



IMUGENE

Developing Cancer
Immunotherapies

ASX:IMU

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NWR Virtual
Healthcare
Conference

FIRST PATIENTS DOSED IN VAXINIA COMBINATION STUDY

May 2023



**OVER RECENT
MONTHS WE
HAVE BEEN
FOCUSSING ON
THE CLINICAL
DEVELOPMENT
OF VAXINIA.**

Leslie Chong
Imugene CEO & Managing Director

CEO UPDATE

It's a pleasure to provide this most recent newsletter to our shareholders, especially after we recently had the opportunity to present to and meet many of you as part of our non-deal roadshow that saw CF33 Co-Founder Professor Yuman Fong and Imugene Non-Executive Director Dr Jakob Dupont in Australia.

Imugene has continued its meaningful progress over recent months, with a particular focus on the clinical development of VAXINIA.

Phase 1 MAST

The Phase 1 MAST (metastatic advanced solid tumours) trial evaluating the safety of VAXINIA continues to hit its milestones on schedule. The monotherapy dose escalation component of the trial has now dosed the first patients in both the intratumoral and intravenous arms of cohort 3. We were also pleased to announce the commencement of dosing in the combination study, which sees the drug administered along with Pembrolizumab.

We're also expanding the trial to Australian centres and are well advanced towards recruitment in the study overall. We expect to be providing further regular updates on this trial as we move forward.

In between the operational requirements and clinical advancements of the business, it remains a priority for Imugene to be presenting itself and its portfolio to audiences both in the medical and scientific world, as well as to current and prospective investors.

Recent roadshows

Following our first invite to the J.P. Morgan Healthcare Conference to kickstart 2023, we've followed this with the non-deal roadshow across Sydney, Melbourne and Perth, as well as presenting to NWR's virtual healthcare investor conference. I'd like to thank our loyal shareholders for their attendance at these events.

On that note, I'm excited to announce that following the roadshow, Professor Yuman Fong has now been invited to deliver the keynote address at this year's Bioshares Biotech Summit, being held in Hobart in July. This is further recognition of the calibre of Professor Yuman Fong and the science he has developed.

Positive CHECKvacc outcomes

On the medical side, we recently reported positive data and outcomes regarding CHECKvacc that were presented at the American Association for Cancer Research Annual Meeting in Orlando, Florida. Management expects a presence and coverage of Imugene's portfolio and trials at other such conferences and symposiums throughout 2023.

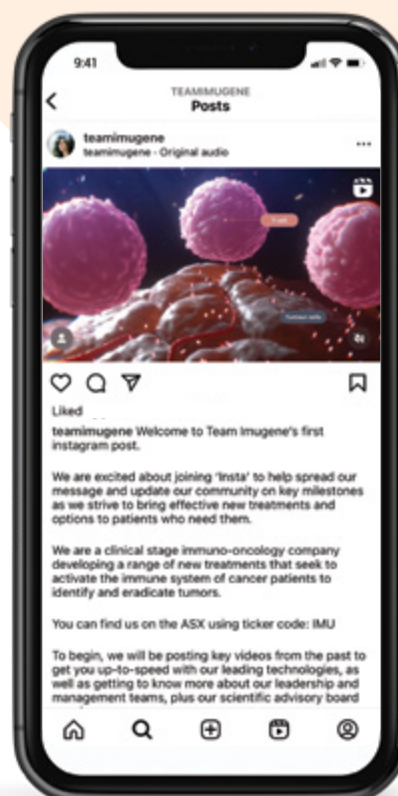
On the topic of CHECKvacc, our Q&A guest for this newsletter is City of Hope breast cancer expert Dr Jamie Rand, who provides some excellent insight into the field of breast cancer and why what Imugene is doing with CHECKvacc is so important.

We've also included a profile on Imugene's Chief Technology Officer Dr Nick Ede, who recently celebrated 10 years with the Company. Nick is incredibly passionate about and dedicated to the Imugene cause, and on behalf of the Board and Management I want to thank him for his decade of service.

