACC TRIAL

In July City of Hope® proceeded to the fourth dose cohort in the Phase I clinical trial of oncolytic virotherapy candidate, CHECKvacc (HOV3, CF33-hNIS-anti-PDL1).

The decision to move forward was based on the safety and tolerability data from the first three cohorts, which showed no dose-limiting toxicities or serious adverse reactions.

This first-in-human, single-center, dose escalation study is aimed at recruiting patients with triple negative breast cancer (TNBC) to evaluate both the safety and initial efficacy of the treatment against metastatic TNBC.

The trial will continue with a dose escalation, leading to an expansion to 12 patients at the final dose.

## FIRST PATIENT DOSED IN COMBINATION STUDY FOR PD1-VAXX IMPRINTER CLINICAL TRIAL

In late May we dosed the first patient in the combination cohort of the IMPRINTER study, a clinical trial to evaluate the safety and efficacy of PD1-Vaxx, a B-cell activating immunotherapy, alone or in combination with atezolizumab (Tecentriq®), an immune checkpoint inhibitor targeting PD-L1 from Roche, in patients with non-small cell lung cancer (NSCLC).

The objectives of the open label, multi-center, dose escalation/expansion, phase 1/1b study are to determine safety, efficacy, and optimal dose of PD1-Vaxx in combination with atezolizumab as therapy in ICI treatment-naïve NSCLC patients or ICI pretreated patients.

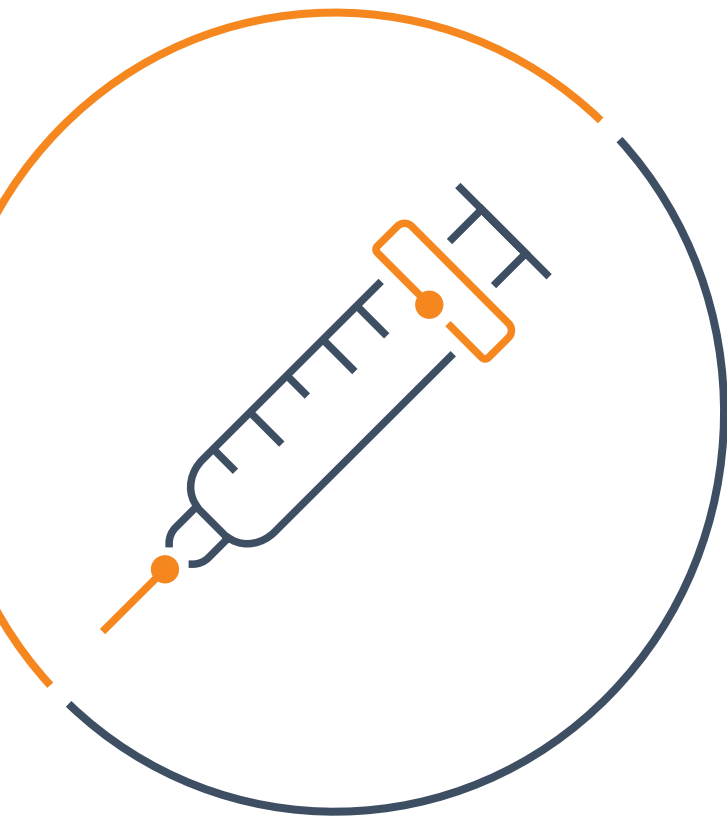
The study is being conducted at sites in USA and Australia. Dual targeting of the PD-1/PDL1 axis is an area of considerable interest, providing treatment options for patients with cancer. Combination with PD1-Vaxx may overcome treatment resistance to ICIs with dual inhibition of the PD-1/PD-L1 axis extending the treatment benefit of atezolizumab. In contrast to the combination of two monoclonal antibodies, PD1-Vaxx induces a unique polyclonal immune response which may increase response rates for the combination therapy.

In June we also announced that the United States Patent Office announced the grant of a patent protecting PD1-Vaxx until 11 February 2040.



