

ASX/Media Release

## Immutep Quarterly Activities Report & Appendix 4C

- Final Overall Survival data from AIPAC Phase IIb trial reported at the SITC 2021 conference, supporting Immutep's planned Phase III clinical development of efti in combination with paclitaxel in metastatic breast cancer
- Encouraging antitumor activity also reported from TACTI-002 trial of efti in 2<sup>nd</sup> line head and neck squamous cell carcinoma (HNSCC) at SITC 2021
- TACTI-003 Phase IIb study patient recruitment and country/site initiation ongoing
- IMP761 GMP manufacturing advanced

**SYDNEY, AUSTRALIA – 25 January 2022** – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel LAG-3 related immunotherapy treatments 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 31 December 2021.

### Efti Development Program for Cancer

#### **AIPAC - Phase IIb clinical trial - final data**

Immutep reported final Overall Survival (OS) data from its Phase IIb AIPAC clinical trial evaluating efti in metastatic breast cancer (MBC) in November 2021, as a *late breaker* poster at the Society for Immunotherapy of Cancer (SITC) Annual Meeting.

The late-stage trial showed very encouraging OS data, including a statistically significant and clinically meaningful benefit in three patient predefined subgroups representing a majority of patients. A survival benefit of +7.5 months was observed in patients < 65 years, reflecting a > 50% improvement compared to the control group. A +19.6 month survival benefit was seen in patients with low monocytes, a benefit of > 150% compared to the control group. Lastly, a survival benefit of +4.2 months was reported in luminal B patients, reflecting a > 33% benefit compared to the control group. The data from these subgroups was improved data versus the interim data presented by Immutep in December 2020.

In addition, a statistically significant Quality of Life preservation was demonstrated in the first 6 months from patients in the efti group in the total population. A statistically significant increase in peripheral CD8 T cells in patients in the efti group of the total population was also observed and positively correlated with improved OS.

These final results have given Immutep additional confidence efti can deliver a meaningful clinical improvement for diverse sets of cancer patients, as the Company started its preparations for a larger clinical trial in MBC via its Phase III clinical trial, AIPAC-003.

#### **AIPAC-003 - planned Phase III trial**

In October 2021, Immutep received positive feedback from the European Medicines Agency (EMA) regarding its clinical development program for efti. Immutep has also been interacting with the US FDA and is providing additional information relating to efti's unique mechanism of action as an agonist that leads to T cell expansion and proliferation (rather than all other LAG-3 products in development which are antagonists that block an immune checkpoint). Interactions with the EMA, US FDA and other regulators are ongoing. The feedback from competent authorities, along with insights from a rigorous

engagement process with Key Opinion Leaders and other stakeholders will help Immutep generate a final study design.

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

During the quarter, Immutep continued recruitment of patients for the TACTI-003 clinical trial. At present, 6 of approximately 154 patients with 1<sup>st</sup> line HNSCC have been enrolled into the trial at active clinical sites. The study is in its start-up phase and additional sites are planned to be initiated in the first quarter of 2022.

Immutep also presented the trial design for TACTI-003 via a poster at the SITC 2021 conference in November 2021. It is a Phase IIb multicentre, open label, randomised and controlled trial. Fast track designation for 1<sup>st</sup> line HNSCC by the US FDA was granted in April 2021.

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

Immutep also reported data from the 2<sup>nd</sup> line HNSCC patients (Part C) of TACTI-002 at the SITC 2021 conference.

Part C is showing encouraging antitumor activity. An encouraging Overall Response Rate (ORR) was reported, with 29.7% of patients responding to the combination therapy of efti and pembrolizumab. In addition, a favourable duration and depth of responses was observed, with 5 Complete Responses and a minimum duration of response extended to > 9 months across all responding patients. The responses continue to be reported in PD-L1 low and high expressors.

During the quarter, Immutep enrolled and dosed the last patient in the expansion stage of Part A (1<sup>st</sup> line non-small cell lung cancer (NSCLC)), completing the recruitment of all cohorts of the TACTI-002 study.

A total of 189 patients are now participating in TACTI-002 across Parts A, B, and C at approximately 20 clinical sites in Australia, Europe, and the US. Additional data from TACTI-002, particularly in NSCLC, are planned to be reported in the first half of calendar year 2022. Data from the 114 patients in Part A (1<sup>st</sup> line NSCLC) is expected to inform potential late-stage development of efti in this important indication.

#### **INSIGHT**

INSIGHT is an investigator-initiated Phase I trial at the Institute of Clinical Cancer Research, Krankenhaus Nordwest (IKF) investigating different combination treatments with efti and a different route of administration for efti. INSIGHT consists of 5 different arms from stratum A to E.

