

ASX/Media Release

## **ImmuteP Quarterly Activities Report & Appendix 4C Q2 FY25**

- Marking ImmuteP's transition to a Phase III biotech, the Company's pivotal **TACTI-004 trial in first-line non-small cell lung cancer (1L NSCLC)** received first regulatory approval
- **Mature data from INSIGHT-003** in 1L NSCLC demonstrates an excellent 32.9-month median overall survival (OS) and 81.0% 24-month OS rate, significantly outperforming historical controls
- **Promising new results in first line head & neck cancer** with PD-L1 CPS <1 reported at ESMO IO 2024, with median OS not reached and 67% 12-month OS rate well above historical controls
- Phase II in soft tissue sarcoma **shows three-fold increase in tumour hyalinization** (trial's primary endpoint, also associated with survival) compared to historical data from radiotherapy
- **Phase I trial of IMP761 reported favourable initial safety results** advancing the first-in-class agonist LAG-3 antibody program
- Publication in *Science Immunology* by Monash University & ImmuteP first to **resolve how human LAG-3 binds to MHC II** and show crystal structure human LAG-3/MHC II complex
- **Strong aggregate cash, cash equivalent and term deposit position** of A\$159.26 million, providing ImmuteP with an expected cash reach to the end of CY2026

**SYDNEY, AUSTRALIA – 31 January 2025** – ImmuteP Limited (ASX: IMM; NASDAQ: IMMP) ("ImmuteP" or "the Company"), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, provides an update on its activities for the quarter ended 31 December 2024 (Q2 FY25).

### **EFTI DEVELOPMENT PROGRAM FOR CANCER**

#### **TACTI-004 – Start of Phase III Trial in 1L NSCLC**

In December 2024, ImmuteP initiated its pivotal TACTI-004 Phase III clinical trial of eftilagimod alfa ("efti") for the treatment of first-line metastatic non-small cell lung cancer (1L NSCLC). The receipt of regulatory approval from the Australian Therapeutic Goods Administration means that ImmuteP has transitioned into a Phase III company; a significant milestone for the Company.

ImmuteP has successfully completed regulatory submissions in the vast majority of the more than 25 countries that will be part of the global TACTI-004 trial. Additional approvals from multiple countries are expected in the weeks and months ahead. The Company expects to enrol the first patient in Q1 of CY2025.

#### **TACTI-003 (KEYNOTE-C34) – Phase IIb Trial in 1L HNSCC**

In December 2024, ImmuteP reported further positive results from Cohort B of the TACTI-003 (KEYNOTE-C34) Phase IIb trial. Cohort B is evaluating efti in combination with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) as first-line treatment of recurrent or metastatic head and neck squamous cell carcinoma patients (1L HNSCC) with PD-L1 negative tumours (CPS <1) who typically do not respond

well to anti-PD-1 therapy alone. The results were presented by Martin Forster, M.D., Ph.D., at the ESMO Immuno-Oncology (IO) Annual Congress 2024.

Adding to the high response rates and favourable safety data previously reported in July 2024, the new data showed that, encouragingly, median overall survival (OS) has not yet been reached and the 12-month OS rate is 67%. A promising progression-free survival (PFS) of 5.8 months, interim median duration of response (DOR) of 9.3 months, 35.5% objective response rate (ORR) and 58.1% disease control rate (DCR) were also reported. The complete response rate increased to 12.9% and 16.1%, according to RECIST 1.1 and iRECIST, respectively. This data compares favourably to historical results from anti-PD-1 therapy alone in 1L HNSCC patients with CPS <1. In addition, efti in combination with KEYTRUDA continues to be well-tolerated with no new safety signals. ImmuteP will continue to follow the maturing data from TACTI-003 and engage with regulatory authorities regarding potential paths forward.

#### **AIPAC-003 – Phase II/III Trial in Metastatic Breast Cancer**

In October 2024, ImmuteP completed patient enrolment in the Phase II portion of the AIPAC-003 trial. The randomised Phase II portion of the trial enrolled 65 metastatic hormone receptor positive (HR+), HER2-negative/low or triple-negative breast cancer patients who exhausted endocrine therapy including cyclin-dependent kinase 4/6 (CDK4/6) inhibitors. Patients across 22 clinical sites in Europe and the United States have been randomised 1:1 to receive either 30mg or 90mg dosing of efti in combination with paclitaxel to determine the optimal biological dose consistent with the FDA's Project Optimus initiative and prior regulatory interaction with FDA. Data cleaning and analysis is ongoing.

#### **INSIGHT-003 – Phase I Trial in Non-Squamous 1L NSCLC**

In November 2024, first overall survival results were reported from the investigator-initiated INSIGHT-003 trial evaluating efti in combination with KEYTRUDA<sup>®</sup> (pembrolizumab) and doublet chemotherapy as first-line treatment for patients with advanced or metastatic non-squamous non-small cell lung cancer (1L NSCLC).