# HER-VAXX INDUCED ANTIBODIES CORRELATED WITH TUMOUR REDUCTION

**IN JUNE WE PRESENTED HER-VAXX DATA AT THE WORLD CONGRESS OF GASTROINTESTINAL CANCER IN BARCELONA.**



For 25 years, the World Congress on Gastrointestinal Cancer has been the foundation for sharing the most advanced research and innovations impacting the field of Gastrointestinal Cancer. As the largest global gathering in the field, the Congress brings together leading gastroenterology, oncology, pathology, and hepatology experts, clinicians, and surgeons, as well as clinical researchers from across the globe to share pioneering research, approaches, and best practices in treating patients with cancers of the gastrointestinal tract.

**Conclusions drawn from Imugene's HERIZON study, presented at the congress, included:**

- ✓ HER-Vaxx treatment produced robust anti-HER-2-IgG (the most common type of antibody found in blood circulation) and IgG1 antibody responses ( $p < 0.001$ ).
- ✓ HER-Vaxx-based vaccination of patients with HER-2 overexpressing gastric/gastro-esophageal junction cancer (GC) induced anti-HER-2-IgG and IgG1 subclass antibody responses ( $p < 0/001$ ).
- ✓ HER-Vaxx induced antibodies correlated with tumour reduction ( $p = 0.001$ ).
- ✓ Compared to chemotherapy alone, the vaccination resulted in a statistically significant overall survival benefit
- ✓ The present data further validate the proof of concept for a first-in-class B-cell immunotherapy based on HER-2/neu peptides.

## Imugene technologies to feature at ESMO

Our CF33 oncolytic virotherapy CHECKVacc and B cell immunotherapy HER-Vaxx will each feature at the upcoming ESMO Congress, to be held in Madrid on 20-24 October 2023.

The European Society for Medical Oncology (ESMO) Congress is the most influential oncology platform for clinicians, researchers, patient advocates, journalists, and healthcare industry representatives from all over the world.

**The abstract titles have been announced for the symposium, with Imugene to feature in the following:**

### Poster Session

**#4581:** Induction of an Inflammatory Tumour Microenvironment with Oncolytic Virus CF33-hNIS-antiPD-L1 Intratumoral Injection in Patients with Metastatic Triple Negative Breast Cancer (mTNBC).

**Presenter: Dr Jamie Rand, City of Hope.**

### Poster Session

**#4720:** HERIZON: A Phase 2 study of HER-Vaxx (IMU-131), a HER2-targeting peptide vaccine plus standard of care chemotherapy in patients with HER2+ advanced stomach Cancer – dose-dependent anti-cancer antibodies correlating with improved clinical outcome.

**Presenter: Dr Joshua Tobias, Medical University of Vienna.**



# INVESTOR ROADSHOW WITH PROFESSOR YUMAN FONG

**During July we welcomed CF-33 co-inventor Professor Yuman Fong back to Australia after he was invited to be the keynote speaker at this year's Bioshares Biotech Summit.**

As part of the roadshow Professor Fong was joined by members of the Imugene management team for presentations to investors in Sydney and Melbourne, including receptions for our supportive shareholders.

A webinar was held to provide all interested parties with an opportunity to hear the presentation provided by Professor Fong, with a replay available at:

[https://us02web.zoom.us/webinar/register/WN\\_n78krTjOREuFQvpiquvsuQ](https://us02web.zoom.us/webinar/register/WN_n78krTjOREuFQvpiquvsuQ)

# NEW BOARD & MANAGEMENT PROFILES



**Ms Kim Drapkin**  
**Non-Executive Director**

With more than 25 years of experience in the biotechnology and pharmaceutical sectors, Ms Drapkin possesses a strong background in finance, capital raising, and strategic financial planning. She held the position of CFO and Treasurer at Jounce Therapeutics, Inc. from 2015 until its acquisition in May 2023, having played a pivotal role in the company's growth and financing since its inception. Alongside the CEO, she represented Jounce in the investment and analyst community and was a key figure in the company's IPO and subsequent NASDAQ listing.

