

ASX/Media Release

## ImmuteP Quarterly Activities Report & Appendix 4C

- Received competent authority and institutional review board approvals for TACTI-003 Phase IIb trial
- Enrolled first patient in INSIGHT-003 study in patients with various solid tumours
- Preparations progressing for new Phase III trial (AIPAC-003) in metastatic breast cancer
- Final Overall Survival data from Phase IIb AIPAC trial accepted as a late breaker poster for SITC 2021

**SYDNEY, AUSTRALIA – 28 October 2021** – [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 30 September 2021.

### **Efti Development Program for Cancer**

#### **AIPAC - Phase IIb clinical trial - ongoing**

ImmuteP will report final Overall Survival (OS) data from its Phase IIb AIPAC clinical trial evaluating efti in metastatic breast cancer as a *late breaker* poster at the Society for Immunotherapy of Cancer (SITC) Annual Meeting 2021 taking place in the US and virtually from 10-14 November.

ImmuteP previously reported initial OS data from approximately 60% of events in December 2020 at the San Antonio Breast Cancer Symposium. The study reported a promising and improving trend in OS in the total population with a median survival benefit of +2.7 months from efti plus chemotherapy, compared to chemotherapy plus placebo. In addition, a statistically significant OS benefit was observed in the efti group in key pre-defined patient groups, including patients under 65 years of age and those with low starting monocyte count.

#### **AIPAC-003 - Phase III - new**

ImmuteP is continuing the preparation and planning steps for its Phase III clinical trial evaluating efti in patients with metastatic breast cancer.

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

In July 2021, ImmuteP completed all the necessary competent authority steps with the US Food and Drug Administration (FDA) and has received institutional review board approval to commence its Phase IIb TACTI-003 trial in the US. Recruitment has also opened in the Ukraine and more sites and countries will be added in the coming months. This follows the receipt of Fast Track designation in 1<sup>st</sup> line recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) from the US FDA in April 2021.

In addition, ImmuteP will be presenting the trial design for TACTI-003 via a poster at the SITC 2021 conference in November.

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

In September 2021, ImmuteP enrolled the last patient into Stage 2 of Part B of the Phase II TACTI-002 study, completing recruitment of 2<sup>nd</sup> line PD-1/PD-L1 refractory non-small cell lung cancer (NSCLC) patients into the trial. Recruitment is continuing for the additional 74 1<sup>st</sup> line NSCLC patients for the expansion of Part A, with 70 patients already enrolled. Recruitment for the expansion of Part A of the study continues to be ahead of the expected recruitment rate.

ImmuteP reported favourable interim Overall Response Rates (ORR) together with encouraging duration and depth of response in 1<sup>st</sup> line NSCLC (Part A) and 2<sup>nd</sup> line HNSCC (Part C) at ASCO in June 2021. The Company will report data from Part C of TACTI-002 at the SITC 2021 conference in November. Additional data from this study trial are planned to be reported in the first half of calendar year 2022.

## **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 August 2021, the first patient was enrolled and safely dosed in INSIGHT-003, also referred to as stratum C of INSIGHT. Patient recruitment is ongoing with 4 out of a total of 20 patients with various solid tumours now participating in the trial. First interim results are expected to be reported in 2022.

### *INSIGHT-004 – combination with avelumab*

Results from INSIGHT-004 were presented at the ESMO Congress 2021 held 16-21 September. The results are in line with the previous poster presentation at ASCO 2021.

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

INSIGHT-005, known as stratum E of INSIGHT, will involve 12 patients with solid tumours and will evaluate efti in combination with bintrafusp alfa. It will be conducted under ImmuteP's collaboration agreement with Merck KGaA, Darmstadt, Germany.

Separately to ImmuteP's ongoing collaboration agreement with Merck KGaA, Merck KGaA and GlaxoSmithKline announced a mutual decision to terminate their agreement to co-develop bintrafusp alfa. Accordingly, ImmuteP and Merck KGaA are working closely to determine the next steps for the INSIGHT-005 study.

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

The investigator-initiated EAT COVID study is continuing at the University Hospital Pilsen in the Czech Republic. Patient recruitment into the trial by the hospital has been slower than anticipated due to a significant decline in the number of infections and improving vaccination rates in the Czech Republic. The Company will provide an update on the trial in due course.

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

During the quarter, ImmuteP continued GMP manufacturing preparations for IMP761 and is planning for toxicology studies and other pre-clinical evaluations of this promising candidate.

## **Partnerships**

### **EOC Pharma**

ImmuteP's Chinese partner for efti, EOC Pharma, announced it plans to expand its clinical trial pipeline for efti (designated EOC202 in China) in China. EOC is preparing to initiate a clinical study of efti in combination with an anti-PD-1 therapy in the first half of calendar year 2022. This new trial builds on EOC's previously announced Phase II trial evaluating efti in combination with chemotherapy in metastatic breast cancer patients.

