

ASX/Media Release

Immutep Quarterly Activities Report & Appendix 4C Q4 FY23

Late-stage & registrational trial progress:

- TACTI-004 Phase III - Positive feedback received from US FDA for planned registrational trial in 1st line non-small cell lung cancer (1L NSCLC)
- TACTI-003 Phase IIb – Randomised study in 1st line head & neck squamous cell carcinoma (1L HNSCC) has reached ~91% patient recruitment and top-line results expected in H2 of CY2023
- AIPAC-003 Phase II/III - First patient dosed in metastatic breast cancer trial

Positive eftilagimod alpha (efti) clinical results in TACTI-002 and INSIGHT-003 trials:

- TACTI-002 Phase II evaluating efti + KEYTRUDA® (pembrolizumab) led to excellent initial Overall Survival (OS) benefit of 25 months in 1L NSCLC patients with $\geq 1\%$ PD-L1 TPS; more mature data in H2 of CY2023
- Final results in 2L HNSCC from TACTI-002 presented at ASCO 2023 showed promising response rates, overall survival, and durable responses including a Complete Response in patient with negative PD-L1
- INSIGHT-003 Phase I evaluating efti + KEYTRUDA® + doublet chemo achieved 67% response rate and 91% disease control rate in 1L NSCLC, despite 81% of patients having low or negative PD-L1 expression

Efti trial expansion:

- INSIGHT-005 - Regulatory approval to commence the investigator-initiated trial in urothelial carcinoma
- EFTISARC-NEO - Investigator-initiated trial commenced in soft tissue sarcoma

Well financed:

- Strong cash position of \$123.4m, following A\$80m capital raise for registrational and late-stage trials of efti and potentially a first-in-human trial for IMP761; extends cash runway to early CY2026

SYDNEY, AUSTRALIA – 31 July 2023 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel LAG-3 related immunotherapy treatments for cancer and autoimmune diseases, provides an update on the ongoing development of its product candidates, eftilagimod alpha (efti) and IMP761 for its fiscal fourth quarter ended 30 June 2023 (Q4 FY23).

EFTI DEVELOPMENT PROGRAM FOR CANCER

TACTI-002 (KEYNOTE-PN798) Phase II clinical trial evaluating efti + KEYTRUDA® (pembrolizumab):

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

Meaningful long-term survival was reported in from Immutep's TACTI-002 (Two **ACTIVE** Immunotherapies) trial in May. An initial median Overall Survival (mOS) of 25 months was achieved in 1L NSCLC patients with $\geq 1\%$ PD-L1 TPS (Tumour Proportion Score), a key area of focus for future clinical development with FDA Fast Track designation granted for efti and pembrolizumab in this patient

population. Encouragingly, the initial mOS of 25.0 months for this chemo-free combination exceeds the reported rates for patients with the same PD-L1 TPS of $\geq 1\%$ from registration trials of anti-PD-1 monotherapy (16.4-month mOS) and combinations of anti-PD-1 with chemotherapy (15.8-to-23.3-month mOS) or with anti-CTLA-4 (17.1-month mOS).

Based on the robust initial results, the trial's Data Monitoring Committee recommended extending OS follow-up data collection to show mature 3-year and potentially 5-year rates. More mature OS data and additional efficacy and safety results will be presented at a major medical conference in H2 CY2023.

- **2nd Line Head and Neck Squamous Cell Carcinoma (2L HNSCC)**

Immutep reported positive final TACTI-002 data in 2L HNSCC patients in a poster presentation at the ASCO 2023 Annual Meeting in June. Deep and durable responses were seen from efti plus pembrolizumab regardless of patients' PD-L1 expression levels (measured by Combined Positive Score or CPS). Encouragingly, median Duration of Response had not been reached (meaning the response is still ongoing) despite a long median follow up of 39 months, providing continued evidence of the durable responses efti helps drive. Notably, one long-lasting Complete Response occurred in a patient with negative PD-L1 expression, who wouldn't typically be expected to respond to PD-L1 monotherapy.

Efti plus pembrolizumab led to an encouraging overall response rate (ORR) of 29.7% and Complete Response (CR) rate of 13.5% in 2L HNSCC patients. Responses were seen across all PD-L1 subgroups. A promising ORR of 38.5% & 60%, median Overall Survival (mOS) of 12.6 & 15.5 months, and 12-month Overall Survival (OS) rate of 52.0% & 66.7%, were seen in patients with a PD-L1 CPS of ≥ 1 and a PD-L1 CPS ≥ 20 , respectively. The results from the chemo-free IO-IO combination of efti plus pembrolizumab in 2L HNSCC patients with a PD-L1 CPS ≥ 1 compare favourably to reported results from a registrational trial of anti-PD-1 monotherapy in the same patient population, which showed a 17.3% ORR, mOS of 8.7 months, 12-month OS rate of 40%, a CR rate of 2%, and mDoR of 18.4 months.¹

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

Immutep's ongoing TACTI-003 trial is evaluating efti in combination with pembrolizumab in the 1st line setting in HNSCC. The trial has reached ~91% patient recruitment, and Immutep is on track to report top-line results from TACTI-003 in H2 of CY2023.