Mature data from patients with a minimum follow-up of 22 months (N=21) demonstrated results significantly exceeding historical controls and expectations. Data included a median OS of 32.9 months, median PFS of 12.7 months, and a 24-month OS rate of 81.0%. Data from all evaluable patients to date (N=40) showed a marked improvement in ORR compared to historical controls. Safety remains favourable with no new safety signals reported.

Subsequent to quarter end, patient enrolment was completed for INSIGHT-003 in January 2025. The trial reached its enrolment target of approximately 50 evaluable patients across multiple clinical sites in Germany led by the Frankfurt Institute of Clinical Cancer Research IKF. Additional data updates are expected in 2025 and beyond.

#### **EFTISARC-NEO – Phase II Trial in Soft Tissue Sarcoma**

Also in November, new data from the EFTISARC-NEO Phase II investigator-initiated trial of efti in combination with radiotherapy plus KEYTRUDA<sup>®</sup> (pembrolizumab) for patients with soft tissue sarcoma (STS) were presented at the Connective Tissue Oncology Society (CTOS) 2024 Annual Meeting.

Based on preliminary analysis, the triple combination therapy demonstrates significant efficacy in the neoadjuvant setting for resectable STS. The combination achieved a greater than three-fold increase in tumour hyalinization/fibrosis (median 50%) at the time of surgery as compared to a historical median of 15% from radiotherapy alone. In addition to being the primary endpoint of the EFTISARC-NEO study, the tumour hyalinization/fibrosis rate has also been identified as a predictor of overall survival for STS patients in the neoadjuvant setting.

The EFTISARC-NEO trial, with a data cut-off of 20 October 2024, also showed 71.4% of patients achieved a pathologic response defined as  $\geq 35\%$  of hyalinization/fibrosis and 9.5% of patients achieved a complete pathologic response. Additionally, the triple combination therapy is safe with no grade  $\geq 3$  toxicities related to efti and KEYTRUDA.

### **IMP761 DEVELOPMENT PROGRAM FOR AUTOIMMUNE DISEASE**

IMP761 is a first-in-class agonist LAG-3 antibody designed to restore balance to the immune system by enhancing the “brake” function of LAG-3 to silence dysregulated self-antigen-specific memory T cells that cause many autoimmune diseases.

In December 2024, ImmuteP reported favourable initial safety data from the placebo-controlled, double-blind first-in-human Phase I study evaluating IMP761. There have been no treatment related adverse events in the first three of five single ascending dose cohorts in healthy participants. Additional safety data and assessment of pharmacokinetic/pharmacodynamic (PK/PD) relationships to follow in the first half of CY2025.

### **PARTNER ACTIVITY**

#### **Collaboration with Monash University**

In December 2024, new findings that resolve how human lymphocyte activation gene 3 (LAG-3) binds to its main ligand MHC Class II (MHC-II), also known as HLA Class II (HLA-II) in humans, were published in *Science Immunology*. The work by Monash University and ImmuteP, is also the first to show the crystal structure of a human LAG-3/MHC-II complex and provides a better foundation for development of blocking LAG-3 therapeutics, including ImmuteP’s anti-LAG-3 small molecule program.

### **INTELLECTUAL PROPERTY**

During the quarter, ImmuteP was granted three new patents for efti and IMP761 in various territories. In particular, ImmuteP was granted a new patent for efti in combination with a PD-1 pathway inhibitor for the treatment of infection from the Brazilian Patent Office and a new patent for the same combination for the treatment of cancer or infection by the Japan Patent Office. In addition, a new patent was granted for IMP761 by the Malaysian Patent Office.

### **CORPORATE & FINANCIAL SUMMARY**

#### **Board & Senior Management Changes**

Independent Non-Executive Director, Anne Anderson, tendered her resignation from the role, effective from 4 October 2024. The Board thanked her for her contribution to ImmuteP and wished her every success with her next endeavours.

As Immutep's efti program has advanced into Phase III development, the Company has continued to grow and evolve its team. As part of this, Christian Mueller, who has been with Immutep for over eight years, most recently as SVP Regulatory and Strategy has been promoted to Chief Development Officer. In addition, Dr Florian Vogl, Immutep's Chief Medical Officer will depart the Company in April 2025. The Company's current Medical Affairs Advisor, who has been working in different roles closely with Immutep for over nine years, Dr Stephan Winckels, has been appointed acting CMO and taken over all related responsibilities.

