

ASX/Media Release

**Immutep Quarterly Activities Report & Appendix 4C
Q1 FY24**

- Excellent survival benefit in 1st line non-small cell lung cancer (1L NSCLC) in TACTI-002 trial: median Overall Survival of 35.5 months (TPS \geq 1% patients) providing additional 12-18 months survival compared to historical data, reported post period
- Late-stage & registrational trial progress:
 - *1st line head & neck squamous cell carcinoma (1L HNSCC)* - Phase IIb TACTI-003 trial recruitment progressing and expected to be complete in November 2023
 - *1L NSCLC* - Preparations ongoing to commence Phase III TACTI-004 registrational trial in CY2024
 - *Metastatic breast cancer (MBC)* - Patient recruitment ongoing for Phase II/III AIPAC-003 trial, first safety data from the open-label safety lead-in portion expected to be reported in Q4 CY2023
- Strong Overall Response Rate in INSIGHT-003 of 71.4%, plus encouraging response rate of 70.6% for low or negative PD-L1 expressors in NSCLC comparing favourably to historical data, reported post period
- Efti trial expansion: First patient enrolled in EFTISARC-NEO Phase II trial in soft tissue sarcoma
- Well financed: Strong cash position of \$110.1m, with cash runway to early CY2026

SYDNEY, AUSTRALIA – 31 October 2023 – [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 the ongoing development of its product candidates, eftilagimod alpha (efti) and IMP761 for the quarter ended 30 September 2023 (Q1 FY24).

EFTI DEVELOPMENT PROGRAM FOR CANCER

In August 2023, Immutep received positive scientific advice from the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) for the continued development of efti. The CHMP advised further toxicology studies are not needed for a future Marketing Authorisation Application (MAA) for efti in Europe. Similar advice was received from the US Food and Drug Administration (FDA) for a potential future Biologics License Application (BLA).

The Company also received regulatory authorisation in September 2023 for efti manufactured at commercial 2,000L scale for use in clinical trials across multiple European countries including Germany, Belgium, Denmark and the United Kingdom. This followed the successful scale up of the manufacturing process of efti (from the 200L process) to commercial scale at WuXi Biologics. Immutep will introduce efti manufactured by the 2,000L scale process into current and future clinical trials.

TACTI-002 (KEYNOTE-PN798)

Phase II clinical trial evaluating efti + KEYTRUDA® (pembrolizumab)

1st line Non-Small Cell Lung Cancer (1L NSCLC)

Following the end of the quarter, Immutep reported excellent Overall Survival results from efti in combination with KEYTRUDA® in patients with metastatic NSCLC at the ESMO Congress 2023 in Spain in October.

Exceeding expectations, median Overall Survival has reached 35.5 months in NSCLC patients expressing PD-L1 (patients with a Tumour Proportion Score (TPS) of $\geq 1\%$), 23.4 months in patients with low PD-L1 expression (TPS 1-49%) and encouragingly, has not yet been reached in patients with high PD-L1 expression (TPS $\geq 50\%$).

A 35.5-month survival benefit gives these patients 12 to 18 months of additional survival compared to historical data from the current best approved option: pembrolizumab in combination with doublet chemotherapy (see Table 1). In addition to the substantial survival benefit, the combination of efti and pembrolizumab is chemo-free, avoiding the toxic side effects seen in chemo options. Efti is enabling deep, durable responses for patients regardless of PD-L1 expression with a favourable safety profile in line with anti-PD-1 monotherapy.

Table 1: Overall Survival of Efti + KEYTRUDA® versus standard-of-care Immuno-Oncology (IO), IO-IO, IO-chemo, and IO-IO-chemo therapies for 1st line treatment of advanced non-small cell lung cancer patients with PD-L1 TPS $\geq 1\%$

Therapy	Median Overall Survival ¹
Efti + Pembrolizumab	35.5 months
Pembro + Doublet Chemo (NSQ)*	23.3 months
Pembro + Doublet Chemo (SQ)*	18.9 months
Ipilimumab + Nivolumab ²	17.1 months
Pembrolizumab monotherapy ²	16.4 months
Ipi + Nivo + 2 cycles Doublet Chemo	15.8 months

* NSQ = Non-squamous; SQ = Squamous

TACTI-003 – Phase IIb clinical trial in 1st line HNSCC

The Phase IIb TACTI-003 trial is ongoing in patients with 1st line HNSCC. Patient recruitment reached ~99% in October and is expected to be complete in November 2023. The primary analysis according to the trial protocol will be performed after all subjects in the randomized part have completed at least three cycles of treatment (18 weeks in total) or discontinued the trial. The Company expects to report data from the trial in H1 CY2024.

TACTI-004 – Phase III registrational trial in 1st line NSCLC

Throughout the quarter, ImmuteP continued its preparations to commence the TACTI-004 trial. The trial is expected to start in CY2024.

AIPAC-003 – Integrated Phase II/III trial in Metastatic Breast Cancer

Patient recruitment into the AIPAC-003 trial continued throughout the quarter with 15 clinical sites now actively recruiting. Six patients were enrolled and have completed the dose limiting toxicity (DLT) window of the first cycle in the open-label safety lead-in portion. The safety evaluation of the six patients is underway with the Independent Data Safety Monitoring Committee (IDMC) review meeting planned for beginning of November 2023. If no dose limiting toxicities are observed in those six patients, the randomized dose optimization (Phase II) part can start in Q4 CY2023.

