

ASX/Media Release

Immutep Quarterly Activities Report & Appendix 4C

- Immutep entered late-stage development in the newly validated LAG-3 space
- Data from 1st line NSCLC and 2nd line HNSCC presented at ASCO
- Efti to be evaluated in new triple combination therapy trial and entered into a new collaboration with Merck KGaA for efti and bintrafusp alpha

SYDNEY, AUSTRALIA – 13 July 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 June 2021.

“In the past quarter Immutep has entered a new phase as a biotech company at the forefront of the LAG-3 immunotherapeutic landscape. We are now advancing the development of efti in multiple different cancers and have the ongoing support of large pharma collaboration partners, including MSD and Merck Germany, for many of our trials. We have begun planning for our new Phase III study in metastatic breast cancer which, if positive, could provide us with registration data and have a number of new and ongoing other trials progressing at pace. Manufacturing scale up of efti to potential commercial quantities is progressing well,” said Marc Voigt, CEO of Immutep.

“All of this company activity is taking place in an exciting LAG-3 landscape where the interaction between MHC class II and LAG-3 has just recently been validated as a therapeutic mechanism for regulating the body’s immune system to fight cancer. With more LAG-3 related programs under development than any other biotech or pharma in the space, we are very excited about the future,” he concluded.

Efti Development Program

AIPAC - Phase IIb clinical trial - ongoing

The trial is on track to report final overall survival (OS) data in H2 of calendar year 2021. Immutep previously reported OS data from approximately 60% of events in Dec 2020.

TACTI-003 - Phase IIb clinical trial - new

Immutep received Fast Track designation in 1st line recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) from the United States Food and Drug Administration (FDA) in April 2021. This opens the potential for expedited development and review of efti in 1st line HNSCC with the FDA.

Following the close of the quarter, Immutep completed the necessary regulatory steps with the US FDA and obtained institutional review board approval in the US to commence the TACTI-003 trial. Patient recruitment is expected to begin in this quarter.

TACTI-002 (also designated KEYNOTE-798) - Phase II clinical trial – ongoing

At ASCO 2021, Immutep reported updated interim results from TACTI-002 showing the combination therapy of ehti and pembrolizumab demonstrates a very favourable overall response rate (ORR) together with very encouraging duration and depth of response in 1st line non-small cell lung cancer (NSCLC) (Part A) and 2nd line HNSCC (Part C). Tumor responses were seen in all PD-L1 subgroups, including in low PD-L1 expressing patients which are typically less responsive to anti-PD-1 therapy. Importantly, the combination therapy continues to be safe and well tolerated.

Recruitment continues for the additional 74 1st NSCLC patients for the expansion of Part A, with 33 patients already enrolled and for Stage 2 of Part B, which has 8 patients now enrolled. Recruitment is tracking better than projected for the expansion cohort of Part A and as originally projected for Stage 2 of Part B. Immutep expects to report further interim data for TACTI-002 in calendar year 2021 or early calendar year 2022.

INSIGHT

INSIGHT is an investigator-initiated phase I trial investigating different combination treatments with ehti and a different route of administration for ehti. INSIGHT consists of 5 different arms from stratum A to E.

INSIGHT-005 – combination with bintrafusp-alpha - new

Immutep signed a collaboration and supply agreement with Merck KGaA, Darmstadt, Germany for a new stratum in 12 patients with solid tumours, known as Stratum E or INSIGHT-005. The trial will be run as an amendment to the protocol of the ongoing INSIGHT trial as the fifth arm and will evaluate ehti in combination with Merck KGaA's and GlaxoSmithKline's bintrafusp alfa. The first patient is expected to be enrolled in H2 of calendar year 2021.

INSIGHT-004 – combination with avelumab- final data

At ASCO 2021, Immutep also reported encouraging final data from its INSIGHT-004 arm (stratum D). Promising activity signals were demonstrated from the combination of ehti and avelumab, with a response rate of 41.7% in patients with different solid tumours. In addition, deep and durable responses were seen in patients with low or no PD-L1 expression and in indications such as gastroesophageal and cervical cancer which typically do not respond to immune checkpoint therapy. Importantly, the combination therapy showed a good safety profile.

INSIGHT-003 – triple combination - new

INSIGHT-003 is a new stratum in up to 20 patients with various solid tumours, also referred to as Stratum C. This is Immutep's first evaluation of ehti in a triple combination therapy of ehti, chemotherapy and anti-PD-1 therapy. All regulatory and ethical approvals have already been received, enabling patient recruitment to commence. The first patient is expected to be enrolled in Q3 of calendar year 2021, with first interim results expected in 2022.

