

**ASX/Media Release**

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

- Clinical development strategy for efti to prioritise non-small cell lung cancer (NSCLC), as well as advance head & neck squamous cell cancer (HNSCC) and metastatic breast cancer (MBC)
- Further encouraging interim data in 2<sup>nd</sup> line NSCLC from TACTI-002 comparing favourably to standard of care chemotherapy-based options
- Three abstracts accepted at the upcoming SITC Annual Meeting 2022 including first interim data from INSIGHT-003 trial and a late breaking abstract
- New investigator-initiated Phase II trial in new indication soft tissue sarcoma
- Board strengthened with LAG-3 pioneer, Professor Frédéric Triebel, Immutep's CSO and CMO
- Fast Track designation granted by US FDA for efti in 1<sup>st</sup> line NSCLC, post period
- Strong cash position of \$73.9 million, giving cash runway into early calendar year 2024

**SYDNEY, AUSTRALIA – 25 October 2022** – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a clinical-stage biotechnology company developing novel immunotherapies for cancer and autoimmune disease, today provides an update on the ongoing development of its product candidates, eftilagimod alpha ("efti") and IMP761 for the quarter ended 30 September 2022 (Q1 FY23).

**Efti Development Program for Cancer**

Immutep has reported consistently strong data from efti across three key cancer indications: NSCLC, HNSCC and MBC, supporting the broad therapeutic potential of the Company's lead product candidate. Based on compelling data, coupled with the large market opportunity and high unmet need for more durable and tolerable options for patients, Immutep has determined to focus its late-stage clinical development efforts on 1<sup>st</sup> line NSCLC in combination with anti-PD-1 therapy. The NSCLC program will be shaped by the maturing TACTI-002 trial data, initial data from the INSIGHT-003 trial, and feedback from regulatory authorities and other stakeholders.

The Company will also continue to advance its late-stage programs in HNSCC via the TACTI-003 trial and MBC through planning, regulatory and other steps. Studies expanding efti into additional indications and combinations are also planned, with a new trial in soft tissue sarcoma already announced in the quarter.

This development strategy will position the Company, or a potential partner to fully exploit efti's compelling potential. Aligned with this core strategy, updates from Immutep's clinical development program are provided below.

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

In August, Immutep reported positive interim data from patients with 2<sup>nd</sup> line NSCLC (Part B) in the ongoing TACTI-002 trial at the 2022 World Conference on Lung Cancer (WCLC 2022) in Austria. The median Overall Survival from therapy with efti in combination with pembrolizumab reported was 9.7 months. 25% of patients were progression free at the key 6-month mark and 36.5% were alive at 18 months. Importantly, the combination treatment continues to be safe and well tolerated, and compares favourably to standard of care chemotherapy-based options.

Following the quarter, the United States Food and Drug Administration (FDA) granted Fast Track designation to efti in combination with pembrolizumab for the treatment of 1<sup>st</sup> line non-small cell lung cancer (NSCLC), offering the potential for expedited development and review. The designation was based on the encouraging Phase II clinical data from 1<sup>st</sup> line NSCLC patients in the TACTI-002 trial reported by Immutep at the ASCO 2022 Conference in June 2022 and marks the second Fast Track designation issued by the FDA for efti.

Further data from the TACTI-002 trial will be presented in Q4 of calendar year 2022.

TACTI-002 is a Phase II trial being conducted in collaboration with Merck & Co. (“MSD”). It is evaluating the combination of efti with MSD’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in NSCLC in 1<sup>st</sup> and 2<sup>nd</sup> line, and in HNSCC in 2<sup>nd</sup> line (Parts A, B and C, respectively). The trial is fully recruited.

#### ***TACTI-003 - Phase IIb clinical trial***

During the quarter, Immutep continued the recruitment of patients with 1<sup>st</sup> line HNSCC into the TACTI-003 trial. To date 53 patients out of approximately 154 have been enrolled to participate in the study across the now 25 active trial sites. A Trial in Progress poster on the Phase IIb TACTI-003 trial will be presented at the upcoming Society for Immunotherapy of Cancer (SITC) Annual Meeting 2022 in early November in Boston, US.

TACTI-003 is a Phase IIb multicentre, open label, randomised and controlled trial. It was granted Fast Track designation for 1<sup>st</sup> line HNSCC by the US FDA in 2021.

#### ***INSIGHT-003 - triple combination***

Patient recruitment continued through the quarter for the INSIGHT-003 investigator-initiated trial. Currently, 14 out of a total of 20 patients are enrolled. First interim data from INSIGHT-003 will be presented in a poster presentation at the SITC Annual Meeting 2022.

The INSIGHT-003 study evaluates a triple combination therapy consisting of efti and an approved standard of care combination of chemotherapy (carboplatin and pemetrexed) and an anti-PD-1 therapy in patients with NSCLC adenocarcinomas. The study is being conducted by the Institute of Clinical Cancer Research (IKF) at Northwest Hospital, Frankfurt, Germany.

#### ***New Phase II trial in Soft Tissue Sarcoma***

In September, Immutep announced a new investigator-initiated Phase II clinical trial which will be conducted in collaboration with the Maria Skłodowska-Curie National Research Institute in Poland. The trial will evaluate efti in combination with pembrolizumab and radiotherapy, prior to surgery, in up to 40 patients with select soft tissue sarcoma. The Maria Skłodowska-Curie National Research Institute of Oncology will primarily fund the study with a grant from the Polish government of € 1.5M (~A\$2.2M), with Immutep providing efti at no cost. Importantly, the trial expands efti’s clinical development pipeline into a new cancer setting.

