IMUGENE
Developing Cancer Immunotherapies

ASX: IMU

Newsletter April 2020

THANK YOU FOR HELPING RAISE $24.6 MILLION IN OUR RECENT PLACEMENT

03

COVID-19 PANDEMIC

We acknowledge that these are unprecedented times in light of the global COVID-19 pandemic.

We at Imugene are implementing strategies for business continuity and risk mitigation so that we can continue our planned activities. We are working closely with our clinical operations partners to ensure the needs of our clinical trials are met whilst ensuring their safety and the safety of our patients. We are grateful that we have the capital to weather this medical, social and economic crisis.

Stay Healthy, Be Kind and try to be Helpful in this very trying and unusual time.

CEO UPDATE

In our last newsletter we brought you up to date on our relationship with renowned surgeon and scientist Professor Yuman Fong and the remarkable research he has undertaken for the development of the cancer fighting oncolytic virotherapy called CF33.

As we told you at the time, we thought CF33 would give us a leading edge in the immuno-oncology biotechnology space. We needed your vote to proceed and in that regard at the recent EGM, you unanimously supported us.

On behalf of the board and the company may I extend a heartfelt thank-you for your confidence.

It was a decision that I believe will lay a new cornerstone in the development of our company.

We are still actively progressing our research and trials in our B-Cell immunotherapy programs but we have bolstered our overall development path by the inclusion of Professor Fong's oncolytic virotherapy platform.

To say we are excited is an understatement.

To give you an example and reinforcement of our enthusiasm, one of our competitors, Turnstone Biologics, recently cemented a $US 120 million up front payment, co-development and commercialisation and $US 900 million in milestones, a deal worth well over $US 1 billion with pharmaceutical giant Takeda.[1]

Turnstone's early stage oncolytic virotherapy research is being combined with Takeda's immuno-oncology research and like our aspirations and commitment to Professor Fong's work, we are progressing along the same path with an eye open to any synergistic opportunities that may arise with a pharmaceutical partner.

Drawing a parallel between both developments is not unrealistic and to strengthen our current team of scientists we have negotiated with and brought aboard a team of clinical developers from Viralytics, the Australian company absorbed by Merck for half a billion dollars, two years ago.

On the practical side of the equation the most common question posed to me by potential investors is, "do you have the funds to carry out this research?"

The answer is yes.

1. Source: https://www.fiercebiotech.com/biotech/turnstone-teams-up-takeda-900m-deal-to-work-biotech-s-oncolytic-cancer-drug

Thanks to your generosity and wisdom we raised $24.6 million in our recent placement.

Accordingly, we will this year be progressing Phase 1 trials for our work with CF33 and PD1-Vaxx, the anti-PD-1 B-Cell immunotherapy trial into lung cancer.

Concurrently we will continue enrolling into the Phase 2 trial for our work with HER-Vaxx in the fight against gastric cancer. More on both these developments later in this note.

There is one field that I will draw your attention to in brief and that is the issue that no form of oncolytic virotherapy has as yet been discovered that can be delivered via intravenous injection. It is the Holy Grail of our sector. Are we working towards such? Yes. Data from our work with CF33 shows promise in that regard. Just one of the many new attributes our joint efforts with Professor Fong and his team are bringing to the Imugene table.

We carried the company flag to industry gatherings including the European Society of Oncology (ESMO) Congress in Spain and the ESMO Asia Congress in Singapore.

Excitingly for both Imugene and our SAB member and PD1-Vaxx inventor Professor Pravin Kaumaya, he has been nominated by the Ohio State University Office of Research as a finalist for OSU's 2019 Innovator of the Year Award. Pravin will find out if he has won this prestigious award in early April. We are very proud of his efforts and wish him well.

Signing off for the moment, I hope you find the balance of this newsletter to be both informative and progressive in explanation of our efforts to continue the good fight against cancer and equally, justify your faith and investment with us.

"Innovation isn't inventing something new, it's making things better, safer, and faster; that's where innovation is going".