INSIGHT-003 – Phase I in 1st line NSCLC

At the ESMO Congress 2023 in October, further encouraging efficacy and tolerability data was presented from the ongoing investigator-initiated INSIGHT-003 trial evaluating efti plus anti-PD-1 therapy and doublet chemotherapy as 1st line therapy in metastatic non-squamous non-small cell lung cancer.

A strong Overall Response Rate of 71.4% and 90.5% Disease Control Rate were reported. Median Overall Survival (OS) has not yet been reached. The median Progression Free Survival (PFS) was 10.1 months.

In this study, 81% of patients have low or negative PD-L1 expression, making them typically less responsive to anti-PD-1 based therapy. For low or negative PD-L1 expressors (TPS <50%), the ORR was 70.6% which compares favourably to reported results from a registrational trial of anti-PD-1 and doublet chemotherapy that yielded a response rate of 40.8% in the same patient population.

INSIGHT-005 – Phase I trial in Urothelial Carcinoma

Following receipt of regulatory approvals to initiate INSIGHT-005, preparations to commence this investigator-initiated trial are continuing at the Frankfurt Institute of Clinical Cancer Research, IKF.

EFTISARC-NEO – Phase II Trial in Soft Tissue Sarcoma

The first soft tissue sarcoma (STS) patient was enrolled and safely dosed in the Phase II EFTISARC-NEO trial in July. The trial is the first chemo-free triple combination therapy of efti and is the first to evaluate it in a neoadjuvant setting. STS is an orphan disease with high unmet medical need and poor patient prognosis. Currently six patients have been recruited into this trial which is funded by a Polish grant program.

IMP761 DEVELOPMENT PROGRAM FOR AUTOIMMUNE DISEASE

During the quarter, Immutep commenced the toxicology study evaluating the safety and toxicity of IMP761, the Company's proprietary preclinical candidate. IMP761 is the world's first LAG-3 agonist that aims to treat the underlying cause of multiple autoimmune diseases. The study is a key step before first-in-human trials can begin.

INTELLECTUAL PROPERTY

Immutep was granted two new patents during the quarter. A new patent protecting IMP761 was granted in September by IP Australia, the Australian Government's patent agency.

The Company was also granted a new patent by the Brazilian Industrial Property Office in September protecting Immutep's potency assay for release testing of efti. This assay is used in the commercial-scale (2,000L) manufacturing process for efti. The Brazilian patent follows similar patents granted in Japan and Australia in 2023, and Korea in 2022.

FINANCIAL SUMMARY

Immutep continued to prudently manage its cashflow over the first quarter of the new financial year (Q1 FY24), while strategically investing into clinical trial programs for efti.

With a cash and cash equivalent balance as at 30 September 2023 of approximately \$110.1 million, Immutep's cash position remains very strong with an expected cash reach till early CY2026.

The Company has sufficient capital to reach key milestones that will potentially add value to efti and IMP761.

Cash receipts from customers in Q1 FY24 were \$132k, compared to \$16k in Q4 FY23. The net cash used in G&A activities in the quarter was \$1.61 million, which is the same as Q4 FY23.

Payments of \$464k to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, comprises Non-Executive Directors' fees and Executive Directors' remuneration.

The net cash used in R&D activities in the quarter was \$9.72 million, compared to \$5.41 million in Q4 FY23. The increase in cash used for the quarter was mainly due to increased clinical trial activities.

Total net cash outflows used in operating activities in the quarter was \$12.86 million compared to \$8.35 million in Q4 FY23.

Payment for the acquisition of Intellectual Property was \$328k in Q1 FY24, compared to nil in Q4 FY23.

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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¹ Arrow lengths in Table 1 are proportional representations of OS data. Data for standard-of-care therapies taken from publications of respective registrational trials (e.g., KN-042, KN-189, KN-407, CM-227, CM-9LA), and comparison of data is from different clinical trials.

² Ipi + Nivo approved in US for 1L NSCLC PD-L1 TPS >1% but not in EU; Pembro monotherapy not approved in Europe for TPS 1-49%.

This announcement was authorised for release by the Board 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")

30 September 2023

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	132	132
1.2 Payments for		
(a) research and development	(9,720)	(9,720)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(155)	(155)
(d) leased assets	-	-
(e) staff costs	(2,293)	(2,293)
(f) administration and corporate costs	(1,610)	(1,610)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1,025	1,025
1.5 Interest and other costs of finance paid	(3)	(3)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material) -Intellectual property management	(231)	(231)
1.9 Net cash from / (used in) operating activities	(12,855)	(12,855)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(10)	(10)
(d) investments	-	-
(e) intellectual property	(328)	(328)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
(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	(338)	(338)

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	(296)	(296)
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)	(71)	(71)
-refund for Overpayment from shareholder	7	7
3.10 Net cash from / (used in) financing activities	(360)	(360)

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	123,418	123,418
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(12,855)	(12,855)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(338)	(338)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(360)	(360)
4.5	Effect of movement in exchange rates on cash held	279	279
4.6	Cash and cash equivalents at end of period	110,144	110,144

5. Reconciliation of cash and cash equivalents	Current quarter \$A'000	Previous quarter \$A'000
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		
5.1 Bank balances	24,868	27,751
5.2 Call deposits	81,683	92,078
5.3 Bank overdrafts	-	-
5.4 Other (provide details if material)	3,593	3,589
-Term deposit		
-Restricted cash (Advance payment from shareholder for SPP)		
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	110,144	123,418

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	464
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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<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 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)	(12,855)
8.2 Cash and cash equivalents at quarter end (item 4.6)	110,144
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	110,144
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	8.57
<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 October 2023

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.