

## ASX/Media Release

### Immutep Quarterly Activities Report & Appendix 4C

- Phase II TACTI-002 trial met its primary objective in 1st line non-small cell lung cancer (NSCLC) patients, with 38.6% Overall Response Rate and favourable anti-tumour activity
- Biomarker and multivariate analysis data from the completed Phase IIb AIPAC trial reported, confirming efti is activating the immune system and helping patients live longer
- Four world leading oncologists join the Clinical Advisory Board
- Well-funded with ~\$80 million in cash, giving Immutep an expected cash runway into early CY2024

**SYDNEY, AUSTRALIA – 28 July 2022** – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel LAG-3-related immunotherapy treatments for cancer and autoimmune disease, provides an update on the ongoing development of its product candidates, eftilagimod alpha (“efti”) and IMP761 for the quarter ended 30 June 2022 (Q4 FY22).

#### Efti Development Program for Cancer

##### *AIPAC - clinical trials*

New biomarker and multivariate analysis data from the Phase IIb AIPAC trial was reported at ESMO’s Breast Cancer Congress in May 2022. The AIPAC trial evaluated efti in combination with paclitaxel chemotherapy in 227 patients with HER2-negative/HR positive metastatic breast cancer (HR+ MBC). While the final Overall Survival results from this trial were reported in November 2021, the biomarker analysis reported highly valuable additional insights.

The analysis showed a statistically significant increase in innate and adaptive immune response biomarkers (monocyte and CD8+ T cell counts and serum CXCL10 levels) and absolute lymphocyte count (ALC) was observed in the efti group, but not in the placebo group. These improved immune parameters correlated with improved overall survival of the patients, confirming efti is activating the immune system and helping patients live longer.

In addition, an observed early rise in ALC in patients treated with efti may provide clinicians with a potential predictor of improved survival, helping them to determine early on if continued treatment with efti is beneficial. The exploratory analysis also identified six patient subgroups that showed improvements in Overall Survival (OS). These subgroups are therefore relevant for patient population selection for future late-stage studies in breast cancer.

Regulatory interactions are ongoing for the further clinical development program for efti in MBC, including with the US Food and Drug Administration (FDA) and European Medicines Agency (EMA). This follows feedback from the EMA regarding the efti program received in October 2021 and the FDA in March 2022.

In light of the exciting 1st line NSCLC data from TACTI-002 (discussed below) Immutep is reviewing clinical plans for MBC and NSCLC in order to potentially prioritize one indication.

***TACTI-002 (also designated KEYNOTE-PN798) - Phase II clinical trial***

New data from 1st line NSCLC patients (Part A) from TACTI-002 was reported in a prestigious Oral Presentation at the American Society of Clinical Oncology's (ASCO) 2022 Annual Meeting in June 2022. The data showed TACTI-002 met its primary objective for 1st line NSCLC patients in this PD-L1 all-comer trial.

Immutep reported an Overall Response Rate of 38.6% to the combination of efti plus pembrolizumab and favourable anti-tumour activity. Encouraging responses were demonstrated in all PD-L1 status groups, including patients who were PD-L1 negative or PD-L1 low, both groups were less likely to respond to anti-PD-1 monotherapy. Immutep also reported improving secondary endpoints, Disease Control Rate (DCR) and interim median Progression Free Survival (PFS), across all PD-L1 expression levels. Efti continues to be safe and well tolerated, with a safety profile consistent with previously reported studies for pembrolizumab monotherapy. The results are supportive of continued late-stage clinical development of efti in 1st line NSCLC.

New interim data from 2nd line NSCLC patients (Part B) has been selected for a poster presentation at the IASLC 2022 World Conference on Lung Cancer (WCLC 2022) taking place in August 2022 in Vienna, Austria. WCLC is the world's largest international gathering of clinicians, researchers and scientists in the field of lung cancer and thoracic oncology.

***TACTI-003 - Phase IIb clinical trial***

Recruitment is ongoing for 1st line head and neck squamous cell carcinoma (HNSCC) patients for Immutep's TACTI-003 trial, with 39 patients out of approximately 154 enrolled to date across the now 24 active trial sites.

TACTI-003 is a Phase IIb multicentre, open label, randomised and controlled trial. It was granted fast track designation for 1st line HNSCC by the US FDA in 2021. Immutep presented the trial design for TACTI-003 at the American Society of Clinical Oncology's (ASCO) 2022 Annual Meeting held in June. Recruitment and trial updates are expected to be reported throughout the remainder of 2022 and into 2023.

