**ASX/Media Release**

# Immutep Quarterly Activities Report & Appendix 4C
# Q2 FY23

- Second US FDA Fast Track designation granted to eftilagimod alpha (efti) supporting planned late-stage development in 1st line non-small cell lung cancer (1L NSCLC)
- Compelling Phase II results in 1L NSCLC, including Overall Response Rate (ORR) of 40.4% in all-comer PD-L1 TACTI (Two ACTive Immunotherapies trial)-002 trial combining efti and pembrolizumab, showcased at SITC 2022 press briefing
- Successful meeting with FDA for efti in metastatic breast cancer (MBC) and agreement for integrated Phase II/III trial design with expanded patient population to include triple-negative breast cancer
- Positive Independent Data Monitoring Committee (IDMC) recommendation for the TACTI-003 Phase IIb trial in 1st line head and neck squamous cell carcinoma (1L HNSCC) to continue as planned
- Promising initial clinical data from triple combination therapy in INSIGHT-003 Phase I trial presented at SITC 2022 conference
- Second agreement signed with Merck KGaA, Darmstadt, Germany and Pfizer for a new, jointly funded Phase I clinical study in patients with urothelial cancer
- Achieved commercial scale in efti manufacturing and established a GMP-compliant manufacturing process for IMP761
- Strong cash position of $68.38 million, with cash runway extended to the end of FY24

**SYDNEY, AUSTRALIA – 30 January 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, efti and IMP761, for the quarter ended 31 December 2022 (Q2 of Fiscal Year 2023).

## EFTI DEVELOPMENT PROGRAM FOR CANCER

### Planned late-stage trial in 1L NSCLC

The United States Food and Drug Administration (US FDA) granted Fast Track designation to efti in combination with pembrolizumab in October 2022 for the treatment of 1L NSCLC, which will be evaluated in the Company's planned late-stage registrational trial. The designation was granted based on the encouraging Phase II clinical data in 1L NSCLC from the TACTI-002 all-comer trial in terms of PD-L1 status, presented at American Society of Clinical Oncology's (ASCO) Annual Meeting in June 2022. It is the second Fast Track designation issued by the FDA for efti (the first is for 1L HNSCC) and offers the potential for expedited development and review.

**TACTI-002 (also designated KEYNOTE-PN798) Phase II clinical trial**
Immutep reported compelling new clinical data from the TACTI-002 trial evaluating efti in combination with MSD's (Merck & Co., Inc., Rahway, NJ., USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in 1L NSCLC via a late-breaking abstract oral presentation at the Society of Immunotherapy of Cancer (SITC) Meeting in November 2022. Immutep's abstract was one of just nine to be showcased at the SITC 2022 press briefing, out of more than 1,500 abstract submissions.

The results showed an ORR of 40.4% in the all-comer PD-L1 trial, meeting the primary endpoint of the 1L NSCLC part of the trial. The ORR improved across all PD-L1 status groups by central assessment compared with data reported at ASC0 2022. Additionally, the interim median Duration of Response (DoR) of 21.6 months, compares favourably to historical controls. Promising results were also achieved in the secondary endpoint of interim median Progression Free Survival (PFS) with overall PFS of 6.6 months and 9.3 months in patients with a PD-L1 TPS (Tumour Proportion Score) $\geq$1% for which efti in combination with pembrolizumab has Fast Track designation.

**TACTI-003 – Phase IIb clinical trial**
In October 2022, the IDMC for Immutep's Phase IIb TACTI-003 trial reviewed the initial safety data from the study and recommended the trial continue with no modifications. The IDMC also reviewed initial efficacy data, although this was not the primary focus of the analysis. The recommendation validates Immutep's decision to evaluate efti in the 1st line HNSCC setting following an encouraging ORR of 29.7% regardless of PD-L1 expression and five complete responses (CR) reported in the 2nd line HNSCC setting in TACTI-002.

The Company also presented a *Trial in Progress* poster on the TACTI-003 study at the SITC 2022 meeting in November 2022. Recruitment is ongoing for the TACTI-003 trial, with more than 50% of the planned 154 patients enrolled till quarter end.

