

ASX/Media Release

## IMMUTEP QUARTERLY ACTIVITIES REPORT & APPENDIX 4C

### Highlights

- Safely dosed the last HNSCC patient for Stage 2 of Part C of the TACTI-002 Phase II study (also designated KEYNOTE-798)
- Initiated enrolment of first line NSCLC patients for the expansion arm of Part A of TACTI-002
- Commenced recruitment of second line NSCLC patients for Stage 2 of Part B of TACTI-002
- Advancement of the Phase II EAT COVID trial into the randomised portion of the study
- Robust operational and financial position, with \$51.7 million in cash as of 31 March 2021, providing cash runway beyond the end of calendar year 2022

**SYDNEY, AUSTRALIA – 19 April 2021** – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune disease, provides an update on the ongoing development of its product candidates, eftilagimod alpha ("efti" or "IMP321") and IMP761, and the activities of its partners for the quarter ended 31 March 31, 2021.

"We continue to lead the world in the development of different LAG-3 related therapies, with a robust pipeline of exciting clinical stage programs and promising data. Throughout the quarter ended 31 March 2021, we have been extremely active advancing and expanding upon these clinical programs, building upon our data generated last year" said Marc Voigt, CEO of Immutep. "We are well-positioned for long-term success, as we have a steady stream of positive data advancing our clinical studies, and decades of experience across our clinical team, which includes the discoverer of the LAG-3 immune control mechanism, as well as a strengthened balance sheet."

"There has recently been broad industry coverage of positive Phase II/III data from another company's LAG-3 program to treat melanoma, which we're pleased to say further validates targeting the LAG-3 pathway to enhance the immune response. While they have additional data to announce, what has been discussed to-date further supports our knowledge of the LAG-3 mechanism and is in line with our MSD collaboration to develop a combination of KEYTRUDA<sup>®</sup> with efti. This year is shaping up to be an exciting period for the clinical development of LAG-3 therapies," added Dr. Frederic Triebel, CSO/CMO of Immutep.

### Efti Development Program Updates

#### Intellectual Property

Immutep recently further strengthened its IP profile for lead active immunotherapy candidate efti, which is a soluble LAG-3 fusion protein (LAG-3Ig). In particular, in March 2021, the United States Patent & Trademark Office granted a new patent number 10,940,181, which is entitled "Combined Preparations for the Treatment of Cancer or Infection". The patent was filed as a divisional application and follows the grant of the parent patent announced on 30 December 2020. The claims of this new patent build on the protection provided by

the parent patent and are patent protecting ImmuteP's methods of treating cancer by administering efti and a PD-1 pathway inhibitor: either pembrolizumab (KEYTRUDA®) or nivolumab. The expiry date of the patent is 20 January 2036 (including a patent term adjustment of 12 days).

***TACTI-002 (Two Active Immunotherapies, also designated KEYNOTE-798) - Phase II clinical trial***

The TACTI-002 study is evaluating the combination of efti with KEYTRUDA® (pembrolizumab), the anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada), in first and second line non-small cell lung cancer (NSCLC) and second line head and neck squamous cell carcinoma (HNSCC). This study is being conducted in collaboration with MSD, which refers to the study as "Keynote-798".

Patients participate in one of three parts:

***Part A - First Line NSCLC, PD-X naïve***

Recruitment of an additional 74 first line NSCLC patients was initiated in accordance with Part A of the TACTI-002 collaboration trial expansion plans announced on 19 November 2020, adding to the 36 patients already enrolled prior to the expansion. ImmuteP and MSD expanded Part A of the TACTI-002 study following the encouraging results presented at the Society for Immunotherapy of Cancer's (SITC) Congress in November 2020.

***Part B - Second Line NSCLC, PD-X refractory***

ImmuteP decided to expand Part B of TACTI-002, under the study's Simon's two-stage clinical trial design. The Company recently commenced recruitment of an additional 13 second line NSCLC patients, forming Stage 2 of Part B. The decision follows a preliminary safety and efficacy review by the Data Monitoring Committee and its recommendation, based on the patients recruited in Stage 1 of Part B.

***Part C - Second Line HNSCC***

The last patient was safely dosed for Stage 2 of Part C of TACTI-002. This completes recruitment for Part C of the study. The Company continues to be excited by this study, as it recently announced encouraging interim data from TACTI-002 at the SITC 2020 Congress. Specifically, the data from second line HNSCC patients was very robust and forms an excellent basis for additional clinical development in this cancer type.

Additional data from TACTI-002 is expected in H1 2021.

