

ASX Announcement

Quarterly Activities and Cash Flow Report Quarter ended 30 June 2021

SYDNEY, Australia, 23 July 2021: 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 2021.

Key highlights this quarter include:

- **\$29.5m cash balance as at 30 June 2021**
- **Quarterly research and development expenditure was \$3.6m**
- **Highest dose cohort in Phase 1 clinical trial of PD1-Vaxx reached**
- **HER-Vaxx presented at AACR 2021 meeting**
- **CF33 CHECKVacc presented at AACR 2021 meeting**
- **Prestigious Clinical Cancer Research Journal Publishes HER-Vaxx Phase 1 Data**
- **Worldwide license of CF33 CD19 (onCARlytics) for the treatment of solid tumours**
- **Appointment of Dr. Monil Shah as Chief Business Officer**
- **HER-Vaxx presented at the ESMO World Congress on Gastrointestinal Cancer 2021 Annual Meeting**
- **CHECKVacc received FDA IND clearance**

Update on Clinical Trials

HER-Vaxx

Following completion of recruitment of the Phase 2 trial in January 2021, Imugene's Chief Medical Officer Dr Rita Laeufle was able to present on the HER-Vaxx cancer immunotherapy program at the American Association for Cancer Research (AACR) 2021 Annual Meeting in April.

On 2nd of July, 2021 HER-Vaxx data was presented at the ESMO World Congress on Gastrointestinal Cancer 2021 Annual Meeting.

The abstract presentation was entitled 'HERIZON: A PHASE 1B/2 OPEN-LABEL STUDY OF IMU-131 HER2/NEU PEPTIDE VACCINE PLUS STANDARD OF CARE CHEMOTHERAPY WITH RANDOMIZATION IN PHASE 2 IN PATIENTS WITH HER2/NEU OVEREXPRESSING METASTATIC OR ADVANCED ADENOCARCINOMA OF THE STOMACH OR GASTROESOPHAGEAL JUNCTION' Updated Interim Analysis Results

The presentation expanded on previously presented interim analysis data presented at AACR2021.

The ESMO presentation highlights and presents the following new data:

- HER-Vaxx treatment resulted in a 50% Overall Response Rate (ORR) compared to 29% in patients treated with chemotherapy alone. The ORR measures the percentage of patients who responded to treatment with a partial response (PR) or better.
- Treatment with HER-Vaxx clearly demonstrates patients develop high levels of HER2-specific antibodies early in the treatment protocol and are maintained during treatment and maintenance phase with only a few booster injections.

- Tumour response is correlated with the amount of antibody levels. Patients with antibody levels higher than 1050ng/ml received greater than 50% tumour reduction and may serve as a potential biomarker.
- In contrast to patients on chemotherapy alone, the reduction of tumour size is substantially higher in patients that received HER-Vaxx + chemotherapy.

Overall, this data demonstrates HER-Vaxx may provide treatment benefits consistent with traditional monoclonal antibodies with a corresponding adaptive immune response without added toxicity.

Phase 1 clinical trial data for Imugene's B cell peptide cancer immunotherapy HER-Vaxx was published in the prestigious American Association for Cancer Research journal Clinical Cancer Research (Ursula Wiedermann et al. Clin Cancer Res 2021;27:3649-3660).

The title of the article was " Clinical and immunologic responses to a B-cell epitope vaccine in HER2/neu overexpressing advanced gastric cancer patients - results from Phase 1b trial IMU.ACS.001" and is authored by Professor Dr. Ursula Wiedermann from the Medical University Vienna and study investigators.

PD1-Vaxx:

The first-in-human, Phase 1, multi-centre, dose escalation study of PD1-Vaxx is recruiting patients with non-small cell lung cancer who have progressed from previous therapies. Medical investigators are testing three different doses of PD1-Vaxx. The primary goal of the Phase 1 trial is to determine safety and an optimal biological dose as a monotherapy (mOBD). Efficacy, tolerability and immune response will also be measured. Determination of mOBD will be made by the Cohort Review Committee (CRC) and requires successive dosing within cohorts of at least 3 patients each.

The Phase 1 study is currently enrolling in cohort 3, the highest dose after successful completion of cohort 2.

Phase 1 trials are generally designed to look for safety, tolerability and early response signals to determine the optimal dose for further development. The company is encouraged that we are seeing positive signals at such an early stage of our PD1-Vaxx Phase I trial even in this late stage patients.

All 6 sites, 3 in Australia and 3 in the U.S.A are open for recruitment. Clinicians have reported no safety, toxicity or tolerability issues with PD1-Vaxx, we anticipate these results to continue in the highest dose of PD1-Vaxx.

onCARlytics (CF33 CD19)

On 18th of May, Imugene entered into a licensing agreement for the patents covering a novel combination immunotherapy. The therapy unleashes a CD19 expressing oncolytic virus to enable CD19 directed chimeric antigen receptor (CAR) T cell therapies to target solid tumours, which are currently otherwise difficult to treat with CAR T cell therapy alone.

