

ASX/Media Release

ImmuteP Quarterly Activities Report & Appendix 4C Q1 FY25

- Positive feedback received from US FDA regarding the planned TACTI-004 Phase III in first-line non-small cell lung cancer successfully concluding regulatory preparations for the trial design
- Efti in combination with MSD's KEYTRUDA® reports positive efficacy and favourable safety in first-line head and neck cancer in TACTI-003 Phase IIb trial
- First participant successfully dosed in the first-in-human Phase I trial of IMP761, a novel LAG-3 agonist antibody designed to treat autoimmune diseases
- ImmuteP added to the S&P ASX 300 Index, recognising its considerable growth and enhancing market visibility
- ImmuteP has a strong aggregate cash, cash equivalent and term deposit position of A\$172.3 million as at 30 September 2024 with an expected cash reach to the end of CY2026.

SYDNEY, AUSTRALIA – 29 October 2024 – 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 30 September 2024 (Q1 FY25).

EFTI DEVELOPMENT PROGRAM FOR CANCER

TACTI-004 (KEYNOTE-PNC91) – 1L NSCLC Phase III Clinical Collaboration with MSD

In July, ImmuteP received positive feedback from the US Food and Drug Administration (FDA) regarding its planned TACTI-004 Phase III trial of eftilagimod alfa (efti) in combination with KEYTRUDA® (pembrolizumab), MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, and histology-based platinum doublet chemotherapy for the treatment of first-line metastatic non-small cell lung cancer (1L NSCLC), regardless of PD-L1 expression.

The FDA feedback builds on previously received guidance from the Paul-Ehrlich-Institut and the Spanish Agency for Medicines and Health Products, successfully concluding the preparatory regulatory interactions for the design of this registrational trial. The study will enrol ~750 patients regardless of PD-L1 expression in order to address the entire 1L NSCLC market eligible for anti-PD-1 therapy.

TACTI-003 (KEYNOTE-C34) – Phase IIb clinical trial in 1L HNSCC

TACTI-003 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). The randomized Cohort A portion of the study is evaluating efti in combination with KEYTRUDA as compared to KEYTRUDA monotherapy in patients with PD-L1 positive (Combined Positive Score [CPS] ≥ 1) tumours, whereas Cohort B is evaluating efti in combination with KEYTRUDA in patients with PD-L1 negative tumours (CPS < 1).

In July, ImmuteP reported updated positive efficacy and safety results from Cohort B of the TACTI-003 Phase IIb trial at an ESMO Virtual Plenary session. In patients with negative PD-L1 expression (CPS < 1) in Cohort B,

efti in combination with KEYTRUDA[®] achieved a 35.5% objective response rate (ORR). This is among the highest recorded for a treatment approach not containing chemotherapy in patients with CPS <1. The immuno-oncology combination with efti also attained a high complete response rate of 9.7%, which compares favourably to a historical control of 0% from anti-PD-1 monotherapy in 1L HNSCC patients with a CPS <1. Additionally, durability of responses was tracking well.

In September, further data was reported from Cohort A of the TACTI-003 trial in a late-breaking abstract and prestigious Proffered Paper oral presentation at ESMO Congress 2024. At ESMO, late-breaking abstracts are generally reserved for high-quality, new research findings from randomised phase II or phase III trials with implications for clinical practice or understanding of disease processes. Proffered Papers are oral presentations of original data of superior quality, followed by expert discussion and perspectives.

In patients with PD-L1 positive tumours (CPS ≥1), efti in combination with KEYTRUDA outperformance was largest in CPS ≥20 with 31.0% ORR (34.5% ORR including a partial response recorded after data cut-off date) versus 18.5% ORR for KEYTRUDA monotherapy. Efti in combination with KEYTRUDA led to a high durability of response of 17.5 months in patients with CPS ≥1 and the combination continues to have favourable safety profile. Additionally, a statistically significant increase in absolute lymphocyte count, measured as an exploratory biomarker, was seen in the efti with KEYTRUDA arm indicating an effective efti-induced immune response in this randomised setting.

ImmuteP will continue to follow the maturing data from TACTI-003, with the most relevant endpoint of Overall Survival expected in 2025 and engage with regulatory authorities regarding potential paths forward.

TACTI-002 (KEYNOTE-PN798) – Phase II clinical trial in 1L NSCLC

ImmuteP continues to follow patients with first-line non-small cell lung cancer (1L NSCLC), in Part A of the TACTI-002 trial, where excellent median Overall Survival (mOS) rates were seen across all levels of PD-L1 expression. ImmuteP has previously reported final data from the other parts of the TACTI-002 trial.

AIPAC-003 – Integrated Phase II/III trial in MBC

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

INSIGHT-003 – Phase I in non-squamous 1L NSCLC

The investigator-initiated INSIGHT-003 trial continued to enrol patients throughout the quarter and they have been safely dosed across six sites in Germany. Further updates from the trial are anticipated in Q 4 CY2024.

INSIGHT-005 – Phase I trial in Urothelial Carcinoma

The INSIGHT-005 trial is evaluating efti and the anti-PD-L1 therapy BAVENCIO[®] (avelumab) in up to 30 patients with metastatic urothelial cancer. The study is jointly funded with Merck KGaA, Darmstadt, Germany.