LESLIE CHONG
IMUGENE CEO

THE ROAD FORWARD

We've not been resting on our laurels since we affirmed our relationship with Professor Fong and his remarkable technology. We are in the process of establishing human trials for 2 constructs of our CF33 technology as well as our B-cell immunotherapy cancer vaccine we call PD1-Vaxx.

CF33

In November we acquired Vaxinia Pty. Ltd. and the worldwide license for CF33, developed in Professor Fong's lab at The City of Hope Cancer Research Centre in Los Angeles.

It's what's known as a chimeric vaccinia pox virus. It's a cancer fighting virus that recombines multiple strains of the vaccinia virus as well as other species of pox virus. In straightforward language it accordingly has much better cancer fighting qualities than a single strain virus.

Pre clinical data has shown that CF33's two constructs, CHECKvacc and VAXinia, shrank injected and equally as important, distant tumours not directly targeted but in the metastatic spread.

Many indications were targeted, including triple negative breast cancer, colon cancer, lung cancer, pancreatic cancer and ovarian cancer. The results were more than encouraging, showing superior replication and subsequent killing of cancerous cells as well as an indication that they are more potent than other existing viruses used in the fight against cancer.

With the positive pre-clinical data to hand we are in the latter stages of establishing two Phase 1 human trials for CHECKvacc and VAXinia. Both contain what is known as a functioning human iodide symporter gene that enables the virus to be tracked in the body and also allows radioiodine therapy as an adjunct support.

In addition, CHECKvacc is armed with a checkpoint inhibitor anti-PD-L1 protein that wakes up the body's immune system to join the fight.

With VAXinia, the company will shortly launch a human Phase1/2, open label, non-randomised dose escalation study investigating intratumoural and intravenous administration lines for the virus.

The trials will be conducted at eminent cancer research centres in the United States, including City of Hope Cancer Center where Professor Fong and his team are based, and the current proposed patient population includes those with metastatic lung, TNBC, melanoma, bladder, GI, head and neck, colorectal cancers refractory to standard therapy or for which no standard therapy exists for the first phase of the study.

The primary focus of the phase 1 trial will be to determine safety and obtain signals that may include efficacy in multiple tumour types; establish a maximum feasible dose for possible further combinations with immune checkpoint inhibitors as an indication to move into Phase 2 clinical trials. The Phase 1 trial will also involve a dose escalation to evaluate intratumoural and intravenous delivery.

PD1-Vaxx

PD1-Vaxx is a B-Cell immunotherapy cancer vaccine designed to fight cancerous tumours in lung, in a similar fashion and effect as other market transforming immuno-oncology drugs such as Keytruda® and Opdivo®.

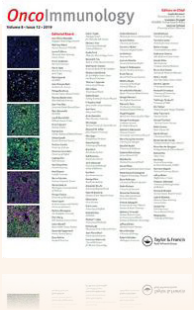
The current PD1-Vaxx trial is targeting non-small cell lung cancer, the most common form of the cancer accounting for 80% of cases. We will be testing three different doses to identify safety, immunological data, and preliminary investigation of an optimal Phase 2 dose for the expansion stage of the study.

Our Phase 1 trial is about to begin and will be at up to 10 cancer research centres within the United States and Australia. These trials are a big step in the right direction. Pre-clinical indication, as positive as it is, is just that, pre-clinical. Moving to human trials is what cancer research is all about. Your Imugene scientists are firing on all cylinders and the evaluating scientists at our various cancer research centres are primed and ready to join us on this tangible and momentous next stage of the company's development.

LATEST PUBLICATION FROM PROF YUMAN FONG

Another ground breaking publication from Imugene's City of Hope colleagues led by Professor Yuman Fong. Triple-negative breast cancer (TNBC) is the most aggressive subtype of breast cancer and is difficult to treat. The study shows that CF33-hNIS-ΔF14.5 (VAXinia) favourably modulates the tumour immune microenvironment in TNBC models making them responsive to immune checkpoint inhibitors and hence warrants further studies to determine the clinical applicability of this combination therapy. VAXinia will enter a Phase 1 clinical trial in 2020.