As we start to see some positive activity and green shoots in the biotech sector both locally and abroad, we're looking forward to seeing what the remainder of 2023 brings, and again thank our shareholders their continued support of Imugene.

Follow along on Instagram

A final note in terms of shareholder communications is that we now also have an Instagram presence, and invite you all to follow [@teamimugene](#) if you're a user of that platform.



Q&A WITH DR JAMIE RAND

What is your area of expertise?

My areas of expertise are in surgical and immunotherapeutic treatments for patients with breast cancer. I trained in General Surgery at Weill Cornell Medicine–New York Presbyterian Hospital in New York City. During this time, I completed a dedicated two year research fellowship at Memorial Sloan Kettering Cancer Center studying ways to improve response rates to immunotherapy treatments. It was this work that stimulated my interest and excitement about immunotherapy. I subsequently completed a fellowship in Complex General Surgical Oncology at Cedars–Sinai Medical Center in Los Angeles, with an emphasis on breast cancer and melanoma treatments. The goal of my work is to develop novel therapies and technologies to improve the effectiveness of breast cancer treatments and improve the quality of life for breast cancer survivors.

In your opinion why is immunotherapy critical for those diagnosed with TNBC

Historically for advanced cancers, once the cancer had spread beyond its site of origin it was no longer considered curable. There were therapies that could stabilise the disease for several years or slow spread, but unfortunately the disease would eventually outgrow these therapies. Immunotherapy has changed this thinking for many types of cancer and is really the only treatment type that is capable of resulting in a cure for patients with metastatic cancer. Triple negative breast cancer (TNBC) is an aggressive form of breast cancer with high rates of recurrence and distant spread. Unfortunately for TNBC, the currently available immunotherapy agents alone have very low response rates (less than 10%). Therefore, TNBC needs better immunotherapy treatments in order to be able to cure patients with this aggressive disease.

Why is the work of Imugene so important?

The work of Imugene is so important because the team is working to find novel types of treatment to harness the immune system to fight cancer. Imugene has made it possible for us as clinicians to bring these novel cancer fighting agents to patients, providing a new avenue for treatment that was otherwise not possible and providing the chance of a cure for patients with advanced cancers.

Dr Jamie Rand, M.D., is an assistant professor in the Division of Breast Surgery, Department of Surgery at City of Hope (COH). Dr Rand is the lead investigator of the CHECKvacc Triple Negative Breast Cancer Investigator Sponsored Trial at COH.

What are you passionate about?

I am passionate about improving quality of life and outcomes for patients with cancer. My mother was diagnosed with a rare and aggressive type of sarcoma during my first week of my Complex General Surgical Oncology training. I unfortunately watched her go through chemotherapy after chemotherapy with no tumour response, as there is currently no good treatment for her type of cancer, and unfortunately the available immunotherapy agents had no efficacy either. My goal is to make sure as few people as possible have to go through this same experience by creating better therapies that can cure these aggressive cancers.

What is your favourite thing to do outside of work, in your free time?

My favorite thing to do outside of work is to spend time with my family and friends. I have an amazing, supportive husband and two daughters, ages four and two, who are a lot of fun. In my free time, I also enjoy running and taking spinning classes.



US PATENT FOR PD1-VAXX

In February we were glad to receive a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) regarding our B-cell activating immunotherapy PD1-Vaxx.

The patent titled “Human PD1 Peptide Vaccines and Uses Thereof” protects to 2038 the composition of matter and method of treatment in cancer of Imugene’s PD1-Vaxx for the generation of a therapeutic antibody response against the programmed death-1 (PD1) checkpoint target.

Our team is currently in the final stages of preparation for a clinical trial combining PD1-Vaxx in combination with Atezolizumab (Tecentriq®), an immune checkpoint inhibitor (ICI) targeting PD-L1, in patients with non-small cell lung cancer (NSCLC).

The objectives of the phase 1b trial, “An Open Label, Multi-Center, Dose Escalation/Expansion, Phase 1

Study of IMU-201 (PD1-Vaxx), a B-Cell Immunotherapy as monotherapy or in combination with Atezolizumab, in Adults with Non-Small Cell Lung Cancer,” are to determine safety, efficacy, and optimal dose of PD1-Vaxx in combination with Atezolizumab as either first-line therapy in ICI treatment-naïve NSCLC patients or ICI pre-treated patients. The study will be conducted at sites in both the USA and Australia.