**Planned Phase II/III trial in Metastatic Breast Cancer**
Immutep reported the positive outcome of its follow-up Type C meeting with the US FDA regarding its late-stage clinical development plans for efti in conjunction with standard-of-care chemotherapy for the treatment of MBC in December 2022. The Company and the FDA have agreed to an integrated Phase II/III trial design to help inform a Biologics License Application (BLA).

Based on the encouraging efficacy, favourable safety and learnings from the randomised AIPAC Phase IIb trial (which administered efti and chemotherapy on different days and ceased chemotherapy at six months), patients will receive efti and paclitaxel on the same day and treatment will continue until disease progression. In addition to HER2–/HR+ metastatic breast cancer, the patient population has also been expanded to include triple-negative breast cancer (TNBC), an aggressive form of breast cancer with limited treatment options.

Subject to regulatory and ethics committee feedback, the Phase II portion of the trial is expected to begin in Q3 FY23 with a safety lead in of 6 to 12 patients who will be given a higher 90mg dose of efti (compared to the completed AIPAC trial). This will be followed by 58 patients for the randomised Phase II portion of the trial. Depending on the Phase II results and Immutep's resources, the Phase III portion will commence.

**Phase II trial in Soft Tissue Sarcoma**
Trial preparations continued during the quarter for a new investigator-initiated Phase II clinical trial which was announced in September 2022. The trial will be conducted in collaboration with the Maria Skłodowska-Curie National Research Institute in Poland and will evaluate efti in combination with pembrolizumab and radiotherapy, prior to surgery, in up to 40 patients with select soft tissue sarcoma. The trial is expected to commence in H1 of calendar year 2023.

**INSIGHT-003 – Phase I triple combination with standard-of-care anti-PD-1 therapy and chemotherapy**
Initial clinical data was reported from the investigator-initiated INSIGHT-003 trial in November at the SITC 2022 conference. The poster provided initial efficacy details on 11 of the 14 patients with metastatic NSCLC adenocarcinomas that had been enrolled as of the 14 October 2022 cut-off date, plus safety data on all 14 patients. The data shows the triple-combination approach is well-tolerated and provides promising early signals of therapeutic activity with an ORR of 72.7% (8/11) and a Disease Control Rate (DCR) of 90.9% (10/11).

**INSIGHT-005 – New Phase I trial with Merck KGaA, Darmstadt, Germany, and Pfizer**
Immutep signed a Clinical Trial Collaboration and Supply Agreement with Merck KGaA, Darmstadt, Germany and Pfizer in November 2022 for a new Phase I clinical study in patients with urothelial cancer, called INSIGHT-005. It is the second agreement entered into by Immutep with Merck KGaA and Pfizer and builds on the encouraging clinical data reported from the completed INSIGHT-004 study in multiple solid tumour indications from efti and avelumab (BAVENCIO®). Under the Agreement, Immutep and Merck KGaA will jointly fund the study, which is expected to start in mid-calendar year 2023.

**Efti Manufacturing Scale-Up**
Immutep successfully scaled-up the manufacturing process for efti with the completion of its first 2,000L manufacturing run by the Company's manufacturing partner, WuXi Biologics. This large-scale manufacturing capability is a significant achievement. Immutep plans to introduce the material manufactured into ongoing and future Phase II/III clinical trials.

**IMP761 DEVELOPMENT PROGRAM FOR AUTOIMMUNE DISEASES**
During the quarter, Immutep established a GMP-compliant manufacturing process for IMP761, its proprietary preclinical candidate for autoimmune diseases. The 200L scale manufacturing process was developed by the Company's manufacturing partner, Northway Biotech and will provide supply of IMP761 for Investigational New Drug (IND)-enabling studies and clinical trials.

