

**ASX: IMU** 



**Imugene Limited ABN 99 009 179 551** 

www.imugene.com



#### **ASX Announcement**

#### **Quarterly Activities and Cash Flow Report**

#### **Quarter ended 31 December 2022**

- First patient dosed in VAXINIA intravenous cohort 2
- Imugene partners with ABL for manufacturing of VAXINIA
- Imugene selected for presentation at J.P. Morgan Healthcare Conference
- onCARlytics (CF33-CD19) oncolytic virus combinations presented at Society for Immunotherapy of Cancer 2022 Annual General Meeting
- Imugene presents new and first CHECKvacc data at the 2022 San Antonio Breast Cancer Symposium
- Imugene's HER-Vaxx & CF33 platforms featured at ASCO Gastrointestinal Cancers Symposium
- HERIZON data presented at ESMO Asia
- New key management appointments announced

**SYDNEY, Australia, 27 January 2023:** 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 31 December 2022.

#### First patients dosed in VAXINIA intratumoral cohort 2 and intravenous cohort 2

In December, the Phase 1 MAST (metastatic advanced solid tumours) study evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA) saw the first patient dosed as part of intravenous (IV) cohort 2 of the trial. This follows the clearance of IV cohort 1 in November, paving the way for the commencement of cohort 2. The intratumoral (IT) arm is in progress after the first patient was dosed in cohort 2 on 27 October 2022.

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.

Once patients in the monotherapy group have been treated with the lowest doses of VAXINIA and acceptable safety has been demonstrated, new study participants will



receive combination treatment, CF33-hNIS with the immunotherapy pembrolizumab. This is expected to begin following cohort 2 being cleared per route of administration. Overall, the study aims to recruit up to 100 patients across approximately 10 trial sites in the United States and Australia.

#### ABL and Imugene partner to advance VAXINIA

During October Imugene announced it has partnered with Contract Development and Manufacturing Organization (CDMO) ABL, who will manufacture Imugene's VAXINIA oncolytic virus for its MAST clinical studies.

ABL has a strong background in handling a broad range of viruses, such as vaccinia, which require work under BSL-2 environments and aseptic conditions. Through this collaboration, Imugene will gain access to ABL's top-of-the-line CDMO services, providing a true end-to end solution with comprehensive analytical support, GMP manufacturing of vaccinia viruses and fill-finish of the drug product, with customizable and flexible development and manufacturing solutions.

#### Imugene presents at J.P. Morgan Healthcare Conference

Post the end of the reporting period, Imugene's CEO Leslie Chong presented at the 41st Annual J.P. Morgan Healthcare Conference in San Francisco.

The event is one of the largest and most prestigious on the healthcare and biotechnology industry calendar each year, with more than 3,000 global investors in attendance at the 2022 event.

#### The audio replay accompanied by slides can be viewed at:

https://www.youtube.com/watch?v=vuneDZVb51g&t=4s

Imugene presents at Society for Immunotherapy of Cancer 2022 Annual General Meeting The Annual Meeting of the Society for Immunotherapy of Cancer (SITC) was held in Boston, USA on 8-12 November 2022, with Imugene featured in three abstracts at the prestigious immunotherapy event.

Data from preclinical studies of Imugene's onCARlytics (CF33-CD19) oncolytic virus in combination with Celularity's placental-derived off-the-shelf allogeneic CYCART-19 T cells was presented at SITC. Dr Anthony Park from Dr Saul Priceman's lab at City of Hope presented the poster, "CF33-CD19t oncolytic virus (onCARlytics) in combination with off-the-shelf allogeneic CYCART-19 T-cells targeting de novo CD19t expressing tumors."



In addition, onCARlytics in combination with Estrella's CD19-Redirected ARTEMIS® T cells was also presented at SITC. Dr Anthony Park again presented the poster, titled "CF33-CD19t oncolytic virus (onCARlytics) targets hepatocellular carcinoma (HCC) and in combination with CD19-Redirected ARTEMIS® T cells results in significant tumor killing."

on CARlytics was featured for a third time at SITC, in combination with CD19 bispecific antibody blinatumomab to target solid tumors. Dr Anthony Park presented "Combination immunotherapy using a novel chimeric oncolytic virus to redirect CD19 bispecific T cell engagers to target solid tumors".

The key findings of each presentations, as well as the posters shown at SITC, can be found on the Imugene website at

## Imugene presents new and first CHECKvacc data at the 2022 San Antonio Breast Cancer Symposium

The 2022 San Antonio Breast Cancer Symposium (SABC 2022) was held on 9 December 2022 AEDT in San Antonio, Texas. Imugene presented new and first data from triple negative breast cancer (TNBC) patients in the Phase I CHECKVacc trial.

The presentation, titled "Phase I study of intratumoral administration of CF33-hNIS-antiPD-L1 (CHECKvacc) in patients with metastatic triple negative breast cancer", was presented by Dr Yuan Yuan M.D., PhD, Cedars Sinai Medicine, Los Angeles and Dr Jamie Rand M.D., City of Hope, Los Angeles.