Before joining Jounce, Ms Drapkin managed a financial consulting firm and served as interim CFO for various early-stage biotech companies, including Eleven Biotherapeutics, Inc., NinePoint Medical, Inc., Blueprint Medicines Corporation, Warp Drive Bio LLC, Edimer Pharmaceuticals, Avila Therapeutics, Inc., and Voyager Therapeutics, Inc. Prior to that, she held CFO positions at EPIX Pharmaceuticals and gained valuable experience at Millennium Pharmaceuticals.

Ms Drapkin also currently serves as the audit committee chair and compensation committee member on Acumen Pharmaceuticals' board (NASDAQ: ABOS). Previously, she served on Proteostasis Therapeutics' board (NASDAQ: PTI) from 2019 to 2020 and continued on Yumanity Therapeutics' board (NASDAQ: YMTX) following its merger with PTI in December 2020 until December 2022.



**Dr Bradley Glover, PhD, MBA**  
**Chief Operating Officer**

Dr Glover brings a wealth of experience to Imugene, with a career spanning various sectors such as cell therapy, biopharmaceuticals, diagnostics, venture capital, finance, research and development, and education. He has demonstrated expertise in deal negotiations, strategic collaborations, acquisitions, and licensing agreements. Additionally, he has made significant academic contributions, with published research articles in biochemistry and genetics.

Prior to joining Imugene, Dr Glover served as the Executive Vice President and Chief Operating Officer at Celularity, playing a pivotal role in strategic planning, business development, and technical operations. Prior to this he was Vice President and Head of Corporate Strategy & Operations at renowned cell therapy company Kite Pharma, overseeing global corporate strategy, planning, portfolio management, product and program management, and global business transformation.

Dr Glover also brings eight years' experience at Genentech / Roche, where he held leadership positions, concentrating on business development, integration, and strategic planning. Notably, he helped lead the integration of Roche's acquisitions, totalling ~\$1.2B, for its Diagnostics Sequencing business.





### **Dr Paul Woodard, MD** **Chief Medical Officer**

Prior to joining Imugene, Dr Woodard worked on a wide range of drug development projects in solid tumours, haematologic malignancies, and non-malignant haematologic disorders. Most recently, Dr Woodard served as the Senior Vice President and Chief Medical Officer at Immune-Onc Therapeutics. In this role, he played a pivotal part in clinical oversight, notably directing the submission of four novel INDs (investigational new drug application) and initiating Phase 1 clinical trials.

At Exelixis, Dr Woodard worked on small molecule tyrosine kinase inhibitors for solid tumours. At Amgen, Dr Woodard was the global development leader for Nplate® (romiplostim) in immune thrombocytopenia and myelodysplastic syndromes. At Genentech, Dr Woodard was the global development team leader for Tecentriq® (atezolizumab) in haematologic malignancies and was an integral team member for the development of Tecentriq® combinations in solid tumours (including triple negative breast cancer) and haematologic malignancies. At Bellicum, Dr Woodard was the Senior Vice President of Clinical and Medical Affairs, with oversight of the company's cellular therapy portfolio and clinical trials in haematologic malignancies and solid tumours.

Dr Woodard has an extensive haematology and oncology background gained in academia and industry. His academic experience focused on paediatric haematopoietic stem cell transplantation and haematologic disorders at world-renowned institutions, including St. Jude Children's Research Hospital, University of California, San Francisco, and Children's Hospital, Los Angeles. In addition to patient care, at St. Jude, Dr Woodard was responsible for Phase 1/2 trials in paediatric haematopoietic stem cell transplantation for malignant and non-malignant disorders.



### **Dr John Byon, MD, PhD** **Senior Vice President of Clinical Development**

Dr Byon boasts an extensive background in the development of novel therapeutics for cancer patients. He has occupied several leadership roles at major biopharmaceutical companies, spearheading clinical development activities.

