

ASX/Media Release

## **Immutep Quarterly Activities Report & Appendix 4C Q4 FY24**

- Entered into third and most important clinical trial collaboration and supply agreement to date with MSD to evaluate eftilagimod alfa (efti) in combination with KEYTRUDA® (pembrolizumab) and chemotherapy for first-line non-small cell lung cancer in a pivotal Phase III trial
- Continuing positive clinical data reported from efti:
  - Positive results from TACTI-003 Phase IIb trial in first-line head and neck squamous cell carcinoma with efti in combination with KEYTRUDA®
  - Encouraging efficacy and safety data from AIPAC-003 Phase II/III trial with efti and paclitaxel in metastatic breast cancer presented at ESMO Breast Cancer 2024
  - Novel triple combination of efti with radiotherapy and KEYTRUDA well tolerated with encouraging initial efficacy data in EFTISARC-NEO Phase II trial in soft tissue sarcoma
- Positive regulatory feedback received from Spanish Agency for Medicines and Health Products (AEMPS) Competent Authority regarding the upcoming TACTI-004 Phase III trial
- Appointed Centre for Human Drug Research (CHDR) to conduct Phase I trial to evaluate IMP761, a first-in-class LAG-3 agonist antibody designed to treat autoimmune diseases
- Exclusive license agreement signed with Cardiff University for development of an orally available, small molecule anti-LAG-3 therapy to treat cancer
- A\$100.2 million equity underwritten financing completed
- Immutep cash runway extended to the end of calendar year 2026, with a strong cash, cash equivalent and term deposit position totalling approximately A\$181.8 million

**SYDNEY, AUSTRALIA – 31 July 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 June 2024 (Q4 FY24).

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

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

In June, Immutep entered into a clinical trial collaboration and supply agreement with MSD (Merck & Co., Inc., Rahway, NJ, USA), through a subsidiary, to evaluate efti in combination with MSD’s anti-PD-1 therapy, KEYTRUDA and chemotherapy for a pivotal Phase III trial in first-line treatment of metastatic non-small cell lung cancer (1L NSCLC). The agreement marks the third and most important collaboration between Immutep and MSD for efti.

The TACTI-004 Phase III trial will enrol approximately 750 patients regardless of PD-L1 expression to address the entire 1L NSCLC market eligible for anti-PD-1 therapy, one of the largest markets in oncology. Under the collaboration, Immutep will conduct the registrational TACTI-004 Phase III trial and MSD will supply KEYTRUDA. Importantly, Immutep retains commercial rights to efti.

In other trials, efti in combination with KEYTRUDA with or without chemotherapy has generated compelling efficacy and favourable safety in 1L NSCLC, across all levels of PD-L1 expression.

During the quarter, Immutep also received positive feedback from the Spanish Agency for Medicines and Health Products (AEMPS) Competent Authority regarding TACTI-004. Following the end of the quarter, Immutep reported that it had received positive feedback from the US Food and Drug Administration (FDA) regarding the planned TACTI-004 trial. This positive feedback concluded the Company's regulatory preparations for the trial design.

### **TACTI-003 (KEYNOTE-PNC34) – Phase IIb clinical trial in 1L HNSCC**

During the quarter, Immutep reported positive topline results from the TACTI-003 Phase IIb trial in first-line head and neck squamous cell carcinoma (1L HNSCC). Efti in combination with KEYTRUDA (pembrolizumab) in 1L HNSCC led to overall response rates that exceed KEYTRUDA monotherapy across all levels of PD-L1 expression. In the overall evaluable TACTI-003 patient population (Cohorts A and B), the objective response rate (ORR) for efti in combination with KEYTRUDA was ~34% regardless of HPV status and PD-L1 expression, including patients with negative PD-L1 expression.

In the randomized controlled Cohort A, comprised of 1L HNSCC patients with any PD-L1 expression (CPS  $\geq 1$ ), the combination showed the strongest performance in patients with high PD-L1 expression (CPS  $\geq 20$ ) with an ORR of 31.0% and 75.9% disease control rate (DCR) in evaluable patients (N=29) as compared to a 18.5% ORR and 59.3% DCR for KEYTRUDA monotherapy in evaluable patients (N=27). In patients with low PD-L1 expression (CPS 1-19), the IO combination achieved an ORR of 34.5% in evaluable patients (N=29) as compared to a 33.3% ORR for KEYTRUDA monotherapy in evaluable patients (N=33), which is higher than historical published data for anti-PD-1 monotherapy including a 14.5% ORR in patients with CPS 1-19 in a registrational study<sup>1</sup>. The large difference of the control arm versus historical results in low PD-L1 patients may be explained by imbalances between the TACTI-003 treatment groups.

