

ASX/Media Release

## IMMUTEP QUARTERLY ACTIVITIES REPORT & APPENDIX 4C

- Encouraging clinical results from TACTI-002 and INSIGHT-004 trials of eftilagimod alpha
- Immutep completes recruitment for Stage 1 of Part B in TACTI-002 Study
- United States patent grants relating to eftilagimod alpha and LAG525

**SYDNEY, AUSTRALIA – 22 October 2020 – Immutep Limited** (ASX: IMM; NASDAQ: IMMP) a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, provides an update on the ongoing development of its product candidates, eftilagimod alpha (“efti” or “IMP321”) and IMP761, and the activity of its new and existing partners.

“Over the quarter, we have continued to report further supportive data from our trials of efti in multiple cancers. This has built a strong pool of data to discuss with potential out licensing and collaboration partners. We already have committed partnerships in place with five of the world’s largest pharmaceutical companies: Merck, Pfizer, Merck MSD, Novartis and GSK, plus our partner in China, EOC Pharma, giving us confidence that we can build on our LAG-3 leadership position,” said Marc Voigt, CEO of Immutep.

### Eftilagimod Alpha Clinical Updates

#### **TACTI-002 - Phase II clinical trial**

Immutep presented encouraging interim results from its TACTI-002 trial in two poster presentations at the ESMO Virtual Congress 2020 in September 2020. These results showed three patients had complete responses (complete disappearance of all lesions) to the combination therapy of efti with KEYTRUDA<sup>®</sup> (pembrolizumab). Two of these patients had second line head and neck squamous cell carcinoma (HNSCC) and one had first line non-small cell lung cancer (NSCLC). Pleasingly, five partial responses were reported from patients (across both indications) with negative (< 1%) or moderate PD-L1 expression. Pembrolizumab monotherapy is typically less effective in these patients.

A median Progression Free Survival (PFS) of 4.3 months was achieved for patients with second line HNSCC and 47% of these patients were progression free at the 6-month landmark in this very aggressive late stage disease. For 1st line NSCLC patients, median PFS continues to improve and is 11.8 months. The combination treatment continues to be safe and well tolerated with no new safety signals reported thus far.

In August, Immutep enrolled and safely dosed the last patient for Stage 1 of Part B (2nd line NSCLC) of TACTI-002, completing recruitment of this stage. Recruitment is also complete for both stages of Part A (1st line NSCLC) and is ongoing for Stage 2 of Part C (2nd line HNSCC). Pending the Data Monitoring Committee’s recommendation, Immutep will consider opening Stage 2 of Part B for recruitment. Overall, recruitment for the trial continues to progress well, with 92 out of up to 109 patients now enrolled.

TACTI-002 is evaluating the combination of efti with Merck & Co’s KEYTRUDA<sup>®</sup> (pembrolizumab) in up to 109 patients with second line HNSCC or NSCLC in first and second line.

#### **INSIGHT-004 - Phase I clinical trial**

Immutep also reported improving interim data from its INSIGHT-004 trial of efti at the ESMO Virtual Congress 2020 in September 2020. In the trial 41.7% of patients showed a Partial Response to the combination therapy of efti and avelumab, building on the previous interim data of 33%.

More importantly, the trial also reported encouraging early anti-tumour activity signals across a variety of cancer indications not typically sensitive to immune checkpoint inhibitor (ICI) therapy, including PD-L1-negative cervical cancer, squamous anal cell carcinoma, and mesothelioma. The combination of efti and avelumab continues to be safe and well tolerated.

INSIGHT-004 is evaluating the combination of efti with avelumab, a human anti-PD-L1 antibody, in 12 patients with different advanced solid malignancies, primarily gastrointestinal indications. The trial is being conducted under Immutep's collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer Inc., as the 4th arm of the ongoing INSIGHT Phase I clinical trial. The Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany ("IKF") is the trial sponsor for INSIGHT-004.

### **IMP761 Preclinical Update**

Immutep is continuing cell line development for IMP761. IMP761 is an immunosuppressive agonist antibody to LAG-3 for the treatment of autoimmune diseases, such as inflammatory bowel diseases, rheumatoid arthritis, and multiple sclerosis.

### **Partner Updates**

#### ***Monash University***

In August, Immutep and its research partner, Monash University, were awarded a A\$671,427 grant under the Australian Research Council's (ARC) Linkage Project scheme to support their research collaboration into Lymphocyte Activation Gene-3 (LAG-3) for a further three years. The collaboration commenced in 2017.