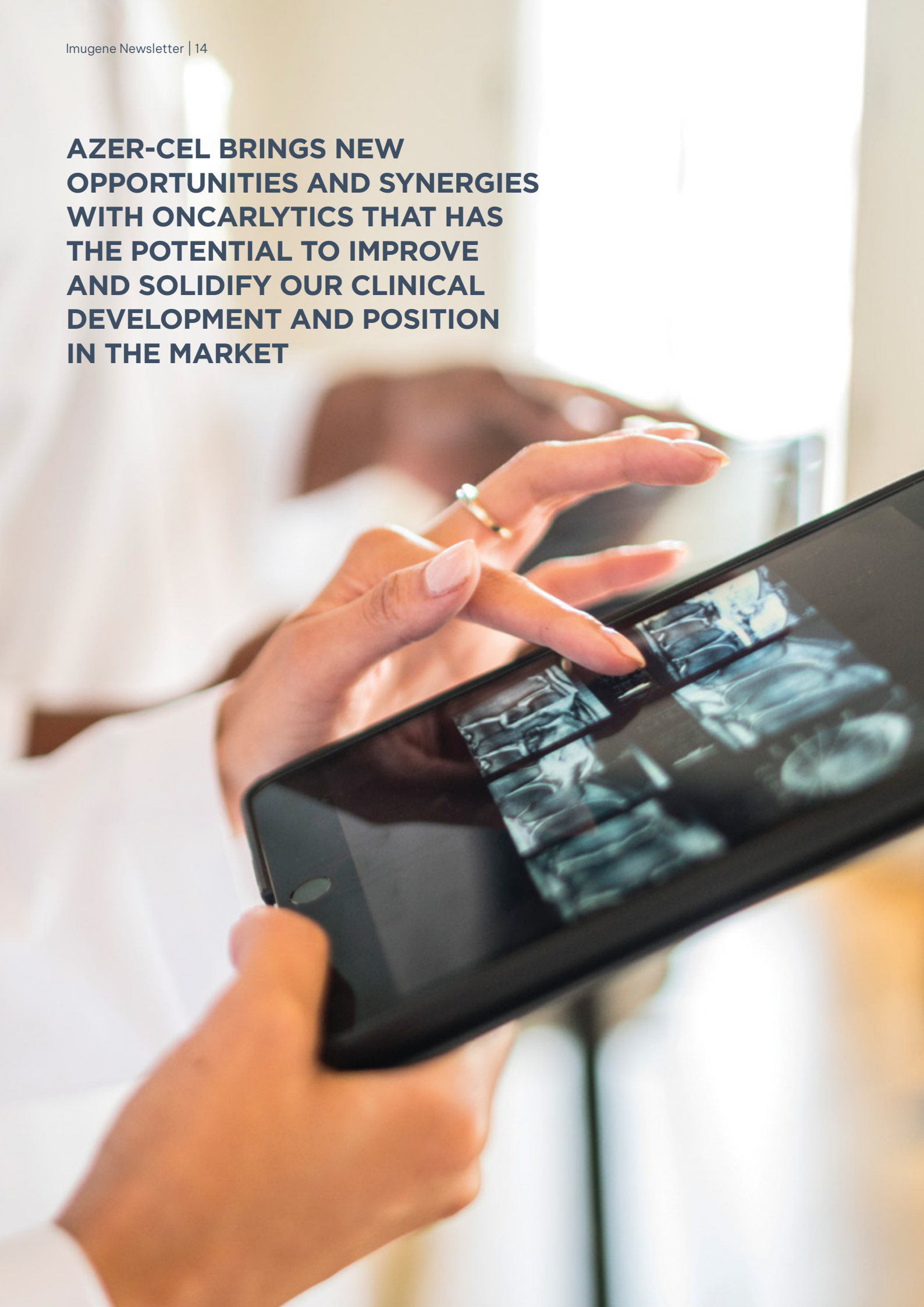
Most recently, Dr Byon served as Vice President of Clinical Development in Hematology and subsequently in acute myeloid leukemia (AML) at Fate Therapeutics. Here, he directed the clinical strategy for the Hematology portfolio, which comprises five assets in B-cell malignancies, AML, and Multiple Myeloma. He provided oversight for all ongoing Hematology trials as well as playing a pivotal role in restructuring the Clinical Development team.

