IMUGENE

Developing Cancer Immunotherapies

ASX: IMU

QUARTERLY ACTIVITIES & APPENDIX 4C CASH REPORT

Quarter Ended:
30 June 2022

Imugene Limited
ABN 99 009 179 551

www.imugene.com

ASX Announcement

Quarterly Activities and Cash Flow Report
Quarter ended 30 June 2022

- Positive final HER-Vaxx Overall Survival Results from the HERIZON study, a Randomized Phase 2 Trial in Advanced Gastric Cancer
- First cohort 2 patient dosed in clinical trial of CHECKvacc in the Phase I clinical trial of oncolytic virotherapy candidate, CHECKvacc (CF33-hNIS-antiPDL1)
- First patient was dosed in a Phase 1 clinical trial evaluating the safety of novel cancer-killing virus CF33-hNIS VAXINIA in patients with advanced solid tumours
- Human Research Ethics Committee approval to commence a Phase 2 clinical trial of its immunotherapy candidate, HER-Vaxx in combination with pembrolizumab
- Mike Tonroe appointed as Chief Financial Officer
- Dr Sharon Yavrom appointed as Executive Director, Clinical Scientist
- Dr. Yanghee Woo, MD, FACS, Surgical Oncologist and Associate Professor of Surgery, City of Hope appointed to the company's Scientific Advisory Board
- $99.9m cash balance as at 30 June 2022
- Quarterly research and development expenditure was $8.5m

SYDNEY, Australia, 25 July 2022: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce its Quarterly Cash Flow report (Appendix 4C) for the quarter ended 30 June 2022.

Final HER-Vaxx Overall Survival Results in Randomized Phase 2 Trial

Imugene presented positive final overall survival data from its Phase 2 study of HER-Vaxx in HER-2/Neu overexpressing advanced/metastatic gastric/GEJ cancer following analysis of safety and efficacy data.

The final analysis results from the randomised clinical HERIZON study, which was designed with a specified 1-sided false positive probability of 0.10, showed a 41.5% survival benefit for patients treated with HER-Vaxx plus standard of care (SOC) chemotherapy compared to SOC chemotherapy alone. This translated into an overall survival HR of 0.585 (80% 2-sided CI: 0.368, 0.930) with a statistically significant p-value of 0.066. There was no difference in safety events between the two treatment arms, suggesting that HER-Vaxx does not add toxicity to SOC chemotherapy.

The longest HER-Vaxx treated patients remain alive 2.5 years (with one patient approaching 3 years) after starting therapy. It is noteworthy that these patients generated the strongest anti-HER-2 antibody levels from their dosing schedule on HER-Vaxx.

HERIZON-extension Cohort Review Committee (CRC) has confirmed a new higher dose of HER-Vaxx (100µg) has been approved for use in the nextHERIZON (pretreated metastatic HER2 positive gastric cancer) and neoHERIZON (perioperative HER2 positive gastric cancer) studies commencing soon. The CRC unanimously agreed HER-Vaxx at 100µg to be safe with no dose-limiting toxicities (DLTs) and no serious adverse reactions observed. The higher dose is expected to accelerate and strengthen antibody generation to further improve the clinical response for HER-Vaxx.

Importantly, Imugene announced completion and delivery of a large-scale batch of HER-Vaxx for use in all planned clinical trials (nextHERIZON and neoHERIZON) in patients with HER-2 positive gastric cancer. The batch which is manufactured by piCHEM (Austria) with final sterile fill and finish at Baccinex (Switzerland) has been QA/QC/QP released and delivered to Imugene's drug depot at Marken (Singapore).

Imugene's HER-Vaxx is a B-cell peptide cancer immunotherapy designed to treat tumours that over-express the HER-2/neu receptor, such as gastric, breast, ovarian, lung and pancreatic cancers. The immunotherapy is constructed from several B cell epitopes derived from the extracellular domain of HER-2/neu. It has been shown in pre-clinical studies, in Phase 1 and now Phase 2 studies to stimulate a potent polyclonal antibody response to HER-2/neu, a well-known and validated cancer target.

The Phase 2 HER-Vaxx study was designed to measure the efficacy, safety and immune response in patients with metastatic gastric cancer overexpressing the HER-2 protein. The study was randomised into two arms of either HER-Vaxx plus SOC chemotherapy or SOC chemotherapy alone. The primary endpoint was overall survival and secondary endpoint was progression-free survival. Safety, tolerability and immune response was also measured.

The Phase 2 trial was conducted at multiple sites across Eastern Europe and India where clinicians have difficulty accessing approved antibody treatments such as Herceptin® and Perjeta®, marketed by Swiss multinational Roche Holding AG. There is also a high prevalence of gastric cancer in the countries selected.

First Cohort 2 Patient Dosed in Clinical Trial of CHECKvacc

Imugene and City of Hope® dosed the first cohort 2 patient in the Phase I clinical trial of oncolytic virotherapy candidate, CHECKvacc (CF33-hNIS-antiPDL1).

