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 tumors.

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Newsletter June 2019

VISIONARY: PROFESSOR MICHAEL CALIGIURI HAS JOINED TEAM IMUGENE.

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UPDATE FROM THE CEO

Welcome to our first newsletter for 2019 and thank you for making time to read about our progress.

With our recent positive clinical results, we are moving confidently towards several significant milestones over the coming quarters.

It is nearly one year since we acquired the promising cancer vaccine research work and intellectual property built over more than a decade by the team at Ohio State University Comprehensive Cancer Centre and The Mayo Clinic.

These programs are now fully integrated into our development schedules with the full resources of our team focused on rapidly advancing these highly promising therapies.

Behind the scenes, it is worth noting we have secured a reliable, FDA-compliant, cost effective manufacturer to guarantee supplies of all our candidates for our clinical programs.

We continue to build a world-class team and in this edition we welcome Professor Michael Caligiuri, President of the prestigious City of Hope National Medical Centre in California.

Our Board has also been bolstered with two highly credentialed international drug development experts and innovators, Dr Lesley Russell and Dr Jens Eckstein.

The focus of management and the Board over the coming quarters will be our Phase 2 trial of HER-Vaxx in patients with gastric cancer and the start the Phase 1 study for PD1-Vaxx in lung and potentially multiple cancers at clinical sites in the US, Australia and UK.

The excellent efficacy and safety data from the HER-Vaxx Phase 1 study has attracted strong international attention and is highlighted in this edition.

Our Phase 1 PD1-Vaxx PD-1 cancer vaccine study is advancing after a positive guidance meeting with the US Food & Drug Administration. Pre-clinical experiments and toxicology studies have commenced and a protocol synopsis is being finalised.

Our B-Vaxx Phase 2 study is recruiting to schedule at participating trial sites.

You may have also noticed our new website and enhanced social media presence. I encourage you to bookmark both so you don't miss our progress.

Imugene is in a great position. We have a well resourced and experienced management team focused on advancing our pipeline of potentially revolutionary cancer therapies through the clinic under the guidance of a world class scientific advisory board. Together we are supported by a Board with industry experience and proven international commercial success.

We look forward to providing you with further updates as we continue to execute our strategy and create shareholder value by delivering effective new cancer therapies to global markets and the people who need them.

LESLIE CHONG
IMUGENE CEO

NEW SCIENTIFIC ADVISORY BOARD APPOINTMENT

Meet Professor Michael Caligiuri
President – City of Hope National Medical Centre, California USA

Imugene is fortunate to have one of the most credentialed and respected scientific advisory boards assembled for cancer immunotherapy. Every member is an international leader who has dedicated their working life to the advancement of new cancer therapies.

Our latest member is Prof Michael Caligiuri, a world-renowned physician, scientist, researcher, and visionary.

For 20 years, Dr Caligiuri has worked as a physician and research leader in the cancer program at Ohio State University. He was formerly the CEO of The James Cancer Hospital and Solove Research Institute and directed the Ohio State University Comprehensive Cancer Center for 14 years, recruiting over 300 cancer physicians and scientists. Dr Caligiuri was elected to the US National Academy of Medicine's Class of 2018 for his breakthrough discoveries in leukemia and cutaneous T cell lymphoma.

He is also the immediate-past president of the American Association for Cancer Research (AACR), the world's largest cancer research organization.

He has helped treat more than 1,500 cancer patients on clinical trials he developed or co-developed.

At City of Hope, Dr Caligiuri describes his goals as working to "speed up the delivery of our discoveries in the laboratory to our patients, to use my inclusive leadership style to foster greater collaboration across the institution and with other institutions, and to optimize the patient care system to ensure the highest quality and safest patient experience."

INTERESTING FACT...

Dr Caligiuri is an active supporter and participant in the US-based cancer research effort called Pelatonia an annual cycling initiative that has raised US$184 million for cancer research since 2009 for the Ohio State University Comprehensive Cancer Centre.

Find out more about this incredible organistion at pelotonia.org

PELOTONIA
08.02.19 → 08.04.19

CLINICAL DEVELOPMENT AND PROGRESS

Positive HER-Vaxx Phase 1b Gastric Cancer Study

We have completed the Phase 1b study of HER-Vaxx (IMU-131) plus chemotherapy in patients with HER2/Neu over-expressing advanced stomach cancer (NCT02795988).

Investigators noted the preliminary immunology and clinical response data as "very promising". They found IMU-131 was well-tolerated with no significant local or systemic reactions and there was no need for pre-treatment or for modification to the dose or treatment schedule due to safety.