## **Novartis**

Immutep's partner, Novartis presented two posters at the ESMO Congress 2021. One poster included data from its PLATForM Phase II study of novel spartalizumab combinations in melanoma, concluding patients with LAG-3+ melanoma may be more likely to respond to spartalizumab + ieramilimab (LAG525) treatment.

Novartis also presented data from its Phase II, open-label, 3-arm study, in patients with advanced triple-negative breast cancer regardless of PD-L1 status progressing after adjuvant or one prior line of systemic therapy for metastatic disease, but who had not received an immune checkpoint inhibitor. Patients were randomised 1:1:1 to LAG525 + spartalizumab, LAG525 + spartalizumab + carboplatin, or LAG525 + carboplatin. As no arms of the study met the proof of preliminary efficacy criteria, no further investigation is planned for this study.

LAG525 is a humanised anti-LAG-3 antibody derived from Immutep's IMP701 antibody, which is out-licensed to Novartis.

## **Intellectual Property**

Immutep was granted three new patents relating to the protection of LAG525 (IMP701), which is fully out-licensed to Novartis, by the Chinese Patent Office, the Indian Patent Office and the Malaysian patent office during the quarter. The patents are co-owned by Novartis AG and Immutep SAS and follow the grant of the corresponding Australian, United States, European, and Japanese patents announced in 2018 through 2020.

## **Financial Summary - Q1 FY22<sup>1</sup>**

Cash receipts from customers for the quarter was \$56k, compared to \$10k in Q4 of FY21 (i.e. the quarter ended 30 June 2021).

The net cash used in G&A activities in the quarter was \$1.01 million compared to \$409k in Q4 FY21. The increase compared with last quarter is mainly due to capital raising related costs that were expensed in July 2021. Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter includes \$135k in payment of Non-Executive Director's fees and Executive Director's salary.

The net cash used in Research and Development activities in the quarter was \$6.83 million, compared to \$5.45 million in Q4 FY21. The significant increase is mainly due to increased clinical trial and manufacturing activities. Total net cash outflows used in operating activities in the quarter was \$5.37 million. In comparison, total net cash outflows from operating activities in Q4 FY21 was \$5.71 million.

Immutep received a €2,126,617 (~\$3.42 million) research and development (R&D) tax incentive payment in cash from the French Government under its Crédit d'Impôt Recherche scheme (CIR) during the quarter in respect of expenditure incurred during calendar year 2020 on eligible R&D activities conducted in the European Union.

As part of the Company's two-tranche financing announced in June 2021, shareholders approved the second tranche of an institutional placement of shares at the Company's Extraordinary General Meeting in July 2021. The second tranche of the institutional placement raised \$46.3 million. In total, Immutep

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

raised \$60 million via the institutional placement, which was supported by multiple institutional investors in Australia and offshore.

A further \$7.2 million was raised from a Share Purchase Plan (SPP) completed in July 2021, which enabled existing eligible shareholders to participate in the financing on the same terms as the institutional placement. Due to strong demand from eligible shareholders, the amount raised exceeded the targeted amount sought to be raised (\$5 million) under the SPP.

The Company's cash and cash equivalent balance as at 30 September 2021 was \$106.39 million compared to a balance of \$60.59 million as at 30 June 2021. The enhanced 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.

#### **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 maximise value to shareholders.

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.

Immutep 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 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 2021

<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	56	56
1.2 Payments for		
(a) research and development	(6,830)	(6,830)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(99)	(99)
(d) leased assets	-	-
(e) staff costs	(1,006)	(1,006)
(f) administration and corporate costs	(975)	(975)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	63	63
1.5 Interest and other costs of finance paid	(4)	(4)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	3,422	3,422
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(5,373)</b>	<b>(5,373)</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)	(1)
(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>(1)</b>	<b>(1)</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	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)	(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)	(63)	(63)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>50,485</b>	<b>50,485</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	60,593	60,593
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,373)	(5,373)

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)	(1)	(1)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	50,485	50,485
4.5	Effect of movement in exchange rates on cash held	681	681
4.6	<b>Cash and cash equivalents at end of period</b>	<b>106,385</b>	<b>106,385</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	26,505	20,533
5.2	Call deposits	71,251	31,313
5.3	Bank overdrafts	-	-
5.4	Other (provide details if material)		
	-Term deposit	8,629	8,282
	-Restricted cash (Advance payment from shareholder for SPP)	-	465
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>106,385</b>	<b>60,593</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	135
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> <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. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(5,373)
8.2 Cash and cash equivalents at quarter end (item 4.6)	106,385
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	106,385
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	19.8
<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.

28 October 2021

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.