The first patient is expected to be dosed in H1 calendar year 2023.

#### **IMP761 Development Program for Autoimmune Disease**

During the quarter, Immutep continued preclinical development steps for its autoimmune disease candidate, IMP761, including progressing the development of a 200 litre scale GMP-compliant manufacturing process.

IMP761 is Immutep's immunosuppressive agonist antibody to LAG-3 which will be tested to treat the causes of autoimmune disease, such as inflammatory bowel disease, rheumatoid arthritis, and multiple sclerosis, rather than merely treating the symptoms.

### **Intellectual Property**

During the quarter, Immutep was granted two new patents by the Japanese Patent Office. The first protects IMP761, pharmaceutical compositions comprising IMP761, and the use of the compositions in the treatment of T-cell mediated inflammatory and autoimmune diseases. It follows the grant of a similar European patent announced in October 2020.

The second Japanese patent is directed to combined therapeutic preparations comprising efti and an anti-PD-(L)1 antibody, and methods of use in the treatment of cancer and infection.

A third patent was also granted during the quarter. This patent was granted by the Russian Patent Office and is directed to combined therapeutic preparations comprising efti and an anti-PD-(L)1 antibody. These new efti related patents in Japan and Russia build on corresponding patents granted in Australia, Europe, United States and China, as announced in 2018 through 2022.

### **Corporate Update**

In September, Immutep appointed its Chief Scientific Officer and Chief Medical Officer, Professor Frédéric Triebel, M.D. Ph.D. as Executive Director on its Board. Professor Triebel pioneered the recently validated LAG-3 field of immuno-oncology, having discovered the LAG-3 gene and is a driving force in the strategic development of Immutep's LAG-3 product candidates.

### **Financial Summary**

Immutep's financial performance over the quarter (Q1 FY23) continues to be pleasing. Cash receipts from customers Q1 FY23 decreased to \$33k, compared to \$96k in Q4 FY22. In September 2022, the company received a €1.8 million (~A\$2.7 million) research and development (R&D) tax incentive payment in cash from the French Government under its Crédit d'Impôt Recherche scheme (CIR).

The net cash used in G&A activities in the quarter was \$595k compared to \$361k in Q4 FY22. The increase compared with the last quarter is mainly due to the payment of annual audit fees.

Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter includes \$167k 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 \$7.17 million, compared to \$7.62 million in Q4 FY22. The cash outflow for clinical trial activities decreased compared with Q4 FY22 while the cash outflow for manufacturing activities significantly increased in Q1 FY2023. Total net cash outflows used in operating activities in the quarter was \$6.34 million compared to \$9.28 million in Q4 FY22.

Immutep's cash and cash equivalent balance as at 30 September 2022 was approximately \$73.9 million compared to a balance of \$80 million as at 30 June 2022, giving the Company an expected cash reach based on current estimates of early calendar year 2024. Immutep will continue to manage its strong cash balance carefully as it reviews its overall clinical strategy, particularly in light of the various potential opportunities for the development of efti in cancer.

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

**About Immutep**

Immutep is a clinical stage biotechnology company leading the development of LAG-3 related immunotherapy products for the treatment of cancer and autoimmune disease. The Company is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximize value to shareholders.

Immutep's lead product candidate is eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3 fusion protein (LAG-3Ig) that is a first-in-class antigen presenting cell (APC) activator being evaluated in multiple clinical trials for cancer. The Company is also developing an agonist of LAG-3 (IMP761) for autoimmune disease. Additional LAG-3 product candidates, including antibodies for immune response modulation, are licensed to and being developed by Immutep's large pharmaceutical partners.

Further information can be found on the Company's website [www.immutep.com](http://www.immutep.com) or by contacting:

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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 September 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	33	33
1.2 Payments for		
(a) research and development	(7,171)	(7,171)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(118)	(118)
(d) leased assets	-	-
(e) staff costs	(1,248)	(1,248)
(f) administration and corporate costs	(595)	(595)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	121	121
1.5 Interest and other costs of finance paid	(29)	(29)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,659	2,659
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(6,348)</b>	<b>(6,348)</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	(10)	(10)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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	-	-
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>(10)</b>	<b>(10)</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)	(51)	(51)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(51)</b>	<b>(51)</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	79,995	79,995
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,348)	(6,348)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(10)	(10)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(51)	(51)
4.5	Effect of movement in exchange rates on cash held	356	356
4.6	<b>Cash and cash equivalents at end of period</b>	<b>73,942</b>	<b>73,942</b>

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	51,090	54,984
5.2	Call deposits	22,550	24,709
5.3	Bank overdrafts	-	-
5.4	Other (provide details if material) -Term deposit	302	302
	-Restricted cash (Advance payment from shareholder for SPP)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>73,942</b>	<b>79,995</b>

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	167
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>		

<b>7.</b>	<b>Financing facilities</b> <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>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
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.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	(6,348)
8.2	Cash and cash equivalents at quarter end (item 4.6)	73,942
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	73,942
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	11.65
	<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.

25 October 2022

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.