

ASX/Media Release

## Immutep Quarterly Activities Report & Appendix 4C Q3 FY23

- Initiation of integrated Phase II/III AIPAC-003 trial evaluating eftilagimod alpha (efti) and paclitaxel in HER2-neg/low metastatic breast cancer and triple-negative breast cancer
- Positive final data reported from patients with 2nd line non-small cell lung cancer refractory to anti-PD-(L)1 therapies, including Overall Survival rate of 39% at 21 months
- Randomised TACTI-003 Phase IIb trial has reached 75% enrolment subsequent to quarter end and top line results anticipated in H2 of CY2023
- Expansion of INSIGHT-003 evaluating triple combination of efti, pembrolizumab and chemotherapy post encouraging initial safety and efficacy in 1st line non-small cell lung cancer
- Solid cash position of \$55.2 million, with cash runway to the end of FY2024 (June 2024)
- Since period end Lis Boyce appointed as Non-Executive Director and Florian D. Vogl, M.D., Ph.D., appointed Chief Medical Officer

**SYDNEY, AUSTRALIA – 27 April 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 the quarter ended 31 March 2023 (Q3 FY23).

### EFTI DEVELOPMENT PROGRAM FOR CANCER

Immutep made strong progress during the quarter to advance its clinical development strategy to position the company, or a potential partner, to fully exploit efti’s broad potential.

### AIPAC-003 - Phase II/III trial in Metastatic Breast Cancer (MBC)

In March, Immutep initiated AIPAC-003 (Active Immunotherapy **PA**clitaxel), its integrated Phase II/III trial evaluating efti in combination with paclitaxel for the treatment of HER2-neg/low metastatic breast cancer and triple-negative breast cancer. These two indications account for ~78% of breast cancer cases. The trial commenced following the regulatory approval in the United States and Institutional Review Board (IRB) approval in Spain. Immutep anticipates enrolling the first patient in Q2 CY2023.

As a first-in-class soluble LAG-3 protein targeting MHC Class II ligands on antigen-presenting cells (APC), efti is well positioned to improve clinical outcomes from standard-of-care chemotherapy due to its unique mechanism of action. Its activation of APC triggers a broad immune response that includes significant increases in cytotoxic CD8<sup>+</sup> T cells armed with chemo-induced tumour antigens to target cancer.

The AIPAC-003 trial employs an integrated clinical design agreed to with the FDA to help inform a potential Biologics License Application (a request for permission to sell a biologic product) and a potential Marketing

Authorisation Application with the European Medicines Agency (EMA). This trial design also allows for a risk-balanced approach with the Phase III portion dependent on the Phase II results, among other items.

### **TACTI-002 (also designated KEYNOTE-PN798) Phase II clinical trial**

Positive final data on safety and efficacy was reported from Part B of the TACTI-002 trial in patients with 2nd line non-small cell lung cancer (NSCLC) refractory to anti-PD-(L)1 therapies in a Mini Oral presentation at ESMO's European Lung Cancer Congress (ELCC) 2023. These patients have few therapeutic options, and the addition of efti to pembrolizumab may help these patients by reverting the confirmed anti-PD-(L)1 therapy resistance.

The Company reported encouraging clinical results, including an Overall Survival (OS) rate of 39% at 21 months. In addition, 83% of patients studied for Tumour Growth Kinetics showed deceleration (50%) in tumour growth or shrinkage (33%) of target lesions. Responses were confirmed and durable with responders participating in the study for more than 19 months.

The ORR, PFS, and OS were more pronounced in patients with high PD-L1 expression (N=6) or who were secondary resistant (N=25). For patients with  $\geq 50\%$  PD-L1 TPS expression, median OS was not yet reached, overall response rate (ORR) was 33.3%, and 6-month progression-free survival (PFS) was 50%. Efti plus pembrolizumab was well tolerated without any new safety signals, and there was no treatment discontinuation due to adverse reactions.

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

In early 2023 Immutep announced it has successfully enrolled over 50% of the planned 154 patients into the randomised Phase IIb TACTI-003 trial. Subsequent to quarter end TACTI-003 has reached 75% enrolment, and Immutep expects to complete enrolment by mid-year positioning the Company to report top-line results in H2 of CY2023.

### **Planned late-stage trial in 1st line NSCLC**

Immutep is continuing its preparations for a late-stage trial evaluating efti in 1st line NSCLC in combination with anti-PD-1 therapy. The NSCLC program will be shaped by the maturing data from the Company's ongoing TACTI-002 and INSIGHT-003 trials. Current activity is focused on trial design and engagement with regulatory authorities and other stakeholders. The Company obtained US FDA Fast Track designation late last year for this indication.

### **INSIGHT-003 – Phase I in 1st line NSCLC**

In February, the investigator-initiated INSIGHT-003 trial reached its enrolment target of 20 patients with 1st line NSCLC for this first triple combination therapy study of efti with standard-of-care combination of anti-PD-1 therapy and chemotherapy. INSIGHT-003 has been now extended to include a total of 50 patients. The expansion of INSIGHT-003 will further inform planning for registrational studies.