PD1-Vaxx is a B-cell activating immunotherapy, currently in clinical development for NSCLC. It is designed to treat tumours by interfering with PD-1/PD-L1 binding and interaction, causing an anti-cancer effect similar to that of other immune checkpoint inhibitor monoclonal antibodies such as Tecentriq®, Keytruda®, and Opdivo®, which are revolutionising cancer treatment.

Given the USA is the largest healthcare market in the world, the new patent is particularly important for securing our intellectual property and protecting our PD1-Vaxx technology as we continue its development.

VAXINIA

FIRST PATIENTS DOSED IN VAXINIA MAST TRIAL COMBINATION STUDY AND MONOTHERAPY IT & IV COHORT 3

We were pleased to provide another update on the progress of our Phase 1 MAST (Metastatic Advanced Solid Tumours) study evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA).

In recent months, the study has progressed rapidly to see the first patients dosed in the intravenous (IV) and intratumoral (IT) cohorts of CF33-hNIS in combination with Pembrolizumab, as well as the first patients in the intravenous (IV) and intratumoral (IT) arms in cohort 3 of the monotherapy dose escalation trial. These are exciting advancements in the development of our VAXINIA virus.

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.

The clinical trial is titled “A Phase I, Dose Escalation Safety and Tolerability Study of VAXINIA (CF33-hNIS), Administered Intratumorally or Intravenously as a Monotherapy or in Combination with Pembrolizumab in Adult Patients with Metastatic or Advanced Solid Tumours (MAST).”

Our plans are to recruit up to 100 patients across approximately 10 trial sites in the United States and Australia. The trial commenced in May 2022 and is anticipated to run for approximately 24 months while being funded from existing budgets and resources.

Still being less than 12 months since the very first patients were dosed as part of the monotherapy dose escalation trial, we have made significant progress in gathering the essential data necessary to report on the study’s outcomes. We remain very positive regarding the potential benefit to patients.

DR NICK EDE'S 10 YEARS AT IMUGENE

In the first of a series of staff Q&A's, we caught up with Imugene's longest serving employee Dr Nick Ede, Chief Technology Officer at Imugene who has served 10 years with the company.

Dr Nick Ede has over 30 years of peptide vaccine and drug development experience. He was formerly CEO of globally recognised peptide and drug development service company Mimotopes Pty Ltd. Prior to that he was VP Chemistry at Chiron Corp (now Novartis) heading medicinal and combinatorial chemistry programs, and was a Research Fellow with the Cooperative Research Centre (CRC) for Vaccine Technology pioneering infectious disease and cancer peptide vaccines.

Why did you initially join Imugene?

Paul Hopper, who I'd met in 2012, was in-licensing HER-Vaxx from the Medical University of Vienna, and given it's a peptide vaccine, I was excited about the opportunity to continue my quest to develop them, which had started with Professor David Jackson at University of Melbourne back in 1994 at the CRC for Vaccine Technology.

What does the role of Chief Technology Officer entail?

Initially in 2013 it was just me and Paul, then we were lucky enough to bring Leslie Chong on board in 2015 from Genentech, but it was still just Leslie and I for a couple of years. Being just the two of us, I had to become proficient at all aspects of running an ASX listed biotech. I've joked that I'm a "jack of all trades, master of none". Whilst I have a chuckle at that description, the beauty of Imugene is that I've learnt from the best, starting with Paul and Leslie, but now expanded to a world-class team of drug developers. Currently, my main role is to look after everything preclinical including R&D, and critical manufacturing of our precious vaccines and oncolytic viruses. I also manage all of our intellectual property and patents, which are important assets of our company.



Photo credit: Jon West Photography

What has been the most memorable moment in your 10 years at Imugene?

From where we started in 2013 there have been so many! I do remember fondly that despite all the lock-downs of 2020, we got our FDA IND for PD1-Vaxx and dosed our first lung cancer patients. One of those dosed in December 2020 is still alive and cancer free today. That's special.