***INSIGHT-003 - triple combination***

Patient recruitment is ongoing for the INSIGHT-003 investigator-initiated trial, with 13 out of a total of 20 patients already enrolled. INSIGHT-003 focuses on a patient population with NSCLC adenocarcinomas and evaluates a triple combination therapy consisting of efti and an existing approved standard of care combination of chemotherapy (carboplatin, pemetrexed) and an anti-PD-1 therapy. Interim results from the study are expected to be reported in Q4 2022. The trial is being conducted by the Institute of Clinical Cancer Research (IKF) at Northwest Hospital, Frankfurt, Germany.

***Potential new trials for efti in cancer***

Due to the positive data from efti presented at ASCO 2022 and other conferences, Immutep has been approached for potential new investigator-initiated trials as well as other potential collaborations for efti in various indications and combinations; we are currently assessing these opportunities. It is very encouraging to see the increased level of industry interest and willingness to support and fund further trials for efti in cancer because of the growing body of positive data generated from efti clinical trials thus far.

At this stage, discussions with various parties are incomplete and still subject to negotiation. Once an agreement is reached, the Company will provide further details in a market announcement.

#### **IMP761 Development Program for Autoimmune Disease**

Preclinical development steps are continuing for IMP761, prior to advancing the candidate into clinical trials. This includes development of a GMP-compliant manufacturing process for IMP761. The GMP manufacturing at 200 litre scale is ongoing. IMP761 is Immutep's immunosuppressive agonist antibody to LAG-3 which will be tested to treat the causes of autoimmune disease, such as inflammatory bowel disease, rheumatoid arthritis, and multiple sclerosis, rather than merely treating the symptoms.

#### **Partnering Updates**

##### ***CYTLIMIC***

Immutep signed clinical collaboration, service and supply agreements with the Japanese biotech, CYTLIMIC (an affiliate of NEC) in 2019 to support its development of a therapeutic cancer vaccine. CYTLIMIC has been conducting studies of CYT001, its lead cancer vaccine which comprises peptides designed using artificial intelligence from the HSP70 and GPC-3 proteins, plus two adjuvants, efiti and Hiltonol. Based on a comprehensive business evaluation, CYTLIMIC has determined to dissolve the company and to transfer its own patents and licensing rights to NEC accordingly. Investigations into CYT001 will not be continuing whilst NEC assesses the future of this cancer vaccine program.

##### ***EAT COVID***

Conducted and funded by the University Hospital Pilsen, Czech Republic, the Phase II EAT COVID study was evaluating the Company's lead product candidate efiti in hospitalised patients with COVID-19. The study aimed to boost a patient's immune response to prevent development of severe COVID-19 symptoms that require intensive care and can lead to respiratory failure and death. While independently reviewed safety run-in data prompted the Company to initiate enrolment for the randomised portion of the study in January 2021, recruitment into the trial has been slow. Accordingly, Immutep has decided to discontinue the supply of efiti for this trial and to terminate the collaboration with the University Hospital Pilsen. Immutep only incurred minimal costs for this investigator-initiated trial.

#### **Intellectual Property**

During the quarter, Immutep and its partner Novartis AG were granted a new patent for ieramilimab (Novartis code: LAG525), a humanised LAG-3 antagonist antibody derived from Immutep's IMP701 antibody, by the Eurasian Patent Office. The patent protects ieramilimab in the member states of the Eurasian Patent Convention, namely Armenia, Azerbaijan, Belarus, Kirgizstan, Kazakhstan, Moldova, Russia, Tajikistan and Turkmenistan. The expiry date of the new patent is 13 March 2035.

## **Corporate Update**

### ***Clinical Advisory Board***

Immutep was delighted to welcome four world leading oncologists to its Clinical Advisory Board (CAB) during the quarter:

- Scott Antonia, M.D., Ph.D. of the Duke Cancer Institute Center for Cancer Immunotherapy
- Leisha A Emens, M.D., Ph.D. Professor of Medicine at the UPMC Hillman Cancer Center
- Martin Forster, M.D., Ph.D., Associate Professor at University College London (UCL)
- Hans Wildiers, M.D., Ph.D. of the University Hospital Leuven, Belgium

The CAB serves as a strategic resource for advancing Immutep's pipeline of LAG-3 programs, including efiti, especially in NSCLC and MBC.