#### ***Novartis***

Novartis has five clinical trials ongoing for LAG525 (Ieramilimab) in multiple cancer indications, including a Phase II clinical trial in triple negative breast cancer. According to the Q2 Novartis earnings call a regulatory submission is planned for LAG525 in 2023.

#### ***Other partnerships***

Immutep's other partnerships with GlaxoSmithKline, EOC Pharma and CYTLIMIC continue to progress well.

### **Intellectual Property**

In August, the United States Patent and Trade Mark Office granted Immutep a new patent entitled "Combined Preparations for the Treatment of Cancer". The new patent relates to the use of efti in combined therapeutic preparations with a chemotherapy agent and follows the grant of similar European, Australian and Japanese patents in May 2019, June 2019 and May 2020, respectively. The expiry date of this United States patent is 25 January 2035.

In July, a new patent was granted by the United States Patent and Trade Mark Office entitled "Antibody molecules to LAG-3 and uses thereof". The patent relates to embodiments of LAG525, a humanised form of Immutep's IMP701 antibody which is out-licensed to Novartis AG. The patent is co-owned by Novartis AG and Immutep S.A.S. and will expire on 26 March 2035.

## Financials

Cash receipts from customers for the quarter were \$23k, compared to \$128k in Q4 FY2020. Cash receipts from government grants and tax incentives for the quarter were \$126k, compared to \$5.1 million in Q4 FY2020.

The net cash used in G&A activities in the quarter was \$0.35 million compared to \$0.36 million in Q4 FY2020. G&A costs for the quarter includes \$127K in payment of Non-Executive Director's fees and Executive Director's salary.

Total net cash outflows used in operating activities in the quarter was \$3.34 million. In comparison, total net cash inflows from the operating activities in Q4 FY2020 were \$0.12 million.

The net cash used in Research and Development activities in the quarter was \$2.10 million, compared to \$3.77 million in Q4 FY2020. R&D expenditure declined further as all patients in the AIPAC Phase IIb clinical trial have completed the treatment and moved into the follow-up phase.

Interest paid of \$6k is the interest component of the office lease under the application of AASB 16 Leases. The cash balance as at 30 September 2020 was \$22.7 million compared to a balance of \$26.3 million as at 30 June 2020. The Company's cash runway extends to the end of calendar year 2021, beyond several significant data read-outs.

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 protein (LAG-3lg) based on the LAG-3 immune control mechanism. This mechanism plays a vital role in the regulation of the T cell immune response. Efti is currently in a Phase IIb clinical trial as a chemoimmunotherapy for metastatic breast cancer termed AIPAC (clinicaltrials.gov identifier NCT02614833); a Phase II clinical trial being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada) referred to as TACTI-002 to evaluate a combination of efti with KEYTRUDA® (pembrolizumab) in several different solid tumours (clinicaltrials.gov identifier NCT03625323); a Phase I clinical trial being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. referred to as INSIGHT-004 to evaluate a combination of efti with avelumab (clinicaltrials.gov identifier NCT03252938); and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT02676869).

Additional LAG-3 products, including antibodies, for immune response modulation in autoimmunity and cancer are being developed by Immutep's large pharmaceutical partners. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

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")**

30 September 2020

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1.</b>	<b>Cash flows from operating activities</b>		
1.1	Receipts from customers	23	23
1.2	Payments for		
	(a) research and development	(2,094)	(2,094)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(122)	(122)
	(d) leased assets	-	-
	(e) staff costs	(936)	(936)
	(f) administration and corporate costs	(350)	(350)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	23	23
1.5	Interest and other costs of finance paid	(6)	(6)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	126	126
1.8	Other (provide details if material)	-	-
<b>1.9</b>	<b>Net cash from / (used in) operating activities</b>	<b>(3,336)</b>	<b>(3,336)</b>
<b>2.</b>	<b>Cash flows from investing activities</b>		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

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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>-</b>	<b>-</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 (Payment for the finance lease liability under AASB 16)	(96)	(96)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(96)</b>	<b>(96)</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	26,322	26,322
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,336)	(3,336)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(96)	(96)
4.5	Effect of movement in exchange rates on cash held	(179)	(179)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>22,711</b>	<b>22,711</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	5,647	10,989
5.2	Call deposits	1,417	1,805
5.3	Bank overdrafts	-	-
5.4	Other (term deposit)	15,647	13,528
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>22,711</b>	<b>26,322</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	127
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' salary</p>		

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7. <b>Financing facilities</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>	<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

8. <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)	(3,336)
8.2 Cash and cash equivalents at quarter end (item 4.6)	22,711
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	22,711
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	6.81
<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.

22 October 2020

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.