Why Cancer Immunotherapies?

Immunotherapy is the fourth pillar of cancer treatment (after surgery, chemo and radiation). It's just so exciting that after 100 years of hit and miss research, the last decade has realised that the immune system can in fact be trained and modulated to fight back and eradicate cancer. The challenge is to make those wonderful complete responses durable, something I think we are already demonstrating with our immunotherapies.

What do you like to do for fun outside of work?

Sailing and in particular racing yachts is my passion. As per the photo above, racing Lasers keeps me fit and refreshed. My Laser is called "I'm Eugene" and with our logo on the side, I can live, breath and promote Imugene 24/7.

What is your favourite travel destination?

I've been lucky that my career in science has taken me to many beautiful and exciting places. I do love London and Vienna though.



FROM THE CHAIR

Paul Hopper
Executive Chairman

Dear Shareholders,

In addition to the update from our CEO and Managing Director Leslie Chong, I'm pleased to provide some further commentary following the start of Imugene's year.

First and foremost, I want to thank those of you who engaged with us during our successful roadshow in March. Alongside Professor Yuman Fong, our Non-Executive Director Dr Jakob Dupont and Leslie Chong, we had a very positive week of engagement while also having the opportunity to present to some parties newer to the Imugene story. The questions and feedback were invaluable, and we appreciate your continued support and interest.

Since I wrote to shareholders to begin the calendar year, it's also pleasing to report on some of the 'green shoots' and positive signs of growth and success recently emerging in the biotechnology sector. Locally we've seen inflection points for companies reaching FDA approvals and revenue milestones, while abroad there's been M&A activity that shines a light on the value being placed on biotechnology companies with the right strategy.

At Imugene, we're committed to advancing a promising strategy in our own right. The focus is on advancing our pipeline of promising immuno-oncology treatments, and we're eager to deliver further clinical trial results as soon as is practically possible.

Once again to our shareholders, thank you for your continued support and investment in Imugene. We remain confident in the potential of our people, company and the industry as a whole, and look forward to delivering on our promise to help patients through high quality science and innovation.

PRESENTATION TO NWR VIRTUAL HEALTHCARE CONFERENCE

Our Managing Director and CEO, Leslie Chong, presented at the NWR Virtual Healthcare Conference on 22 March 2023.

The conference provided a platform for us to showcase our innovations in the field and engage with key stakeholders in the healthcare and biotech investment landscape.

The presentation covered our unique technology platforms including B Cell Immunotherapy and onCARlytics, the ongoing clinical program and key mechanisms involved in each study.

The replay of this presentation can be found at the following link:
<https://youtu.be/qQkAHmDTLeM>

NON-DEAL INVESTOR ROADSHOW WITH PROFESSOR YUMAN FONG & DR JAKOB DUPONT

In March, we were excited to host a roadshow where shareholders and prospective investors had the opportunity to hear from the co-inventor of our onCARlytics platform Professor Yuman Fong, alongside Non-Executive Director Dr Jakob Dupont.

The event saw Professor Fong and Dr Dupont presenting to a combined audience of over 350 investors across Melbourne, Sydney and Perth. Imugene's Executive Chairman Paul Hopper and Managing Director and CEO Leslie Chong also presented to the attendees.

We're planning to host our next roadshow in July 2023, and will be in contact via our email and social media channels with the full details in due course.





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

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Connect



imugene.com

Financial Snapshot as at 30 April 2023

ASX code	IMU
Market cap	\$835m
52 week high/low	\$0.315 / \$0.12
Cash balance	\$152M (31 Mar 2023)
Industry	Biotechnology

Note: All figures are in Australian dollars. Market capitalisation calculations based on ordinary shares (5.866b) only and excludes the dilutive impact of options outstanding (0.368b).

Top 5 Shareholders

JP Morgan Nominees Australia Pty Limited	9.09%
HSBC Custody Nominees Australia	5.36%
Paul Hopper	4.94%
Richard Mann and Assoc.	4.60%
Citicorp Nominees Pty Limited	4.60%