### ***Financial Summary***

Overall, the financial performance for the quarter ended 30 June 2022 (i.e. Q4 FY22) was very pleasing. Cash receipts from customers Q4 increased to \$96k, compared to \$8k in the previous quarter (i.e. Q3 FY22).

The net cash used in G&A activities in the quarter was \$361k compared to \$1.6 million in Q3 FY22. The decrease compared with the last quarter is mainly due to the inclusion of certain annual expense prepayments in the previous quarter.

Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter includes \$189k in payment of Non-Executive Director's fees and Executive Director's remuneration.

The net cash used in Research and Development activities in the quarter was \$7.62 million, compared to \$8.13 million in Q3 FY22. The lower cash outflows in Q4 FY22 were mainly due to the decrease of efiti and IMP761 contract manufacturing payments. The cash outflow for clinical trial activities increased compared with Q3 FY 22 and were in line with increased activity in TACTI-003. Total net cash outflows used in operating activities in the quarter was \$9.28 million compared to \$10.95 million in Q3 FY22.

The Company's cash and cash equivalent balance as at 30 June 2022 was approximately \$80 million compared to a balance of \$87 million as at 31 March 2022. Immutep's higher than planned cash balance continues to put the Company in a strong financial position with an expected cash reach based on current estimates of early calendar 2024. The company will continue to manage its strong cash balance carefully as it reviews its overall clinical strategy, particularly in light of the various potential opportunities for the development of efiti in cancer.

A copy of the Appendix 4C - Quarterly Cash Flow Report for the quarter is attached.

### **About Immutep**

Immutep is a globally active biotechnology company that is a leader in the development of LAG-3 related immunotherapeutic products for the treatment of cancer and autoimmune disease. Immutep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to

maximize value to shareholders. Immunetep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Immunetep's current lead product candidate is efitigimod alpha ("efti" or "IMP321"), a soluble LAG-3 fusion protein (LAG-3Ig), which is a first-in-class antigen presenting cell (APC) activator being explored in cancer. Immunetep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

Additional LAG-3 products, including antibodies for immune response modulation, are being developed by Immunetep's large pharmaceutical partners.

Further information can be found on the Company's website [www.immunetep.com](http://www.immunetep.com) or by contacting:

**Australian Investors/Media:**

Catherine Strong, Citadel-MAGNUS  
+61 (0)406 759 268; [cstrong@citadelmagnus.com](mailto:cstrong@citadelmagnus.com)

**U.S. Media:**

Tim McCarthy, LifeSci Advisors  
+1 (212) 915.2564; [tim@lifesciadvisors.com](mailto:tim@lifesciadvisors.com)

This announcement was authorised for release by the Board of Immunetep Limited.

## Appendix 4C

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

**Name of entity**

Immutep Limited

**ABN**

90 009 237 889

**Quarter ended ("current quarter")**

30 June 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	96	174
1.2 Payments for		
(a) research and development	(7,621)	(27,248)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(166)	(482)
(d) leased assets	-	-
(e) staff costs	(1,206)	(4,534)
(f) administration and corporate costs	(361)	(3,142)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	42	224
1.5 Interest and other costs of finance paid	(62)	(85)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,434
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(9,278)</b>	<b>(31,659)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(6)	(22)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	(38)

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)	-	15
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(6)</b>	<b>(45)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	52,975
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(2,427)
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 (provide details if material)		
	-Payment for the finance lease liability under AASB 16)	(68)	(209)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(68)</b>	<b>50,339</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	87,196	60,593
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(9,278)	(31,659)

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(45)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(68)	50,339
4.5	Effect of movement in exchange rates on cash held	2,151	767
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>79,995</b>	<b>79,995</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	54,984	56,970
5.2	Call deposits	24,709	29,924
5.3	Bank overdrafts	-	-
5.4	Other (provide details if material)		
	-Term deposit	302	302
	-Restricted cash (Advance payment from shareholder for SPP)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>79,995</b>	<b>87,196</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	189
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.*

The amount at 6.1 includes payment of Non-Executive Directors' fees and Executive Directors' remuneration.

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<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>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
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

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(9,278)
8.2 Cash and cash equivalents at quarter end (item 4.6)	79,995
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	79,995
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	8.62
<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:	
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:	
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:	
<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.

28 July 2022

Date: .....

By the Board

Authorised by: .....  
 (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.