### **IMP761 DEVELOPMENT PROGRAM FOR AUTOIMMUNE DISEASES**

During the first quarter, our preclinical development continued for IMP761, including preparations to begin the toxicology study. As the first immunosuppressive agonist antibody to LAG-3 acting upstream on activated

T cells to target the root cause of self-antigen-specific T cell induced disease, IMP761 is a potential game-changer in how autoimmune diseases are treated. The Company currently anticipates that clinical development will begin in the first half of CY2024.

### **INTELLECTUAL PROPERTY**

During the quarter, Immutep was granted three new patents directed to efti. The first is a United States patent drawn to methods of treating cancer with a combination of efti and chemotherapy, where the efti is administered in a dose of more than 6 mg. This is the third United States patent granted from this family.

The second patent is an Indian patent that protects Immutep's intellectual property relating to combined preparations of efti with a PD-1/PD-L1 therapy for the treatment of cancer or infection. The third patent is an Australian patent which relates to a potency assay for release testing of efti. The assay is used in Immutep's commercial-scale (2,000L) manufacturing process. This new Australian patent follows the grant of a similar patent in South Korea in 2022.

### **BOARD AND MANAGEMENT CHANGES**

On 11 April, Lis Boyce was appointed as Non-Executive Director replacing Lucy Turnbull, who re-joined the board after the sudden and untimely death of Grant Chamberlain in January 2022. The Board is grateful to Lucy for stepping in under such tragic circumstances and for her boundless energy and valued insights.

Ms Boyce is a highly experienced corporate lawyer and currently a partner at Piper Alderman. She has extensive experience in the Life Sciences and Healthcare sectors as well as in capital raisings, strategic collaborations, commercial contracts and mergers and acquisitions. Lis is currently deputy chair of AusBiotech's AusMedtech Advisory Group and a member of AusBiotech's State Committee for NSW.

On 26 April, Immutep announced that it expanded its leadership team with the appointment of Florian D. Vogl, M.D., Ph.D., MSc., as Chief Medical Officer (CMO) with effect from 1 May 2023. Dr. Vogl has over a decade of experience in the biopharmaceutical industry with extensive clinical development expertise in the field of oncology. Most recently, he was CMO of Cellestia Biotech where he focused on delivering new treatments to patients with cancer and autoimmune disorders that had limited therapeutic options. Prior to Cellestia, Dr. Vogl held senior management roles in Europe and the United States, including Head of Clinical Development Europe at Rainier Therapeutics, Senior Global Medical Leader, Oncology Development at Novartis, and as Early Development Leader, Oncology Pipeline at Amgen.

Dr. Vogl assumes the CMO role from Frédéric Triebel, M.D., Ph.D., who previously acted as both Chief Scientific Officer (CSO) and CMO of Immutep. Dr. Triebel's foremost focus will be on his responsibilities as CSO and as a member of Immutep's Board.

### **FINANCIAL SUMMARY**

Immutep continued to focus on prudent cash management during the past quarter (Q3 FY23). The Company remains well funded with a cash runway extending to the end of FY24.

Cash receipts from customers in the quarter increased to \$30k, compared to \$8k in Q2 FY23. The net cash used in G&A activities in the quarter was \$1.12million compared to \$734k in Q2 FY23. Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, includes \$257k in payments for Non-Executive Director's fees and Executive Director's remuneration.

The net cash used in R&D activities in the quarter was \$11.52 million, compared to \$5.87 million in Q2 FY23. The increase was mainly due to the increased clinical trial and manufacturing activities.

Total net cash outflows used in operating activities in the quarter were \$14.17 million compared to \$7.02 million in Q2 FY23.

Immutep's cash and cash equivalent balance at 31 March 2023 was approximately \$55.2 million, giving the Company an expected cash reach based on current estimates to June 2024. Immutep will continue to manage its solid cash balance carefully as it pursues its overall clinical development strategy.

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 market for patients in need and to maximise value for shareholders. For more information, please visit [www.immutep.com](http://www.immutep.com) or contact:

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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")**

31 March 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	30	71
1.2 Payments for		
(a) research and development	(11,524)	(24,560)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(83)	(305)
(d) leased assets	-	-
(e) staff costs	(1,666)	(4,408)
(f) administration and corporate costs	(1,117)	(2,446)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	196	499
1.5 Interest and other costs of finance paid	(2)	(32)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,645
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(14,166)</b>	<b>(27,536)</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	(1)	(44)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(1)</b>	<b>(28)</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	-	-
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)	(46)	(150)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(46)</b>	<b>(150)</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	68,376	79,995
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(14,166)	(27,536)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1)	(28)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(46)	(150)
4.5	Effect of movement in exchange rates on cash held	1,038	2,920
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>55,201</b>	<b>55,201</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	32,023	45,179
5.2	Call deposits	19,625	22,895
5.3	Bank overdrafts	-	-
5.4	Other (provide details if material)		
	-Term deposit	3,553	302
	-Restricted cash (Advance payment from shareholder for SPP)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>55,201</b>	<b>68,376</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	257
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)	(14,166)
8.2 Cash and cash equivalents at quarter end (item 4.6)	55,201
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	55,201
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	3.90
<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.

27 April 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.