Before his tenure at Fate, Dr Byon was the Senior Medical Director, Head of Clinical Science at Lyell Immunopharma. In this capacity, Dr Byon led clinical strategy development for portfolio assets, established the internal clinical science function, and represented clinical development in joint collaborations.

Additionally, Dr Byon served as Senior Medical Director at Juno Therapeutics, where as the Global Clinical Development Lead he was instrumental in the clinical development of orvacabtagene autoleucel (orva-cel/ JCARH125) for relapsed/refractory multiple myeloma and other novel CAR T-cell targets.

He also assumed various Medical Director roles over a four-year span at Genentech, focused largely on managing clinical development activities for Tecentriq® (Atezolizumab) in various haematological malignancies. During this period, he conceptualized new clinical trials and represented the company at global advisory board meetings.

**AZER-CEL BRINGS NEW OPPORTUNITIES AND SYNERGIES WITH ONCARLYTICS THAT HAS THE POTENTIAL TO IMPROVE AND SOLIDIFY OUR CLINICAL DEVELOPMENT AND POSITION IN THE MARKET**





## FROM THE CHAIR

Paul Hopper  
Executive Chairman

**In the several months since our last newsletter, your company has taken further key steps in its mission to make a difference for cancer sufferers.**

First and foremost, it was a coup for Imugene to complete the acquisition of Azer-cel, and we expect this will prove a transformational step in the evolution of the company. Azer-cel brings new opportunities and synergies with onCARlytics that has the potential to improve and solidify our clinical development and position in the market. With the acquisition comes a very talented and well credentialed team and a state-of-the-art manufacturing facility in North Carolina. The US team who has and will continue to develop Azer-cel shares our passion for innovation and excellence, and together we look forward to fulfilling the promise and potential of this exciting CAR T.

We recently announced the closure of a Placement and Share Purchase Plan which raised \$53.2 million, and this garnered solid participation from our existing shareholders.

I would like to take this moment to express my thanks to our shareholders for your support, in the face of difficult conditions for biotech investment markets, and in particular our own share price, which has fallen so sharply.

But as Leslie has discussed elsewhere in this newsletter, Imugene is in good shape with a solid balance sheet and promising assets, so it is difficult to understand the negative sentiment reflected in the low share price.

Your investment in Imugene is important to the Board, and we are fully aware of the responsibility this brings to us and the management team. We are all deeply committed to achieving a return to a more favourable share price.

As we continue our pace in the MAST study for VAXINIA, and soon begin dosing patients in the Phase 1 onCARlytics trial, we look forward to sharing more milestones and successes with you.



# IMUGENE

Developing Cancer  
Immunotherapies

ASX:IMU

## About

Imugene is a clinical stage immuno-oncology company developing a range of new treatments that seek to activate the immune system of cancer patients to identify and eradicate tumours.

## Contact

[info@imugene.com](mailto:info@imugene.com)

## Connect



[imugene.com](http://imugene.com)

## Financial Snapshot as at 29 September 2023

ASX code	IMU
Market cap	\$330m
52 week high/low	\$0.210 / \$0.046
Cash balance	\$153M (30 June 2023)
Industry	Biotechnology

Note: All figures are in Australian dollars. Market capitalisation calculations based on ordinary shares (7.165b) only and excludes the dilutive impact of options outstanding (0.479b).

## Top 5 Shareholders

Mr Paul Hopper	4.64%
The Vanguard Group, Inc	4.30%
Mann Family	4.22%
State Street Corporation	2.10%
JPMorgan Chase & Co	1.93%