The study was conducted at 14 sites in Georgia, Hong Kong, Moldova, Taiwan and Thailand to determine the safety and tolerability of IMU-131 and identify the recommended Phase 2 Dose in combination with chemotherapy. The objectives also included:

- Collection of humoral and tumoral immunogenicity data to further explore the mechanism of action for anti-tumor effects
- Radiographic data to determine clinical response including best overall response and change in tumor size according to the standard response evaluation criteria in solid tumors (RECIST) 1.1 guidelines.

The recommended dose for Phase 2 was defined as the dose resulting in the best safety, tolerability and immunology results (antibody production) and was determined after all dose cohorts had completed day 56 of the study and an interim analysis of the Phase 1b data had been conducted by the cohort review committee.

Several patients continue to be treated as part of the long-term maintenance phase of the study to continue receiving IMU-131 with booster doses from day 98 (14 weeks).

Each patient was administered three injections of IMU-131 (P467-CRM197-Montanide emulsion), at a single dose level on days 0, 14 and 35, accompanied by chemotherapy cycles every 21 days starting from day 14.

Chemotherapy was ceased by the investigator when clinically indicated for the care of the patient. Patients were discontinued from the study and ceased IMU-131 vaccinations when there was documented evidence of disease progression according to the RECIST 1.1 criteria or if unacceptable toxicity occurred.

The design included three doses with up to six patients per dose cohort with a maximum number of 18 patients. Interim analysis of the Phase 1b study data was conducted after all patients had completed the study up to day 56 (eight weeks).

14 patients were enrolled. Three patients in the first cohort received 10 µg (micrograms), six patients in the second cohort received 30 µg and five in the third cohort received 50 µg.

All 14 patients were included in the safety population of which 11 (78.6%) patients completed the treatment period per protocol. Three (21.4%) patients discontinued treatment and 10 (71.4%) discontinued the study.

At the time of interim analysis, one patient in the second cohort and three patients in the third cohort continued participation in the study.

Of the 14 enrolled, 11 were evaluable for tumor progression assessment per the RECIST 1.1 guidelines. The best overall response during the study participation period to date is one complete response, five partial responses, four saw a stabilization of their disease and one saw their disease progress.

Of the 11 patients evaluable at day 56, one patient had 'non-target lesions' leaving 10 patients evaluable for change in tumor size per the RECIST 1,1 guidelines. Encouragingly, two of the three patients dosed with the recommended Phase II dose of 50 µg demonstrated greater than 40% reduction in tumour size from baseline to day 56 and all 3 patients remain on the study (See Figure 1).

The 50 µg dose of IMU-131 produced the most consistent p467 specific antibodies and HER-2 specific antibodies compared to the 10 and 30 µg doses with preliminary response data demonstrating 50 µg IMU-131 was

also associated with reduction in tumor size and 50 µg dose is the RP2D to be used in the phase 2 expansion cohort (see Figure 2).

The adverse events observed in this study were expected and consistent with those known to occur with the concomitant chemotherapy. The researchers believe the adverse events across the treatment groups were balanced.

No dose limiting toxic effects were observed and there were no events leading to study drug discontinuation. Clinical laboratory findings including vital signs, electrocardiogram and physical examinations were unremarkable and did not impact the overall safety results.