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

In May, Immutep received positive feedback from the US Food and Drug Administration (FDA), which is supportive of a registrational trial to evaluate efti in combination with an anti-PD-1 for the treatment of 1L NSCLC. Among the items discussed at the meeting were the toxicological package and general aspects of the trial design, including statistics and potential patient population with a focus on 1st line NSCLC patients with a Tumor Proportion Score (TPS) PD-L1 of $\geq 1\%$ for which efti plus pembrolizumab has already received Fast Track designation. The Company is advancing its preparations for the trial.

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

Immutep enrolled and safely dosed the first patient in its integrated Phase II/III AIPAC-003 trial in May. Recruitment has continued with 12 clinical sites now actively recruiting patients, and the trial currently has 3

patients enrolled in the open-label lead-in portion of the trial. This lead-in portion of 6 to 12 patients dosed at 90mg efti will be followed by a randomized (1:1) portion of the Phase II consisting of up to 58 evaluable patients who will receive 30mg efti or 90mg efti to determine the optimal biological dose in combination with paclitaxel.

INSIGHT-003 – Phase I in 1st line NSCLC

Immutep reported new encouraging clinical data in 1L NSCLC patients in May from the INSIGHT-003 trial, an investigator-initiated Phase I trial conducted by the Frankfurt Institute of Clinical Cancer Research IKF as part of the investigator-initiated INSIGHT platform of studies. The new data showed the therapy is well tolerated and promising initial efficacy signals were observed including a 67% response rate and 91% disease control rate in metastatic 1st line non-small cell lung cancer patients, despite 81% of patients having low or negative PD-L1 expression.

INSIGHT-005 – Phase I trial in Urothelial Carcinoma

Regulatory approval was received from the Paul-Ehrlich-Institut (“PEI”), German Federal Institute for Vaccines and Biomedicines, to initiate INSIGHT-005 in May. This study is an investigator-initiated trial, open-label Phase I trial evaluating the safety and efficacy of efti in combination with BAVENCIO® (avelumab) in up to 30 patients with metastatic urothelial carcinoma which is being conducted by Frankfurt Institute of Clinical Cancer Research IKF as part of the investigator-initiated INSIGHT platform.

EFTISARC-NEO - Phase II Trial in Soft Tissue Sarcoma

The investigator-initiated study, EFTISARC-NEO, was initiated by the Maria Skłodowska-Curie National Research Institute of Oncology in April. The study is an open-label Phase II trial evaluating efti in combination with radiotherapy and pembrolizumab in up to 40 soft tissue sarcoma (STS) patients in the neoadjuvant (prior to surgery) setting and is the first time efti will be studied in neoadjuvant, non-metastatic cancer setting. The first patient has been enrolled and safely dosed in July 2023.

IMP761 DEVELOPMENT PROGRAM FOR AUTOIMMUNE DISEASE

In May, Immutep appointed a clinical research organisation to conduct its GLP toxicology study evaluating the safety and toxicity of IMP761, Immutep’s proprietary preclinical candidate and the world’s first LAG-3 agonist for autoimmune diseases. This study is a key step before the commencement of first-in-human trials to treat the underlying cause of multiple autoimmune diseases.

INTELLECTUAL PROPERTY

Immutep was granted three patents during the quarter. A new patent was granted by the US Patent Office protecting Immutep’s intellectual property for treating cancer by administering efti and a PD-1 pathway inhibitor, specifically BMS-936559, durvalumab, atezolizumab or avelumab.

The US Patent Office also granted a new patent for composition-of-matter claims covering Immutep’s pre-clinical immunosuppressive product candidate, IMP761, which is designed to target the root cause of autoimmune diseases by directly silencing self-antigen-specific effector T cells.

Finally, the Japan Patent Office granted a new patent protecting Immutep’s intellectual property for a potency assay for release testing of efti which is used in the commercial-scale (2,000L) manufacturing process for efti.

This new Japanese patent follows the grant of a similar patents in Australia and South Korea in 2023 and 2022 respectively.

CORPORATE OVERVIEW

Financing Completed

During the quarter, Immutep completed a fully underwritten pro rata accelerated non-renounceable entitlement offer (Entitlement Offer) and a placement to institutional investors (Placement) to raise a total amount of A\$80 million. The funds raised extends Immutep's cash runway to early CY2026 and will support its registrational and late-stage trials of efti and ongoing expansion of its clinical pipeline including potentially a first-in-human trial for IMP761. Immutep was pleased to have very strong support from its existing shareholders and welcomed new healthcare-focussed and specialist funds to its register.