The first-in-human, Phase 1, single-centre, dose escalation study of CHECKvacc is recruiting patients with triple negative breast cancer (TNBC). The purpose of the study is to evaluate the safety and initial evidence of efficacy of intra-tumoral administration of CF33-hNIS-antiPDL1 against metastatic TNBC. The current trial design will involve a dose escalation, followed by an expansion to 12 patients at the final dose, which will be the recommended phase 2 dose (RP2D).

The clinical trial is titled "A Phase I Study of Intratumoral Administration of CF33-hNIS-antiPDL1 in Patients with Advanced or Metastatic Triple Negative Breast Cancer". The Principal Investigator leading the trial is Dr Yuan Yuan MD, PhD.

CF33-hNIS-antiPDL1 is an immune checkpoint inhibitor armed chimeric vaccinia poxvirus from the lab of CF33 inventor Professor Yuman Fong, Chair of Sangiacomo Family Chair in Surgical Oncology at City of Hope, and a noted expert in the oncolytic virus field.

First Patient Dosed in Phase 1 Trial to Test Oncolytic Virus against Solid Tumours

The first patient was dosed in a Phase 1 clinical trial evaluating the safety of novel cancer-killing virus CF33-hNIS VAXINIA when used in people with advanced solid tumours. 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 multicenter Phase 1 trial will start by delivering a low dose of CF33-hNIS to cancer patients with metastatic or advanced solid tumours who have had at least two prior lines of SOC treatment. The investigational treatment will be delivered either as an injection directly into tumours or intravenously.

Once patients in the single therapy group have been treated with the lowest doses of CF33-hNIS and acceptable safety has been demonstrated, certain new study participants will receive the experimental oncolytic virus in combination with the immunotherapy pembrolizumab, an engineered antibody that improves the immune system's ability to fight cancer-causing cells. The study aims to recruit ~100 patients across approximately 10 trial sites in the United States and Australia.

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)." The trial is anticipated to run for approximately 24 months and is funded from existing budgets and resources.

The U.S. component of the Phase 1 trial is conducted under the U.S. Food and Drug Administration (FDA) investigational new drug (IND) process following FDA IND clearance in December 2021. Site activation and patient recruitment is proceeding.

The first clinical institution in the U.S. to receive ethics approval is City of Hope, a world-renowned cancer research and treatment organization in Los Angeles. Additional clinical sites have opened and will continue throughout 2022.

Ethics Approval to start Phase 2 nextHERIZON Clinical Trial of HER-Vaxx

Imugene received Human Research Ethics Committee (HREC) approval to commence a Phase 2 clinical trial of its immunotherapy candidate, HER-Vaxx, in Australia. This approval confirms that Imugene has completed all the necessary pre-clinical safety and efficacy testing of HER-Vaxx required to commence its nextHERIZON clinical trial in Australia.

nextHERIZON is an open-label, multi-centre, signal generating, Phase 2 clinical trial designed to assess the safety and efficacy of HER-vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic HER-2/neu over-expressing gastric or gastroesophageal junction adenocarcinomas who have previously progressed on trastuzumab. The study's primary endpoints are safety and response rate. Secondary endpoints include duration of response, progression free survival, overall survival, and biomarker evaluation.

The Australian component of the Phase 2 trial will be conducted under Australia's Clinical Trials Notification (CTN) Scheme meaning Imugene will notify the Therapeutic Goods Administration (TGA) of HREC approval and complete local site initiation activities. The first hospital to receive ethics approval is the Queen Elizabeth Hospital in Adelaide under the direction of Principal Investigator Dr Tim Price. Additional clinical sites will be opened in Australia, and also in the US under the FDA IND approval received in December 2021.

CHECKVacc, PD1-Vaxx publications presented at ASCO

Imugene was pleased to present publications on its CHECK-Vacc and PD1-Vaxx programs at the American Society of Clinical Oncology's (ASCO) 2022 Annual Meeting, held in Chicago in June.

The abstract on CHECKVacc detailed its Phase 1 trial in adults with triple negative breast cancer, titled "Phase I study of intratumoral administration of CF33-HNIS-antiPDL1 in patients with metastatic triple negative breast cancer". The abstract can be viewed at: https://meetings.asco.org/abstracts-presentations/209942

The PD1-Vaxx abstract showed results from its Phase 1 IMPRINTER trial in adults with non-small cell lung cancer. It was titled "IMPRINTER: An open label, multicenter, 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 (IMU.201.101)". The abstract can be viewed at: https://meetings.asco.org/abstracts-presentations/212919

Financial Update

At the end of the period Imugene has $99.9 million in cash or equivalents, providing a runway to support its clinical pipeline and operations into 2025.

Net cash used in operating activities for the quarter amounted to $10.2 million, with direct Research and Development amounting to $8.5 million and with Staff costs accounting for over 99% of the $10.2 million for the quarter.

Imugene also successfully raised $0.8 million through the exercise of options during the quarter. The funds will be used to support the Company's commercial and clinical milestones.

The Company continues to monitor its expenditure carefully across all facets of the business, though this is expected to increase as clinical programs ramp up.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C include payments for remuneration of director fees to executive and non-executive directors in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

Appointment of new Chief Financial Officer

After the end of the period, Imugene appointed Mike Tonroe as Chief Financial Officer. Mr Tonroe has extensive experience as a CFO and Company Secretary within the biopharmaceutical industry and also brings international finance leadership experience having worked in the US, Canada, UK and Hong Kong, in addition to Australia.