EFTISARC-NEO – Phase II Trial in Soft Tissue Sarcoma

New data from the EFTISARC-NEO Phase II investigator-initiated trial of efti in combination with radiotherapy plus KEYTRUDA® (pembrolizumab) for patients with soft tissue sarcoma (STS) will be presented on 14 November at the Connective Tissue Oncology Society (CTOS) 2024 Annual Meeting taking place in San Diego, California.

IMP761 DEVELOPMENT PROGRAM FOR AUTOIMMUNE DISEASE

In August, ImmuteP successfully dosed the first participant in the first-in human Phase I trial of IMP761 after receiving regulatory clearance from the ethics and competent authority in the Netherlands to initiate the study. Safety data from this first-in-human study is anticipated by the end of the calendar year 2024, with pharmacokinetics and pharmacodynamics data in first half CY2025.

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.

INTELLECTUAL PROPERTY

During the quarter, ImmuteP was granted seven new patents for efti, IMP761 and LAG525 (ieramilimab) in various territories.

Two patents were granted for efti in combination with a PD-1 pathway inhibitor in South Korea and Brazil and one patent was granted in Mexico for a binding assay for determining MHC Class II binding activity. The assay is used in the characterisation of efti in GMP-grade manufacturing.

New patents were also granted for IMP761 in India and Israel. For LAG525, which is exclusively licensed to Novartis by ImmuteP, two new patents were granted in Australia and Taiwan.

CORPORATE & FINANCIAL SUMMARY

ImmuteP enters the ASX 300

Following the September quarterly review of the S&P Dow Jones Indices, ImmuteP was added to the S&P/ASX 300 index. Joining the ASX 300 recognises the Company's considerable growth over the years, enhances its market visibility and supports investor confidence.

Cash Flow Summary

During the quarter, ImmuteP continued to advance its clinical trial programs for efti and preclinical program for IMP761 to create value for shareholders. The Company is well funded with a strong cash and cash equivalent balance as at 30 September 2024 of approximately A\$120.3 million. In addition to this cash balance, ImmuteP has an A\$52.0 million bank term deposit, which has been recognised as a short-term investment due to the maturity date of 5-12 months. This aggregate position of A\$172.3 million as at 30 September 2024 gives ImmuteP an expected cash reach to the end of CY2026.

Cash receipts from customers in Q1 FY25 were \$20k. During the quarter, Immutep received a €2,194,918 (~A\$3,602,362) research and development (R&D) tax incentive payment in cash from the French Government under its Crédit d'Impôt Recherche scheme and \$549k from the Australian government R&D tax rebate.

The net cash used in G&A activities in the quarter was \$961k, compared to \$1.9 million in Q4 FY24. Payments to Related Parties (detailed in item 6.1 of the Appendix 4C) comprises Non-Executive Directors' fees and Executive Directors' remuneration of \$576k.

The net cash used in R&D activities during the quarter was \$9.5 million, compared to \$3.8 million to Q4 FY24. The increase is mainly due to the increased level of clinical trial activities. Payment for staff costs was \$2.8 million in the quarter compared to \$2.0 million in Q4 FY24.

Total net cash outflows used in operating activities in the quarter were \$8.6 million compared to \$7.4 million in Q4 FY24.

For the cash flow used in investing activities, the company invested \$32.4 million in bank term deposits with maturity between 5 and 6 months which has been recognised as a short-term investment.

Net cash outflow from financing activities for the quarter was approximately \$373 k including \$254k for the payment of capital raising cost.

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.

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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")

30th September 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	20	20
1.2 Payments for		
(a) research and development	(9,472)	(9,472)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(77)	(77)
(d) leased assets	-	-
(e) staff costs	(2,775)	(2,775)
(f) administration and corporate costs	(961)	(961)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1,202	1,202
1.5 Interest and other costs of finance paid	(11)	(11)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	4,152	4,152
1.8 Other (provide details if material) -Intellectual property management	(671)	(671)
1.9 Net cash from / (used in) operating activities	(8,593)	(8,593)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(1)	(1)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
	(d) investments		
	-Short term deposit	(32,408)	(32,408)
(e)	intellectual property	-	-
	(f) other non-current assets	-	-
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	(32,409)	(32,409)

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	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(254)	(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)	(119)	(119)
3.10	Net cash from / (used in) financing activities	(373)	(373)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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	161,790	161,790
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(8,593)	(8,593)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(32,409)	(32,409)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(373)	(373)
4.5	Effect of movement in exchange rates on cash held	(72)	(72)
4.6	Cash and cash equivalents at end of period	120,343	120,343

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	47,727	14,167
5.2	Call deposits	16,182	80,766
5.3	Bank overdrafts	-	-
5.4	Other (provide details if material) -Term deposit	56,434	66,857
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	120,343	161,790

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	576
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>		

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)	(8,593)
8.2	Cash and cash equivalents at quarter end (item 4.6)	120,343
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	120,343
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	14.00
	<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.

29 October 2024

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.