Figure 1: Phase 1b best response change in tumor size (%) from baseline visit

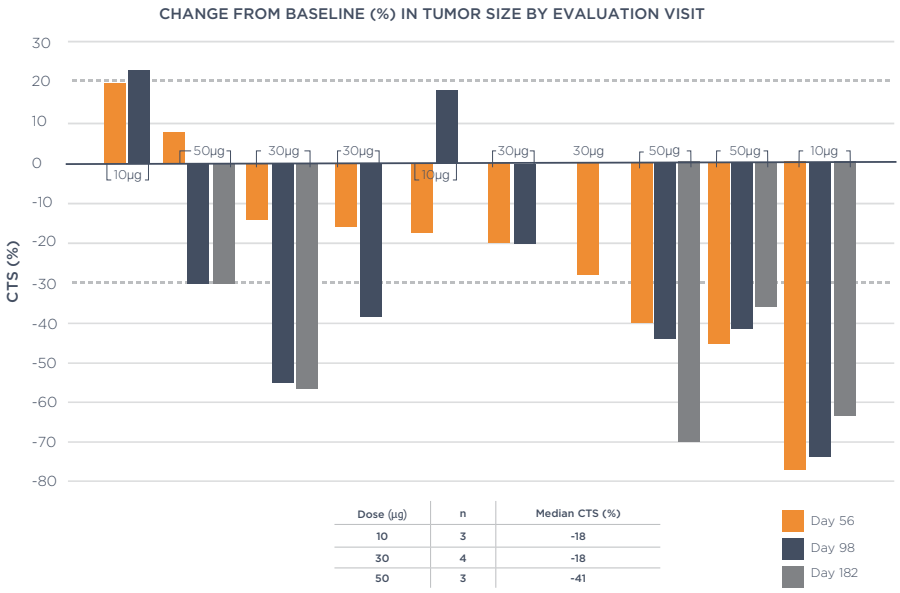
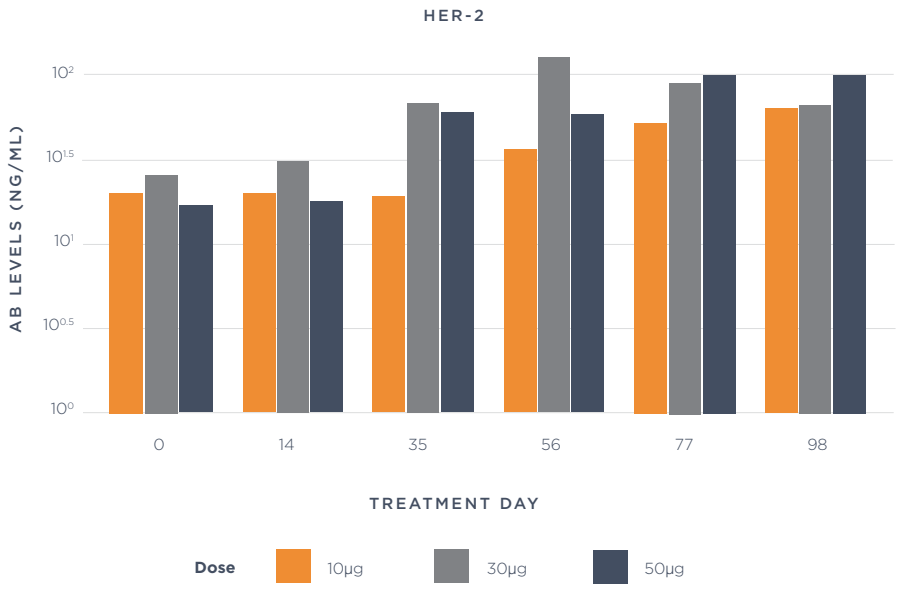


Figure 2: HER2-specific IgG ANTIBODIEs in Cohort 1, 2, and 3 measured in sera obtained at treatment visits.



All 14 patients reported adverse events with majority of the events assessed as Grade 1 to three severity and were not related to IMU-131.

HER-VAXX PHASE 2 STUDY IS NOW ACTIVELY RECRUITING WITH PATIENTS DOSED

The big news recently was the start of our 68-patient Phase 2 HER-Vaxx trial. This is a very important development milestone for Imugene's leading clinical program.

The 68-patient, open-label, randomised, multi-centre study with HER-Vaxx is now actively recruiting HER-2 positive gastric cancer patients.

The first patient was dosed at the Oncological Institute in the city of Chisinau, the capital of Moldova, in Eastern Europe.

The institute is Moldova's leading cancer treatment and research centres.

The site is one of several in Eastern Europe and Asia where there are often fewer options for some cancer patients. The incidence of gastric cancer is higher in the local populationdue to range of factors.

Interest among participating treatment sites and medical investigators is high following publication of the promising Phase 1b study results.

We selected HER-2 positive gastric cancer as this type of cancer is not nearly as well served as HER-2 positive breast cancer. It is also potentially more severe and harder to treat than breast cancer meaning a potentially strong market need for HER-Vaxx.

The Phase 2 study is randomised into two arms. One group receives HER-Vaxx plus standard-of-care (chemotherapy) and the other receives standard-of-care alone.

The clinical endpoints will be safety, immune response, progression-free survival and overall survival.

We look forward to providing you with updates on this exciting and important study.

New 10-page analyst research note

Edison Investment Research has issued a new research note following the release of the positive HER-Vaxx B-cell vaccine data and the start of our Phase II study of HER-Vaxx in gastric cancer.

Edison is a the leading equity research group with a reputation for integrity and credibility. Unlike other commissioned company research, it is widely distributed and read by international investors, advisors and stakeholders.

Imugene is one of many companies in a crowded market competing for investor attention and credible research like this plays an important role in building awareness among investors worldwide.

Importantly, the research is prepared under regulations set out by the UK's Financial Conduct Authority register.fca.org.uk

We recommend all shareholders take time to read this latest report.