**INTELLECTUAL PROPERTY**
Immutep was granted four new patents during the quarter. The first two patents were filed as divisional applications and were granted by the Japanese and South Korean Patent Offices. These patents protect Immutep's intellectual property relating to combination preparations comprising efti and a chemotherapy agent which is oxaliplatin, carboplatin, or topotecan. They follow the grant of the Japanese parent patent and corresponding patents in the United States, Europe, China and Australia, as announced in 2019 through 2021.

The Company was granted another patent by the South Korean Patent Office, which relates to a potency assay for release testing of efti. The assay is used in Immutep's commercial-scale (2,000L) manufacturing process.

Immutep was also granted a new patent by the Chinese Patent Office. The patent protects IMP731 in the territory of mainland China. The patent is co-owned with the French Institute of Health and Medical Research (INSERM) and exclusively licensed to GSK, Immutep's development partner for IMP731.

**FINANCIAL SUMMARY**

Immutep's financial performance over the quarter (Q2 FY23) continues to reflect prudent cash management. The Company's cash runway was expanded to the end of FY24 (previously early H2 FY24).

Cash receipts from customers Q2 FY23 were $8k, compared to $33k in Q1 FY23. The Company received a A$986,286 cash rebate from the Australian Federal Government's R&D tax incentive program in relation to expenditure incurred on eligible R&D activities conducted in Australia in the 2021 fiscal year.

The net cash used in G&A activities in the quarter was $734k compared to $595k in Q1 FY23.

Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, includes $402k 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 $5.87 million, compared to $7.17 million in Q1 FY23. The decrease was mainly due to a reduction in manufacturing activities during the quarter.

Total net cash outflows used in operating activities in the quarter were $7.02 million compared to $6.35 million in Q1 FY23.

Immutep's cash and cash equivalent balance at 31 December 2022 was approximately $68.38 million, giving the Company an expected cash reach based on current estimates to the end of FY24. Immutep will continue to manage its strong 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 globally active biotechnology company that is a leader in the development of LAG-3 related immunotherapeutic products for the treatment of cancer and autoimmune disease. Immutep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximize value to shareholders. Immutep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Immutep's current lead product candidate is eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3 fusion protein (LAG-3Ig), which is a first-in-class antigen presenting cell (APC) activator being explored in cancer and infectious disease. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

Additional LAG-3 products, including antibodies for immune response modulation, are being developed by Immutep's large pharmaceutical partners.

Further information can be found on the Company's website 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** | **Quarter ended ("current quarter")** |
| 90 009 237 889 | 31 December 2022 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (6 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | 8 | 41 |
| 1.2 | Payments for | | |
| | (a) research and development | (5,865) | (13,036) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | (104) | (222) |
| | (d) leased assets | - | - |
| | (e) staff costs | (1,494) | (2,742) |
| | (f) administration and corporate costs | (734) | (1,329) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 182 | 303 |
| 1.5 | Interest and other costs of finance paid | (1) | (30) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 986 | 3,645 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(7,022)** | **(13,370)** |

| **2.** | **Cash flows from investing activities** | | |
|---|---|---|---|
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | (33) | (43) |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 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 | 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** | **(17)** | **(27)** |

| | | | |
|---|---|---|---|
| **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 | - | - |
| 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) | (53) | (104) |
| **3.10** | **Net cash from / (used in) financing activities** | **(53)** | **(104)** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 73,942 | 79,995 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (7,022) | (13,370) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 months) $A'000 |
|---|---|---|---|
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (17) | (27) |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (53) | (103) |
| 4.5 | Effect of movement in exchange rates on cash held | 1,526 | 1,881 |
| **4.6** | **Cash and cash equivalents at end of period** | **68,376** | **68,376** |

| 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 | 45,179 | 51,090 |
| 5.2 | Call deposits | 22,895 | 22,550 |
| 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** | **Cash and cash equivalents at end of quarter (should equal item 4.6 above)** | **68,376** | **73,942** |

| 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 | 402 |
| 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.

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **Total facility amount at quarter end $A'000** | **Amount drawn at quarter end $A'000** |
|---|---|---|---|
| 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) | (7,022) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 68,376 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 68,376 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 9.74 |

*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.*

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:

*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.*

## 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.

30 January 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.