***TACTI-003 (Two Active Immunotherapies) - Phase IIb clinical trial - First Line HNSCC***

ImmuteP will also conduct a new randomised, controlled Phase IIb clinical study in approximately 160 first line HNSCC patients, which is a more commercially relevant indication than second line HNSCC. This study will evaluate the safety and efficacy of efti when given in combination with MSD's KEYTRUDA®, compared to KEYTRUDA® alone. TACTI-003 will be executed in 20+ clinical sites in the United States, Australia and Europe, and study is expected to start in mid-2021.

This is ImmuteP's second collaboration with MSD for a combination of KEYTRUDA® and efti.

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

The investigator-initiated Phase II clinical trial being conducted by the University Hospital Pilsen in the Czech Republic advanced from the safety run and into the randomised portion of the study, which is evaluating efti in up to 110 hospitalised patients with COVID-19.

In January 2021 ImmuteP reported that the independent Data Safety Monitoring Board (DSMB) had completed a safety run-in data review of the first six patients from the Phase II clinical trial of Eftilagimod Alpha Treatment by immune modulation in COVID-19 disease (EAT COVID). Following this data review, the DSMB recommended that the study advance with enrolment for the randomised portion of the study. All six patients (age range, 50-83 years; 2 women and 4 men) received the three planned 10 mg efti injections and were since discharged from hospital with no adverse events reported.

### **Partner Updates**

#### ***GlaxoSmithKline***

As announced in January 2021, GSK stopped its Phase II clinical trial evaluating GSK2831781 (derived from ImmuteP's IMP731 antibody) in ulcerative colitis based on the assessment of clinical data as part of a planned interim analysis conducted in consultation with the trial's Data Review Committee. ImmuteP's collaboration with GSK remains in place and GSK2831781 continues to be under an exclusive license with GSK.

#### ***Other Partners***

Selected for its in-depth LAG-3 expertise and knowledge, ImmuteP entered into a Licence and Collaboration Agreement with Laboratory Corporation of America Holdings, known as LabCorp, to support its development of immuno-oncology products or services in October 2020.

LabCorp co-authored with Bristol Myers Squibb an abstract released in March 2021 on the distribution and prevalence of LAG-3 expression in samples of melanoma and gastric/gastroesophageal junction cancer for the American Association for Cancer Research Annual Meeting 2021.

ImmuteP's other licensing partnerships with Novartis, EOC Pharma and CYTLIMIC continue to progress well.

### **Financial Summary - Q3 FY21**

Cash receipts from customers for the quarter was \$59k, compared to \$336k in Q2 (i.e. the quarter ended 31 December 2020).

The net cash used in G&A activities in the quarter was \$242k compared to \$1.82 million in Q2. The significant decrease compared with last quarter is mainly due to the prepayment of certain annual expenses in Q2. G&A costs for the quarter includes \$125k 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 \$1.74 million, compared to \$3.18 million in Q2. Year to date cash flow used in R&D activities for the 9 months from July 2020 to March

2021 was \$7.0 million compared to \$16.1 million for the 9 months from July 2019 to March 2020. The decline is mainly due to the declining AIPAC expenses since patients in the AIPAC Phase IIb clinical trial have completed the treatment and moved into the follow-up phase. The cash used in R&D activities is expected to increase with the commencement of the new Phase IIb TACTI-003 clinical trial.

Total net cash outflows used in operating activities in the quarter was \$3.05 million. In comparison, total net cash outflows from operating activities in Q2 was \$5.58 million.

The cash and cash equivalent balance as at 31 March 2021 was \$51.7 million compared to a balance of \$54.9 million as at 31 December 2020.

ImmuteP is in an excellent financial position with a cash runway into calendar year 2023 and beyond several significant data read-outs.

#### **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, infectious disease 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, 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](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")**

31 March 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	59	418
1.2 Payments for		
(a) research and development	(1,744)	(7,016)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(102)	(330)
(d) leased assets	-	-
(e) staff costs	(1,055)	(2,891)
(f) administration and corporate costs	(242)	(2,409)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	36	87
1.5 Interest and other costs of finance paid	(2)	(10)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	160
1.8 Other (provide details if material)	-	26
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,050)</b>	<b>(11,965)</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	(8)	(13)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	(7)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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>(8)</b>	<b>(20)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	29,572
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	10,661
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(21)	(1,502)
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)	(39)	(168)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(60)</b>	<b>38,563</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	54,880	26,322
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,050)	(11,965)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(8)	(20)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(60)	38,563
4.5	Effect of movement in exchange rates on cash held	(64)	(1,202)
4.6	<b>Cash and cash equivalents at end of period</b>	<b>51,698</b>	<b>51,698</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	9,000	8,243
5.2	Call deposits	22,311	24,448
5.3	Bank overdrafts	-	-
5.4	Other (term deposit)	20,387	22,189
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>51,698</b>	<b>54,880</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	125
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)	(3,050)
8.2 Cash and cash equivalents at quarter end (item 4.6)	51,698
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	51,698
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	16.95
<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.

19 April 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.