Download the document at edisongroup.com or send us an email for a pdf copy.

7 quick facts about gastric cancer

01	It usually begins in the lining in the upper part of the stomach.
02	It occurs most commonly in East Asia and Eastern Europe.
03	It is rare in people under 50 years of age and affects nearly twice as many men as women.
04	The most common cause is infection by the bacterium Helicobacter pylori, which accounts for more than 60% of cases.
05	Genetics, smoking and diet are also factors.
06	The five year survival rate for gastric cancer is 30%.
07	Globally, gastric cancer is the fifth leading cause of cancer and the third cause of death from cancer.

TWO MORE LEADING INTERNATIONAL LIFE SCIENCE EXECUTIVES JOIN THE IMUGENE BOARD

Our potential to revolutionise cancer treatment continues to attract the attention and endorsement of established leaders in oncology drug development.

We were excited to recently announce the appointment of **Dr Lesley Russell** and **Dr Jen Eckstein** to our board as a Non-Executive Directors. We welcome these highly credentialed life science leaders to team Imugene.

LIFE SCIENCE ENTREPRENEUR:

Dr Jens Eckstein founded the world's largest life science accelerator program.

Dr Jens Eckstein is an established international venture investor and active mentor of life science entrepreneurs and start-up teams.

Jens is currently Managing Partner of Apollo Ventures a venture firm focusing on age-related diseases and health span. Before joining Apollo he was president of SROne for eight years. SR One is the corporate venture capital arm of global pharmaceutical giant GlaxoSmithKline which invests in emerging life science companies pursuing innovative science with significant impact on medical care and patients.

Jens is also a founder and co-founder of several innovative life science and health care information technology companies as well as being the creator of OneStart, the world's largest life science and healthcare start-up accelerator program.

Dr Eckstein brings more than 15 years of venture capital funding of earlier-stage biopharmaceutical companies, technology transfer, operational and research management experience in drug discovery and biotechnology.

He has served on the boards of several listed and private biotechnology companies including Palleon Pharma, Gladius Pharmaceuticals and Decibel Therapeutics.

He has served on the boards of ZappRx, Thrasos Therapeutics and Alios Biopharma (acquired by Johnson & Johnson in 2014).

Jens is a Kaufman Fellow, founder of Action Potential Venture Capital (APVC) and has held senior roles with the trans-Atlantic venture capital firm TVM Capital.

In addition, he holds several issued patents and has authored over 25 scientific publications. He earned his Doctorate, summa cum laude, in Biological Chemistry in at the University of Konstanz and Harvard University.

CLINICAL DEVELOPMENT EXPERT:

Dr Lesley Russell brings additional global drug development and operational experience to our Board.

Dr Lesley Russell has extensive knowledge and experience with new drug development and strategic joint ventures will greatly enhance the Board's mix of skills and help advance our promising cancer vaccine pipeline.

She brings more than 25 years of senior international operational and leadership experience with some of the world's leading pharmaceutical companies including Amgen, Eli Lilly, Teva, and Cephalon.

She is a Non-Executive Director of several NASDAQ listed companies and has extensive operational experience with dozens of new drug clinical trials.

Over the course of her career, she has submitted more than a dozen new drug applications and supplemental new drug applications to the US Food and Drug Administration.

Dr Russell has broad expertise leading clinical research initiatives to develop innovative pharmaceutical products and has particular strength in oncology.

At Cephalon Inc, she was responsible for managing all clinical, medical, regulatory, drug safety and biometrics matters. She oversaw the design, implementation and conduct of Cephalon's global clinical trial program as well as medical affairs and scientific communications.

Before joining the pharmaceutical industry, Dr Russell was trained in Hematology Oncology at the Royal Infirmary of Edinburgh and Royal Hospital for Sick Children Edinburgh UK and received her MB ChB from the University of Edinburgh, Scotland, Faculty of Medicine. She serves as a member of the Royal College of Physicians, UK and is registered with the General Medical Council, UK.

Professional and industry interest in our work

Cancer specialists around the world are watching the progress of our revolutionary B-cell cancer vaccine strategy

The scientific and medical credibility of our work is reflected in the multiple invitations we receive to publish and present our clinical results at the leading international meetings.

The selection process to present at these meetings is rigorous and competitive.

Receiving an invitation is acknowledgement by an independent expert committee that our clinical data and work is significant and should be promoted.

Over the past few months, our collaborators at Ohio State University, the Mayo Clinic and Medical University of Vienna have made multiple presentations.

In February, data from our Phase 1 B-Vaxx were published in the prestigious American Association for Cancer Research journal Clinical Cancer Research.