In Cohort B, comprised of patients with negative PD-L1 expression (CPS  $< 1$ ), efti in combination with KEYTRUDA achieved a 35.5% response rate in evaluable patients (N=31). This response rate is among the highest recorded for a treatment approach not containing chemotherapy in patients with CPS  $< 1$  and compares favourably to a historical control of 5.4% ORR from anti-PD-1 monotherapy.<sup>1</sup> Additionally, the IO combination attained a high complete response rate of 9.7% (3 of 31 patients), which compares favourably to a historical control of 0% from anti-PD-1 monotherapy in 1L HNSCC patients with a CPS  $< 1$ .<sup>1</sup> This efficacy and safety data from Cohort B was announced and presented by Dr. Robert Metcalf during an oral presentation at the ESMO Virtual Plenary session following the quarter end and represented a substantial improvement on preliminary Cohort B data Immutep reported in April 2024.

Based on the encouraging results from both Cohorts and high unmet medical need, the path forward in 1L HNSCC will be discussed with regulatory agencies. Efti has previously received FDA Fast Track designation in 1L HNSCC regardless of PD-L1 expression. Immutep expects to present additional clinical data from TACTI-003 in H2 CY2024.

### **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), 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**

Immutep reported encouraging efficacy, safety, and pharmacodynamic data from the safety lead-in phase of the AIPAC-003 Phase II/III trial at European Society for Medical Oncology (ESMO) Breast Cancer 2024 in May. This lead-in represents the first ever 90mg dosing of efti, given in combination with weekly paclitaxel. Positive efficacy results were reported in six metastatic breast cancer (MBC) patients including a confirmed 50% overall response rate (one complete response and two partial responses) and a 100% disease control rate.

The patient with a confirmed complete response (CR), who was diagnosed with triple-negative breast carcinoma (TNBC) in 2019 and failed multiple lines of therapy including a CDK 4/6 inhibitor for ER+/PR+ metastasis, started treatment in AIPAC-003 in May 2023. During treatment with efti and paclitaxel, this patient achieved a partial response that subsequently turned into a CR. As of the latest scan in mid-June, this patient's ongoing CR has been maintained for over four months since stopping paclitaxel and being treated with efti monotherapy.

The efti and paclitaxel combination continues to be well tolerated with a favourable safety profile. Currently, 49 patients have been enrolled into the randomization phase. Further updates from AIPAC-003 will be provided in CY2024.

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

The investigator-initiated INSIGHT-003 trial continued to enrol patients throughout the quarter, with 43 out of a target of 50 patients enrolled and safely dosed across six sites in Germany. INSIGHT-003 evaluates a triple combination therapy consisting of efti and an approved standard of care combination of chemotherapy (carboplatin and pemetrexed) and anti-PD-1 therapy (pembrolizumab) in patients as first line treatment in non-squamous NSCLC adenocarcinomas. Further updates from INSIGHT-003 will be provided in CY2024.

### **INSIGHT-005 – Phase I trial in Urothelial Carcinoma**

The study is evaluating efti and the anti-PD-L1 therapy BAVENCIO® (avelumab) in up to 30 patients with metastatic urothelial cancer and is jointly funded with Merck KGaA, Darmstadt, Germany. Currently, 2 out of a target of 30 patients have been enrolled.

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

Immutep announced initial encouraging data from EFTISARC-NEO, a Phase II investigator-initiated trial of efti in combination with radiotherapy, a standard-of-care treatment, plus KEYTRUDA for patients with soft tissue sarcoma (STS).

The triple combination has revealed no new safety findings and has been well tolerated in the first six patients who have completed the 10 weeks of treatment followed by surgery 2-3 weeks later. Initial efficacy data is very encouraging with 4 of 6 patients (67%) having near-complete pathological responses (the primary

endpoint of the study). These deep responses are rarely seen in STS patients with standard therapeutic approaches including radiotherapy.

The EFTISARC-NEO study is the first to evaluate efti in a neoadjuvant setting, which takes place before intended surgery, and the first to combine efti with radiotherapy. Importantly, the neoadjuvant setting allows for the impact of this novel combination to be assessed in the tumour microenvironment.

Currently, 18 out of a target of 40 patients have been enrolled. Further clinical data from the EFTISARC-NEO trial is expected to be reported at a medical conference in H2 CY2024.

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

In April, Immutep entered into an agreement with the Centre for Human Drug Research (CHDR), a world-class institute in Leiden, the Netherlands specialising in cutting-edge early-stage clinical drug research, to perform Immutep's first-in-human clinical study of IMP761. As a proprietary LAG-3 agonist antibody, IMP761 has been designed to restore balance to the immune system by enhancing the "brake" function of LAG-3 and address the underlying cause of many autoimmune diseases. CHDR will utilise its unique challenge model that enables insights into IMP761's pharmacological activity early in clinical development.

The trial is expected to enrol its first participants during Q3 CY2024.

### **PARTNERS**

#### **Cardiff University**

In June, Immutep entered into an exclusive License Agreement with Cardiff University granting the Company exclusive rights to develop and commercialise anti-LAG-3 small molecules, which represent the next generation of anti-LAG-3 therapies. The Agreement builds on many years of collaborative work between Immutep and the expert team at Cardiff University.