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

In December 2021, the first five patients were enrolled and safely treated in the INSIGHT-003 study, also referred to as stratum C of INSIGHT. No additional safety signals were observed in the study which is the first time a triple combination therapy consisting of efti and an existing approved standard of care combination of chemotherapy (carboplatin) and an anti-PD-1 therapy has been administered.

Patient recruitment is ongoing with 6 out of a total of 20 patients with various solid tumours now participating in the trial. Interim results are expected to be reported in 2022.

##### *INSIGHT-005 – combination with bintrafusp alpha*

INSIGHT-005, known as stratum E of INSIGHT, will include 12 patients with solid tumours and will evaluate efti in combination with bintrafusp alfa. In the light of the suboptimal results from Merck KGaA's bintrafusp alpha in other studies, this arm of the INSIGHT study is currently under review.

### **EAT COVID - Phase II clinical trial - ongoing**

The investigator-initiated EAT COVID study is continuing at the University Hospital Pilsen in the Czech Republic. Immutep will provide an update on the trial in due course.

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

During the quarter, Immutep appointed Northway Biotech, an end-to-end biopharmaceutical contract development and manufacturing organisation (CDMO), to manufacture IMP761 ahead of clinical testing.

Northway has commenced development of a GMP-compliant manufacturing process of IMP761 and will manufacture IMP761 in large scale bioreactors. After Immutep completes the required preclinical development evaluations, the material will be used for clinical trials of IMP761. Planning for preclinical and clinical development is ongoing.

### **Intellectual Property**

Immutep was granted two new patents by the Chinese Patent Office, protecting Immutep's intellectual property relating to combined therapeutic preparations comprising efti and either a PD-1 pathway inhibitor or a chemotherapy agent. These new patents follow the grant of corresponding patents in other key global markets announced previously.

### **Financial Summary – Q2 FY22<sup>1</sup>**

Cash receipts from customers for the quarter were \$14k, compared to \$56k in Q1 FY22 (i.e., the quarter ended 30 September 2021).

The net cash used in G&A activities in the quarter was \$0.2 million compared to \$1.0 million in Q1 FY22. The difference compared with the last quarter is mainly due to capital raising expenses included in Q1 FY22. Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter includes \$217k in payment of Non-Executive Director's fees and Executive Director's remuneration.

The net cash used in Research and Development activities in the quarter was \$4.67 million, compared to \$6.83 million in Q1 FY22. The higher cash outflows in Q1 FY2022 is mainly due to an upfront payment associated with the commencement of the TACTI-003 clinical trial. Total net cash outflows used in operating activities in the quarter was \$6.06 million. In comparison, total net cash outflows from operating activities in Q1 FY22 was \$5.37 million, which was net of the \$3.42m research and development (R&D) tax incentive payment received in cash in Q1 FY22 from the French Government under its Crédit d'Impôt Recherche scheme (CIR).

The Company's cash and cash equivalent balance as at 31 December 2021 was \$99.66 million compared to a balance of \$106.39 million as at 30 September 2021. Immutep's cash balance puts the company in a strong financial position with an estimated cash reach of December 2023.

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

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<sup>1</sup> All cash amounts shown are in Australian currency, unless noted differently.

**About Immunetep**

Immunetep 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. Immunetep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximise value to shareholders.

Immunetep's current lead product candidate is efitlagimod 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. Immunetep 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 Immunetep's large pharmaceutical partners.

Immunetep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

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 Immunetep 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 December 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	14	70
1.2 Payments for		
(a) research and development	(4,672)	(11,502)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(111)	(210)
(d) leased assets	-	-
(e) staff costs	(1,135)	(2,141)
(f) administration and corporate costs	(214)	(1,189)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	67	130
1.5 Interest and other costs of finance paid	(5)	(9)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,422
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(6,056)</b>	<b>(11,429)</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	(5)	(6)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	(25)	(25)

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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	-	-
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>(30)</b>	<b>(31)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	52,975
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	-	(2,427)
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)	(34)	(97)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(34)</b>	<b>50,451</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	106,385	60,593
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,056)	(11,429)

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

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)	(30)	(31)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(34)	50,451
4.5	Effect of movement in exchange rates on cash held	(609)	72
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>99,656</b>	<b>99,656</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	39,947	26,505
5.2	Call deposits	59,407	71,251
5.3	Bank overdrafts	-	-
5.4	Other (provide details if material)		
	-Term deposit	302	8,629
	-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>99,656</b>	<b>106,385</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	217
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. 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.</i>		
<i>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)	(6,056)
8.2 Cash and cash equivalents at quarter end (item 4.6)	99,656
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	99,656
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	16.46
<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 January 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.