Most recently, Mr Tonroe was CFO and Company Secretary at ASX-listed Opthea Limited and Genetic Technologies Limited, and prior to that was in the same role for private business Australian Synchotron Company Ltd. These tenures included management of the US IPO and NASDAQ listing of Opthea along with M&A, restructuring, capital raising and leading the finance function across these businesses. Adding to the depth of Mr Tonroe's experience, he has exposure to the technology, energy and travel sectors from earlier roles which also include time with major accounting firms KPMG and Deloitte.

Mr Tonroe graduated in Business Studies with Honours from Buckingham University UK, later becoming a Member then Fellow of the Institute of Chartered Accountants in England & Wales and being Australian Institute of Company Directors accredited.

Appointment of new Executive Director, Clinical Scientist

After the end of the period, Imugene appointed Dr Sharon Yavrom as Executive Director, Clinical Scientist to the management team. Dr. Yavrom is an accomplished clinical scientist with nearly 20 years of industry experience in both established and emerging pharmaceutical companies. She has previously held positions at industry leading companies such as TAP Pharmaceuticals, Amgen and BMS and has spent her recent career lending her expertise to start-up companies such as Synta Pharmaceuticals, Puma Biotechnology, Tocagen, Aduro, MEI Pharma and Oncternal, with a focus on the oncology therapeutics space.

Dr. Yavrom has been the clinical study lead for several clinical trials and has experience with multiple tumour types including HER2+ breast cancer, NSCLC, glioblastoma, colorectal cancer, non-invasive bladder cancer, NHL, CLL and Ewing's Sarcoma.

Dr. Yavrom received her Bachelor of Science degree in Biology from San Jose State University and her Ph.D. in Pathobiology from University of Southern California, Keck School of Medicine.

Changes to Scientific Advisory Board

Dr. Yanghee Woo, MD, FACS, Surgical Oncologist and Associate Professor of Surgery, City of Hope was appointed to the company's Scientific Advisory Board (SAB).

Dr. Woo is an internationally recognised surgeon-scientist with clinical expertise in robotic surgery and gastric cancer. She holds several key positions at City of Hope including Director of GI Minimally Invasive Therapies Program, Vice Chair of International Affairs and is also a Visiting Professor at Xiangya Medical School, China.

In addition to her clinical and teaching experience, Dr. Woo is currently researching gastric cancer inception and viral oncolytic therapy based on the CF33-platform. Dr. Woo is part of the team that created a chimeric orthopoxvirus, CF33-hNIS-antiPDL1, which has exhibited strong potential in targeting solid tumours and the most common type of pancreatic cancer, pancreatic ductal adenocarcinoma (PDAC).

Before commencing at the Department of Surgery at City of Hope in 2015, Dr. Woo held various positions at Columbia University Medical Center's (CUMU) Pancreas Center where she was Assistant Professor of Surgery and later Director of the Center for Global Excellence in Gastric Cancer Care.

Dr. Woo received her Medical Doctorate from Drexel University Medical School and completed the Health Careers Program at Harvard University. She completed a general surgery residency at CUMC, a research fellowship at Memorial Sloan Kettering Cancer Center and a clinical fellowship at Severance Hospital, Yonsei University, Seoul.

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About Imugene (ASX:IMU)

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CAR T's for solid tumours. We are supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets.

Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

Release authorised by the Managing Director and Chief Executive Officer

Imugene Limited, Level 3, 62 Lygon Street, Carlton, VIC, 3053, Australia

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Imugene Limited	
ABN	**Quarter ended ("current quarter")**
99 009 179 551	30 June 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(8,457)	(28,887)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,289)	(5,118)
	(f) administration and corporate costs	(780)	(4,749)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	42	193
1.5	Interest and other costs of finance paid		(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	6,542
1.8	Other (provide details if material)	335	1,113
1.9	**Net cash from / (used in) operating activities**	**(10,149)**	**(30,907)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(156)	(161)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(156)**	**(161)**

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	95,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	798	13,917
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(6,581)
3.5	Proceeds from borrowings	-	134
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – repayment of debt	-	(1,361)
3.10	**Net cash from / (used in) financing activities**	**798**	**101,109**

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	109,127	29,487
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(10,149)	(30,907)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(156)	(161)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	798	101,109
4.5	Effect of movement in exchange rates on cash held	268	360
4.6	**Cash and cash equivalents at end of period**	**99,888**	**99,888**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	70,888	59,117
5.2	Call deposits	29,000	50,010
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**99,888**	**109,127**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	415
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Item 6.1 – Include payments for remuneration of director fees to executive and non-executive directors in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(10,149)
8.2	Cash and cash equivalents at quarter end (item 4.6)	99,888
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	99,888
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	9.8

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 25 July 2022

Authorised by: The Board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

IMUGENE

Developing Cancer Immunotherapies

ABN 99 009 179 551

www.imugene.com