Immutep's program aims to develop an orally available small molecule anti-LAG-3 treatment for cancer patients at a lower cost compared with the anti-LAG-3 monoclonal and bi-specific antibodies that are commercially available or under clinical development today.

A number of promising compounds that block LAG-3 have been identified in collaboration with the world-leading scientists at Cardiff University.

### **INTELLECTUAL PROPERTY**

During the quarter, Immutep was granted three new patents. A new divisional patent was granted by the European Patent Office protecting Immutep's combination preparations comprising efti and a chemotherapy agent, which is either a platinum-based anti-neoplastic agent or a topoisomerase I inhibitor.

The Canadian and Indian Patent Office each granted a new patent protecting Immutep's intellectual property for a binding assay for determining MHC Class II binding activity. The assay is used in the characterisation of efti in GMP-grade manufacturing.

## **CORPORATE & FINANCIAL SUMMARY**

### **Fully Underwritten Financing**

Immutep raised a total of approximately A\$100.2 million during the quarter via an Institutional Placement (approximately A\$72.0 million) together with an Institutional Entitlement Offer (A\$17.6 million) and a Retail Entitlement Offer (A\$10.6 million). The Placement attracted strong demand from existing institutional shareholders of the Company, and also introduced several new institutional investors to the Immutep register. In addition, the Institutional Entitlement Offer had strong support with a take-up rate from eligible institutional investors of approximately 100%.

The new funds will be used predominantly to advance Immutep's pivotal Phase III TACTI-004 trial in first-line non-small cell lung cancer and to fund manufacturing, working capital and Offer costs.

### **Cash Flow Summary**

During the quarter, Immutep continued to fund the advancement of 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 June 2024 of approximately A\$161.8 million. In addition to this cash balance, Immutep has an A\$20 million bank term deposit, which has been recognised as a short-term investment due to the maturity date of 6-12 months. This aggregate position of A\$181.8 million as at 30 June 2024 gives Immutep an expected cash reach to the end of CY2026.

Cash receipts from customers in Q4 FY24 were \$14k, which was the same as for Q3 FY24. The net cash used in G&A activities in the quarter was \$1.9 million, compared to \$0.7 million in Q3 FY24. The increase is mainly due to prepayment of certain annual G&A costs. Payments to Related Parties (detailed in item 6.1 of the Appendix 4C) comprises Non-Executive Directors' fees and Executive Directors' remuneration of \$300k.

The net cash used in R&D activities in the quarter was \$3.8 million, compared to \$6.9 million to Q3 FY24. Payment for staff costs was \$2.0 million in the quarter which was consistent with the last quarter.

Total net cash outflows used in operating activities in the quarter were \$7.4 million compared to \$9.0 million in Q3 FY24.

For the cash flow used in investing activities, the company invested \$20 million in bank term deposit with maturity between 6 and 12 months which has been recognised as a short-term investment.

The Company completed a capital raising of approximately \$100.2m in June 2024 and paid capital raising costs of \$4.6 million in the quarter. Net cash inflow from financing activities for the quarter was approximately \$95.7 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).

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<sup>1</sup> *Burtness, B. et al. Pembrolizumab Alone or With Chemotherapy for Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma in KEYNOTE-048: Subgroup Analysis by Programmed Death Ligand-1 Combined Positive Score. Journal of Clinical Oncology 2022 40:21, 2321-2332. Note, the 5.4% ORR is calculated from the 37 evaluable patients with CPS <1.*

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 June 2024

<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	14	198
1.2 Payments for		
(a) research and development	(3,750)	(27,240)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(114)	(495)
(d) leased assets	-	-
(e) staff costs	(1,986)	(8,530)
(f) administration and corporate costs	(1,946)	(5,108)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	974	3,692
1.5 Interest and other costs of finance paid	(7)	(28)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,774
1.8 Other (provide details if material) -Intellectual property management	(616)	(1,025)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(7,431)</b>	<b>(34,762)</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)	(26)
(d) investments	(20,000)	(20,086)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
(e) intellectual property	-	(863)
(f) other non-current assets	-	16
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	-	(37)
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	-	-
2.5 Other (provide details if material)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(20,006)</b>	<b>(20,996)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	100,236	100,236
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	(4,587)	(4,883)
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)	6	(182)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>95,655</b>	<b>95,171</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	95,414	123,418
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(7,431)	(34,762)



<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)	(20,006)	(20,996)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	95,655	95,171
4.5	Effect of movement in exchange rates on cash held	(1,842)	(1,041)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>161,790</b>	<b>161,790</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	14,167	11,024
5.2	Call deposits	80,766	49,465
5.3	Bank overdrafts	-	-
5.4	Other (provide details if material) -Term deposit	66,857	34,925
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>161,790</b>	<b>95,414</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	300
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. 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)	(7,431)
8.2 Cash and cash equivalents at quarter end (item 4.6)	161,790
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	161,790
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	21.77
<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.

31 July 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.