In April, the data from the early HER-Vaxx and PD1-Vaxx studies was highlighted in four presentations at the prestigious American Association for Cancer Research (AACR) annual meeting.

You can see the posters presented at imugene.com

In June, new data from the HER-Vaxx Phase 1b study will be showcased at the American Society for Clinical Oncology (ASCO) in Chicago in June.

ASCO is the world's largest clinical cancer research meeting and brings together more than 45,000 oncology professionals. ASCO's purpose it to educate and advance the practical knowledge of cancer physicians and healthcare professionals in the field of clinical oncology.

In July, further new data from the Phase 1b HER-Vaxx study will be featured in an oral presentation to attendees at European Society of Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer in Barcelona, Spain.

The annual ESMO meeting is also focused on professional development and highlighting the latest clinical advances to improve outcomes for people living with gastrointestinal cancer.

Both presentations will be available on the publications page of our website.

PD1-VAXX MANUFACTURING UPDATE

PD1-Vaxx is a peptide vaccine which aims to enable a patient's immune system to fight cancer. It is one of the new additions to our pipeline from Ohio State University and is currently being readied for Phase 1 clinical trial.

Dr Elizabeth Mittendorf, the Robert and Karen Hale Distinguished Chair in Surgical Oncology at the Brigham and Women's Hospital has stated "Peptide vaccines have the benefit of being easy to construct and manufacture on a large scale, they're inexpensive, and very importantly they are off-the-shelf therapy".

In technical terms, PD1-Vaxx is a 41-amino acid peptide. The peptide comprises a B-cell epitope (amino acids 92-110 from programmed cell death 1 receptor [PD-1]) linked to a promiscuous T-cell epitope (amino acid residues 288-302 from measles virus fusion protein) via a 4-amino acid linker.

We are pleased to report a clinical -grade (cGMP) batch of peptide vaccine has been manufactured successfully by Ambiopharm Inc in North Augusta South Carolina.

In May the peptide will be sterile, filled and finished into dosing vials at The University of Iowa Pharmaceuticals Inc before being shipped and stored at Imugene's logistics supplier Marken Clinical trial Logistics in the US.

We are very pleased manufacturing of PD1-Vaxx will be completed well in advance of it being required for dosing patients in the pending Phase 1 trial which is on track to commence later this year.

Imugene SAB member Prof. Pravin Kaumaya (co-inventor of PD1-Vaxx) and CTO Dr Nick Ede audited our GMP manufacturer of PD1-Vaxx Ambiopharm in November 2019

Pre-IND FDA Meeting Provides Guidance for PD1-Vaxx Immunotherapy Clinical Development PLAN

We were happy to recently announce we had received and accepted the minutes from a pre-investigational new drug meeting with the US Food and Drug Administration for PD1-Vaxx peptide vaccine.

The purpose of the meeting was to obtain formal guidance from the FDA on the studies required for Phase 1 clinical development of PD1-Vaxx. Topics addressed included the anticipated clinical indication and the treatment of cancers that overexpress PD-L1 including but not limited to non-small cell lung cancer.

The meeting was productive and provided Imugene with a clear roadmap for a successful IND submission and subsequent clinical development of PD1-Vaxx The FDA panel members encouraged Imugene to pursue the planned IND submission and subsequent clinical studies.

Imugene's team met with a seven member panel of the FDA Division of Regulatory Project Management Office of Tissues and Advanced Therapies in Washington DC.

FINANCE

Market cap
$61.4M AUD

Average daily volume
9.0M SHARES
(Aug-Nov 2018)

Investment to date
~$42.5M PUBLIC
~$5.5M VC

Ordinary shares
$3.610B

12 month price range
1.3c–4.0c AUD

Cash & equivalents
$21.0M
(as at March-2019)

Options on issue	NO. OF OPTIONS	EXERCISE PRICE	EXPIRY
Listed: (IMUOA)	242.5M	$0.026	30/11/2020
Listed: (IMUOB)	248.3M	$0.04	30/11/2021
Unlisted	59.5M	$0.0247*	09/03/2020*
Total	**550.3M**	**$0.03***	**02/01/2021***

*Average

Top 5 shareholders (as at April 2019)

Private Portfolio Management	6.2%
HSBC Custody Nominees (Australia)	3.6%
Dr. Nicholas Smith	3.2%
Paul Hopper	2.1%
Sarah Cameron	1.7%

Note: As of 10 April 2019 Market capitalization calculations based on ordinary shares (3.61n) only and excludes the dilutive impact of options outstanding (625m)