The worldwide exclusive licence of the patents covering the cell therapy technology, which includes CF33-CD19, known as onCARlytics™, or an agent that tags cancer cells for CAR T cell destruction, was developed at City of Hope.

City of Hope scientists genetically engineered an oncolytic virus to enter tumour cells and force the expression of CD19 on the cell surface. The scientists were then able to use CD19 directed CAR T cells to recognize and attack these solid tumours. The preclinical research was published recently and featured on the front cover of the prestigious journal Science Translational Medicine.

This discovery highlights a City of Hope research collaboration including Priceman, Anthony Park, Ph.D., postdoctoral research fellow in Priceman's Lab, Stephen Forman, M.D., professor of the Department of Hematology & Hematopoietic Cell Transplantation and director of City of Hope's T Cell Therapeutics Research Program, and Yuman Fong, M.D., professor and Sangiacomo Family Chair in Surgical Oncology at City of Hope.

CF33 Oncolytic Virus

City of Hope's, Dr Yanghee Woo MD, Associate Clinical Professor, Department of Surgery and Director, Gastroenterology Minimally Invasive Therapy Program presented on the CF33 oncolytic virus program at the American Association for Cancer Research (AACR) 2021 Annual Meeting.

The abstract presentation was entitled 'Subcutaneous Intratumoral Administration of CF33-hNIS-anti-PD-L1 Eradicates Distant Peritoneal Tumors'. Dr Woo's team engineered CF33-hNIS-antiPDL1, a unique chimeric orthopoxvirus, which shows robust preclinical activity against many solid tumors and inherent strong anti-cancer activity against pancreatic ductal adenocarcinoma (PDAC). The team investigated CF33-hNIS-antiPDL1 for its ability to track and kill distant peritoneal metastases after local virus administration in vivo. They showed that subcutaneous intratumoral (SC.IT) delivery of CF33-hNIS-antiPDL1 decreases peritoneal tumor burden and improves survival in a PDAC mouse model.

The US Food and Drug Administration (FDA) Investigational New Drug (IND) approval to initiate a Phase I clinical trial of Imugene's oncolytic virotherapy candidate, CHECKvacc (CF33-hNIS-antiPDL1) was received on 30 June 2021.

The FDA approval of the IND allows Imugene and City of Hope to start patient recruitment and dosing in a Phase 1 clinical trial for triple-negative breast cancer (TNBC) patients.

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.

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 trial will involve a dose escalation, followed by an expansion to 12 patients at the final dose, the recommended phase 2 dose (RP2D).

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

Human Resources

In June the company announced the appointment of Dr Monil Shah, PharmD, MBA, as Chief Business Officer (CBO) and a member of the Company's executive management team.

Dr Shah will lead the Company's global business development and partnering activities, and support our clinical development.

Dr Shah has over 20 years of pharmaceutical and biotechnology industry experience in oncology drug development. His most recent appointment was as Chief Development Officer at WindMIL Therapeutics, responsible for the cell therapy platform. He was the Chief Operating Officer of Brooklyn Immuno Therapeutics leading cytokine drug development for oncology patients. Prior to that, he was the Medical Affairs Lead for Immuno-Oncology at Bristol Myers Squibb responsible for checkpoint inhibitor development programs.

Cash Flow

The Company continued to monitor expenditure carefully during the period under review of the clinical trials and associated expenditure.

Imugene currently has \$29.5 million cash and cash equivalents on hand as at 30 June 2021 and is funded to support its near-term clinical milestones.

As the business continues to develop and support four clinical programs, the business will expect to see an increase in expenditures; however the management team will continue to manage this proactively.

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.

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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 tumors. 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 tumors. 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

99 009 179 551

Quarter ended ("current quarter")

30 June 2021

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	(3,573)	(15,619)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(626)	(2,340)
(f) administration and corporate costs	(532)	(1,990)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	17	171
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	25	4,874
1.8 Other (provide details if material)	37	228
1.9 Net cash from / (used in) operating activities	(4,652)	(14,676)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(141)	(141)
(d) investments	-	-
(e) intellectual property	(3,876)	(3,876)
(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	(4,017)	(4,017)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	8,699	18,064
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(133)
3.5	Proceeds from borrowings	-	144
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	8,699	18,075

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	29,457	30,107
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,652)	(14,676)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4,017)	(4,017)

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)	8,699	18,075
4.5	Effect of movement in exchange rates on cash held	-	(2)
4.6	Cash and cash equivalents at end of period	29,487	29,487

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	8,486	4,457
5.2	Call deposits	21,001	25,000
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)	29,487	29,457

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	211
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

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 <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	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)	(4,652)
8.2	Cash and cash equivalents at quarter end (item 4.6)	29,487
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	29,487
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	6.3
	<i>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.</i>	
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	
	<i>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.</i>	

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:23 July 2021.....

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.