### **Cash Flow Summary**

During the quarter, Immutep continued to advance its clinical trial programs for efti and for IMP761. The Company is well funded with a strong cash, cash equivalent and term deposit balance as at 31 December 2024 of approximately A\$159.26 million in total, which gives Immutep an expected cash reach to the end of CY2026. The A\$159.26 million total balance consists of: 1) a cash and cash equivalent balance of \$73.89 million and 2) bank term deposits totalling A\$85.37 million, which have been recognised as short-term investments due to having maturities of more than 3 months and less than 12 months.

In Q2 FY25, cash receipts from customers were \$8k. The net cash used in G&A activities in the quarter was \$566k, compared to \$961k in Q1 FY25. Payments to Related Parties (detailed in item 6.1 of the Appendix 4C) comprises Non-Executive Directors' fees and Executive Directors' remuneration of \$344k.

The net cash used in R&D activities during the quarter was \$16.2 million, compared to \$9.5 million to Q1 FY25. The increase is mainly due to the increased level of clinical trial activities especially the commencement of the phase III TACTI-004 clinical trial. Payments for staff costs were \$2.5 million in the quarter compared to \$2.8 million in Q1 FY25.

Total net cash outflows used in operating activities in the quarter were \$19.0 million compared to \$8.6 million in Q1 FY25.

Total cash flow used in investing activities for the quarter was \$30.4 million, mainly due to the net increase of \$30.0 million in short-term investments. The short-term investments are comprised of term deposits with maturities of greater than 3 months and less than 12 months. During the quarter, the company invested \$35.3 million in short-term investments and transferred back \$5.3 million from short-term investments that had matured to cash at bank, resulting in a net increase in short-term investments of \$30.0 million.

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

### **About Immutep**

Immutep is a clinical-stage biotechnology company developing novel LAG-3 immunotherapy for cancer and autoimmune disease. We are pioneers in the understanding and advancement of therapeutics related to Lymphocyte Activation Gene-3 (LAG-3), and our diversified product portfolio harnesses its unique ability to stimulate or suppress the immune response. Immutep is dedicated to leveraging its expertise to bring innovative treatment options to patients in need and to maximise value for shareholders. For more information, please visit [www.immutep.com](http://www.immutep.com).

**Australian Investors/Media:**

Catherine Strong, Sodali & Co

+61 (0)406 759 268; [catherine.strong@sodali.com](mailto:catherine.strong@sodali.com)

**U.S. Investors/Media:**

Chris Basta, VP, Investor Relations and Corporate Communications

+1 (631) 318 4000; [chris.basta@immutep.com](mailto:chris.basta@immutep.com)

This announcement was authorised for release by the CEO of Immutep 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")**

31 December 2024

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	8	28
1.2 Payments for		
(a) research and development	(16,222)	(25,694)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(32)	(109)
(d) leased assets	-	-
(e) staff costs	(2,464)	(5,239)
(f) administration and corporate costs	(566)	(1,527)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	799	2,001
1.5 Interest and other costs of finance paid	(6)	(17)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	4,152
1.8 Other (provide details if material) -Intellectual property management	(478)	(1,149)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(18,961)</b>	<b>(27,554)</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	(10)	(11)
(d) investments	(35,331)	(67,739)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
	(e) intellectual property	(276)	(276)
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	5,266	5,266
	(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	<b>Net cash from / (used in) investing activities</b>	<b>(30,351)</b>	<b>(62,760)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(254)
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)	(54)	(173)
3.10	<b>Net cash from / (used in) financing activities</b>	<b>(54)</b>	<b>(427)</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	120,343	161,790
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(18,961)	(27,554)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(30,351)	(62,760)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(54)	(427)
4.5	Effect of movement in exchange rates on cash held	2,910	2,838
4.6	<b>Cash and cash equivalents at end of period</b>	<b>73,887</b>	<b>73,887</b>

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	19,206	47,727
5.2	Call deposits	12,452	16,182
5.3	Bank overdrafts	-	-
5.4	Other (provide details if material) -Term deposit	42,229	56,434
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>73,887</b>	<b>120,343</b>

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	344
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<p><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></p> <p>The amount at 6.1 includes payment of Non-Executive Directors' fees and Executive Directors' remuneration.</p>		



<b>7.</b>	<b>Financing facilities</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>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
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.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	(18,961)
8.2	Cash and cash equivalents at quarter end (item 4.6)	73,887
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	73,887
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	3.90 <sup>1</sup>
	<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:	

<sup>1</sup> In addition to the total available funding at item 8.4, which does not include term deposits with maturities of greater than 90 days, Immutep has \$85.37 million in bank term deposits with maturity greater than 90 days, resulting in an aggregate cash, cash equivalent and term deposit position of \$159.26 million as at 31 December 2024 and an expected cash reach to end of CY2026.

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:

*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.

31 January 2025

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.