The poster presented at the event can again be viewed at:

https://www.imugene.com/conference-presentations

# Imugene's HER-Vaxx & CF33 platforms featured at ASCO Gastrointestinal Cancers Symposium

The ASCO Gastrointestinal Cancers Symposium, was held on 19–21 January 2023 in San Francisco, California. The 20th annual international event highlights the latest developments and breakthroughs in the field of gastrointestinal oncology, attended by more than 4,000 scientific figures, clinical researchers, academics, oncologists and medical practitioners from around the world.



Imugene presented its HER-Vaxx HERIZON study in an oral presentation, trial in progress for NextHERIZON and 2 abstracts for CF33 technologies at this symposium across four separate sessions. The slides and posters presented are available at <a href="https://www.imugene.com/conference-presentations">https://www.imugene.com/conference-presentations</a>

#### HER-Vaxx HERIZON data presented at ESMO Asia Congress 2022

Positive new data regarding overall survival results in the HER-Vaxx HERIZON study was provided in an oral presentation at the ESMO Asia Congress in Singapore during December.

Principal investigator of the study, Marina Maglakelidze, outlined the study design, information regarding demographics and characteristics of the 36 patients in the trial, and data covering safety and adverse events.

#### Key conclusions of the overall survival benefit of HER-Vaxx included:

- HER-Vaxx + chemotherapy showed a statistically significant 42% overall survival benefit compared to chemotherapy alone (13.9 vs 8.3 months)
- Duration of response is longer in the HER-Vaxx + chemotherapy arm over chemotherapy alone (30 vs 19 weeks)
- Vaccination with HER-Vaxx induced persistent HER-2 specific antibodies which correlated with clinical response as proof of concept for a first-in-class B-cell immunotherapy based on HER-2 peptides
- No significant additive toxicity was seen when HER-Vaxx was administered in combination with chemotherapy

#### The full presentation provided at ESMO can be viewed at:

https://www.imugene.com/conference-presentations

#### **Management Appointments**

In October, Dr Giovanni Selvaggi joined Imugene as Chief Medical Officer. A pulmonologist trained in thoracic malignancies with a focus on lung cancers and mesothelioma, he has over a decade of experience in the pharmaceutical industry. Dr Selvaggi held a pivotal role in Novartis successful development and approval of ceritinib (or Zykadia, targeting nonsmall cell lung cancer/NSCLC) and was part of the immunotherapy team at Bristol Myers Squibb that led to the approval of nivolumab (Opdivo) in third line small cell lung cancer.

Paul Wright was appointed to the role of Vice President CMC (Chemistry, Manufacturing and Controls). Mr Wright is an accomplished bioprocess development leader with over 25



years of experience in the fields of protein and virus production. He spent 21 years at Pfizer holding positions of increasing responsibility within the Global Manufacturing and Vaccine Research and Development organisations. Most recently he led a team responsible for the process, analytical, and formulation development of cancer vaccine projects from preclinical to first-in-human study stage.

#### **Financial Update**

At the end of the December quarter Imugene has \$161.9 million in cash or equivalents, providing a runway to support its clinical pipeline and operations.

Net cash used in operating activities for the quarter amounted to \$8.1 million, with direct research and development and staff costs accounting for 92%.

Net proceeds from the exercise of listed option was \$8.1 million received in the December quarter. The funds will be used to support the Company's clinical development.

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. Options granted to directors that are included in Imagene's Remuneration Report under share-based payments, are non-cash amounts and represent valuations using the Black-Scholes methodology. Share-based payments relating to option grants to directors are therefore not included in item 6.1 of the Appendix 4C.

#### **Annual General Meeting**

Imugene's Annual General Meeting was held on 17 November 2022, with all resolutions carried on a poll.

For more information please contact:

#### Leslie Chong

Managing Director and Chief Executive Officer

info@imugene.com

### **Investor Enquiries**

shareholderenquiries@imugene.com

### **Media Enquiries**

Matt Wright matt@nwrcommunications.com.au



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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. Imagene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imagene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imagene and its shareholders are at the forefront of this rapidly growing global market.

Release authorised by the Managing Director and Chief Executive Officer Imagene 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

31 December 2022

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(5,709)	(14,406)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,760)	(4,165)
	(f) administration and corporate costs	(1,418)	(2,669)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	289	361
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	482	571
1.9	Net cash from / (used in) operating activities	(8,116)	(20,308)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(5)	(5)
	(d) investments	-	-
	<ul><li>(e) intellectual property</li><li>(f) other non-current assets</li></ul>	-	-
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	(5)	(5)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	80,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	8,176	8,415
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(119)	(5,402)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – repayment of debt	-	-
3.10	Net cash from / (used in) financing activities	8,057	83,013

ASX Listing Rules Appendix 4C (17/07/20)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	163,815	99,888
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(8,116)	(20,308)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(5)	(5)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	8,057	83,013
4.5	Effect of movement in exchange rates on cash held	(1,843)	(680)
4.6	Cash and cash equivalents at end of period	161,908	161,908

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	132,907	134,808
5.2	Call deposits	29,001	29,007
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)	161,908	163,815

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	356
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 qu	uarter 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)	(8,116)
8.2	Cash and cash equivalents at quarter end (item 4.6)	161,908
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	161,908
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	19.9
	Note: if the entity has reported positive net operating cash flows in item 1.9. answer item	8.5 as "N/A" Otherwise a

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**

- 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: 27 January 2023

Authorised by: The Board

(Name of body or officer authorising release – see note 4)

#### **Notes**

- 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".
- 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.