Board Changes

In April, Immutep was pleased to appoint highly experienced corporate lawyer, Lis Boyce to its Board as Non-Executive Director. Ms Boyce is currently a partner at Piper Alderman. She has extensive involvement in the Life Sciences and Healthcare sectors and is currently deputy chair of AusBiotech's AusMedtech Advisory Group and a member of AusBiotech's NSW Leadership Committee. Ms Boyce replaces Lucy Turnbull who resigned from the Board at the same time.

Senior Leadership

The Company appointed Florian D. Vogl, M.D., Ph.D., MSc, as Chief Medical Officer (CMO) in May. Dr Vogl brings over a decade of experience in the biopharmaceutical industry to the role, with extensive clinical development expertise in the field of oncology. Prior to Immutep, Dr. Vogl held senior management roles in Europe and the United States, including CMO of Cellestia Biotech, Head of Clinical Development Europe at Rainier Therapeutics, Senior Global Medical Leader, Oncology Development at Novartis, and Early Development Leader, Oncology Pipeline at Amgen. He assumed the CMO role from Frédéric Triebel, M.D., Ph.D., who is now primarily focused on his responsibilities as CSO and as a member of Immutep's Board of Directors.

FINANCIAL SUMMARY

Immutep's financial performance over the final quarter (Q4 FY23) continues to reflect prudent cash management as well as investment into its clinical trial program for efti, as aligned with its strategy. Following its financing completed in June, Immutep is fully funded for its current and expanded clinical program through to early CY2026.

Cash receipts from customers Q4 FY23 were \$16k, compared to \$30k in Q3 FY23. The net cash used in G&A activities in the quarter was \$1.61 million, compared to \$1.12 million in Q3 FY23. The increase is mainly due to the prepayment of certain G&A expenses, including insurance premiums.

Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter includes \$282k in payment of Non-Executive Director's fees and Executive Director's remuneration.

The net cash used in R&D activities in the quarter was \$5.41 million, compared to \$11.52 million in Q3 FY23. The decrease in cash used for the quarter was mainly due to reduced manufacturing activities in the current quarter and the prepayment of clinical trial expenses in the previous quarter.

Total net cash outflows used in operating activities in the quarter was \$8.35 million compared to \$14.17 million in Q3 FY23.

The company completed a capital raising of \$80m in June 2023, which consisted of a placement and institutional component of the Entitlement Offer of approximately \$68m and a retail Entitlement Offer component of approximately \$12m. Net cash inflow from financing activities for the quarter was \$76.2m.

Immutep's cash and cash equivalent balance as at 30 June 2023 was approximately \$123.4 million. Immutep will continue to manage its strong cash balance carefully as it pursues its overall development strategy for efiti and IMP761.

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

KEYTRUDA[®] is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

1. Ezra E W Cohen et al., Pembrolizumab versus methotrexate, docetaxel, or cetuximab for recurrent or metastatic head-and-neck squamous cell carcinoma (KEYNOTE-040): a randomised, open-label, phase 3 study; The Lancet 2019. [http://dx.doi.org/10.1016/S0140-6736\(18\)31999-8](http://dx.doi.org/10.1016/S0140-6736(18)31999-8)

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 market for 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 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 June 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	16	87
1.2 Payments for		
(a) research and development	(5,411)	(29,971)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(126)	(431)
(d) leased assets	-	-
(e) staff costs	(1,624)	(6,032)
(f) administration and corporate costs	(1,613)	(4,059)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	414	913
1.5 Interest and other costs of finance paid	(3)	(35)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,645
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(8,347)	(35,883)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(3)	(47)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

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	-	16
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	(3)	(31)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	80,083	80,083
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	(3,849)	(3,849)
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)	(35)	(185)
	-Overpayment from shareholder to be refunded	(7)	(7)
3.10	Net cash from / (used in) financing activities	76,192	76,042

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	55,201	79,995
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(8,347)	(35,883)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(31)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	76,192	76,042
4.5	Effect of movement in exchange rates on cash held	375	3,295
4.6	Cash and cash equivalents at end of period	123,418	123,418

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	27,751	32,023
5.2 Call deposits	92,078	19,625
5.3 Bank overdrafts		-
5.4 Other (provide details if material) -Term deposit -Restricted cash (Advance payment from shareholder for SPP)	3,589	3,553 -
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	123,418	55,201

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	282
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)	(8,347)
8.2 Cash and cash equivalents at quarter end (item 4.6)	123,418
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	123,418
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	14.79
<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 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.