Read more online: https://www.tandfonline.com/doi/full/10.1080/2162402X.2020.1729300



OUR BIG GUNS

Oncolytic Virotherapy Scientific Advisory Board

In October 2019, the company appointed Professor Yuman Fong, MD, Chair of the Department of Surgery at City of Hope to head up the oncolytic virotherapy (OV) Scientific Advisory Board (SAB).

In November 2019, the company appointed Professor Prasad S. Adusumilli, MD FACS FCCP, Deputy Chief, Thoracic Service; Co-Director, Mesothelioma Program; Head, Solid Tumours Cell Therapy, Cellular Therapeutics Center at the Memorial Sloan Kettering Cancer Center in New York, to the newly formed OV SAB.

Dr Adusimilli is a world-renowned thoracic surgeon with expertise in the diagnosis and treatment of cancers in the chest, lung cancer, esophageal cancer, mesothelioma, and thymoma.

In December 2019, the company appointed Dr Rebecca Auer, MD MSc FRCSC, Associate Professor, Department of Surgery and Department of Biochemistry, Microbiology and Immunology, Faculty of Medicine, University of Ottawa; Surgical Oncologist, The Ottawa Hospital; Tier 2 Clinical Research Chair in Perioperative Cancer Therapeutics University of Ottawa, to its newly formed OV Scientific Advisory Board SAB.

The OV SAB, Prof. Peter Schmid (appointed to Imugene's Scientific Advisory Board in December, 2017) and the OV development team met in New York city in February to discuss the clinical development of CHECKVacc and VAXinia.

Prof Schmid is Chair of Cancer Medicine at the prestigious Barts Cancer Institute at Queen Mary University London. He is also Clinical Director of the Breast Cancer Centre at the St. Bartholomew Cancer Centre and Honorary Consultant Medical Oncologist at Barts Hospital. He leads the Centre of Experimental Cancer Medicine at Barts Cancer Institute and the Barts/Brighton Experimental Cancer Medicine Centre. Prof Schmid's specialist cancer interests are breast and lung cancer, cancer immune therapy and early drug development.

He has successfully led more than 20 national and international academic clinical studies, of which he was the Principal Investigator for the TNBC study for the approval of TECENTRIQ® study for Genentech/Roche.

He is a member of several national and international cancer organisations and research groups. He has authored or co-authored 165 publications and published a book on the management of bone metastases currently in its third edition.

Last but by no means least we have Dr. Len Post acting as senior scientific advisor to our SAB. He is a specialist in the field of oncolytic virotherapy and is currently chief scientific officer for Vivace Therapeutics. His distinguished background includes roles with pharmaceutical companies such as Biomarin, Onyx Pharma, Parke-Davis and Upjohn. We know him here in Australia through his work as a director of Viralytics ltd.

PROF YUMAN FONG

PROF PRASAD ADUSUMILLI

DR REBECCA AUER

PROF PETER SCHMID

WHAT'S OLD IS NEW AGAIN!

As the old saying goes, when you're on a good thing, stick with it. We have a new Oncolytic Virus focused Clinical Development Team made up of our chairman, Paul Hopper, myself and key personnel we have acquired from Viralytics Ltd., arguably the success story of 2018.

They are former Viralytics director Dr. Len Post, Lisa Guttman, Dr. Seymour Fein, Dr. Evan Siegal and Dr. Mike White.

HER-VAXX

Data from our concluded Phase 1B trial showed a potent polyclonal response to HER2/Neu, a readily identifiable cancer target. The preliminary immunology and clinical response data was encouraging indeed. We were able to publish and present this data across various cancer conferences around the world.

We are currently enrolling into the open label Phase2 study and waiting on patients to progress to review the interim safety data. This data will be reviewed by the Independent Data Monitoring Committee (IDMC).

Definition of IDMC: An Independent Data Monitoring Committee ensures the interests of patients entered on the trial are being well-served (i.e., that the risk-benefit ratio is appropriate) and that the scientific integrity of the trial is maintained between trial initiation and completion. A key benefit of IDMC review of trial data is an independent assessment to assure that study participants are not exposed to unnecessary or unreasonable risks as a consequence of their trial participation.

The IDMC is key process by which the highest scientific and ethical standards are maintained in a clinical trial. The IDMC conducts business in "closed sessions" with meetings attended only by members of the IDMC, thereby maintaining independence from the Sponsor. IDMCs analyse ongoing data for randomised studies, including those that involve multiple sites and important clinical endpoints such as survival or disease progression. Ethical principles mandate that clinical trials begin with uncertainty as to which treatment is better (clinical equipoise). This uncertainty is maintained during study conduct.

Independent monitoring of trial data is critical when conducting trials with vulnerable patients, such as cancer patients, as it protects the safety and well-being of patients while enhancing the scientific and ethical integrity of data obtained during the clinical trial. The HER-Vaxx Phase 2 IDMC roster consists of an experienced IDMC chair with immuno-oncology experience, gastric-oncologist and bio-statistician.

FINANCE

Financial Snapshot
(as at April 2020)

ASX code	**IMU**
Market cap	**$88.52M** Apr 2020
Shares on issue	**4.43B**
52 week high/low	**6.3c/1.3c**
Cash balance	**$36.8M** Dec 2019
Industry	**Biotechnology**

Note: All figures are in Australian dollars. Market capitalization calculations based on ordinary shares (4.43b) only and excludes the dilutive impact of options outstanding (1.24b).

Board & management

Directors

Ms Leslie Chong
Chief Executive Officer & Managing Director

Mr Paul Hopper
Executive Chairman

Mr Charles Walker
Non-Executive Director

Dr Axel Hoos
Non-Executive Director

Dr Lesley Russell
Non-Executive Director

Dr Jens Eckstein
Non-Executive Director

Senior Management

Dr Nick Ede
Chief Technology Officer

Dr Mark Marino
Chief Medical Officer

Dr. Anthony Good
Vice President of Clinical Research

Ms Bonnie Nixon
Project Manager

Mr. Phillip Hains
Company Secretary

Mr Justyn Stedwell
Company Secretary

Scientific Advisory Board

Dr Josep Tabernero
President ESMO, Vall d'Hebron University Hospital Spain

Prof Pravin Kaumaya
OSU, USA

Prof Ursula Wiedermann
Medical University of Vienna

Dr Tanios Bakaii-Saab
Mayo Clinic USA

Dr Neil Segal
MSKCC USA

Dr Yelena Janjigian
MSKCC, USA

Prof Peter Schmid
Barts Cancer Institute at Queen Mary University London

Dr Michael Caligiuri
City of Hope, USA

OV Scientific Advisory Board

Dr Yuman Fong
City of Hope, USA

Prof Prasad Adusumilli
MSKCC, USA

Dr Rebecca Auer
Ottawa Hospital, Canada

FROM THE CHAIR

May I say a quick hello to you and bring you up to date on a few key business issues that work in tandem with the great science our Team Imugene innovators are producing.

Firstly, our financial standing.

We are healthy indeed. Last December we raised $24.6 million from sophisticated and professional investors. It in fact was over-subscribed. As at December 31, 2019 we had $36.8 million in the bank. Whilst the primary focus of your company is science driven, Leslie and I keep a weather eye open on the movements and potential of a synergistic relationship with Big Pharma.

Not withstanding the medical, social and economic turmoil being generated by the current pandemic, we remain focused on our core business. Our science shows great promise, our team is outstanding, our collaborations are blue chip, and our balance sheet is strong.

What the future brings is conversation for another day. For now, know that your company is in robust financial health matched only by the incredible work flowing from our scientists.

PAUL HOPPER
CHAIRMAN

IMUGENE
Developing Cancer Immunotherapies

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.

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