The results of INSIGHT-003 are expected to inform a potential Phase II evaluating ehti as part of a triple combination therapy along with an anti-PD-1 therapy and a chemotherapy, potentially in NSCLC.

EAT COVID - Phase II clinical trial - ongoing

The randomised portion of the investigator-initiated EAT COVID study is progressing at the University Hospital Pilsen in the Czech Republic. It is evaluating ehti in up to 110 hospitalised patients with COVID-19.

Preclinical Pipeline

Immutep continues to work on GMP manufacturing preparations for IMP761 and is planning for toxicology studies and other pre-clinical evaluations.

In addition, under a collaboration project commenced in 2019 with Cardiff University, Immutep has advanced the discovery and development of a potential new generation of small molecule anti-LAG-3 therapies. The project aims to make an oral treatment available to cancer patients and at a lower cost compared with the current anti-LAG-3 antibodies being developed by several other companies.

Partnerships

Immutep's licensing and collaboration partnerships with Labcorp, GSK, Novartis, EOC Pharma and CYTLIMIC continue to progress.

Intellectual Property

Immutep was granted three new patents during the quarter, further expanding the company's global patent estate. The European Patent Office granted a patent directed to combination therapy with leramlimab (LAG525), Immutep's IMP701 antibody which is out-licensed to Novartis AG, and also a new divisional patent for efti in combination with a PD-1 or PD-L1 inhibitor. In addition, the Chinese Patent Office granted a new patent for efti in combination with chemotherapy, building on corresponding Australian, European, Japanese and United States patents.

Financial Summary - Q4 FY21

Cash receipts from customers for the quarter was \$10k, compared to \$59k in Q3 of FY 2021 (i.e. the quarter ended 31 March 2021).

The net cash used in G&A activities in the quarter was \$409k compared to \$242k in Q3. The increase compared with last quarter is mainly related to capital raising related activities. Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter includes \$128k 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 \$5.45 million, compared to \$1.74 million in Q3. The significant increase is mainly due to the payment of upfront costs for the TACTI-003 clinical trial in Q4. Cash flow used in R&D activities for FY2021 was \$12.47 million compared to \$19.87 million for FY 2020. The decline of cash used in R&D activities in FY 2021 compared with FY 2020 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 and due to more material expenses related to the Phase IIb TACTI-003 clinical trial only starting to become payable during Q4 FY 2021. Total net cash outflows used in operating activities in the quarter was \$5.71 million. In comparison, total net cash outflows from operating activities in Q3 was \$3.05 million.

Immutep received a A\$1,155,055 cash rebate from the Australian Federal Government's R&D tax incentive program during the quarter.

In June 2021, Immutep secured commitments for \$60 million via a two-tranche institutional placement which was supported by multiple institutional investors in Australia and offshore.

The Company's cash and cash equivalent balance as at 30 June 2021 was \$60.59 million compared to a balance of \$51.7 million as at 31 March 2021. This includes \$13.7m from the first tranche of the institutional placement and \$605k from the exercise of US warrants over American Depository Shares.

A further \$46.3 million will be raised from the second tranche of the placement conditional on shareholder approval at the Company's Extraordinary General Meeting on 26 July 2021.

In addition, Immutep is seeking to raise a further ~\$5 million from eligible shareholders via a Share Purchase Plan (SPP), which closes on Monday, 19th July 2021 at 5pm (Sydney, Australia time).

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 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. 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

90 009 237 889

Quarter ended ("current quarter")

30 June 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	10	428
1.2 Payments for		
(a) research and development	(5,453)	(12,469)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(163)	(493)
(d) leased assets	-	-
(e) staff costs	(871)	(3,762)
(f) administration and corporate costs	(409)	(2,818)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	26	113
1.5 Interest and other costs of finance paid	(3)	(13)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,155	1,315
1.8 Other (provide details if material)	-	26
1.9 Net cash from / (used in) operating activities	(5,708)	(17,673)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(4)	(17)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	(7)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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)	-	-
2.6	Net cash from / (used in) investing activities	(4)	(24)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	13,735	43,307
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	605	11,266
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(622)	(2,124)
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)		
	-Initial SPP proceeds received during offer period up to 30 Jun 2021 (offer opened 28 June & closes 19 July 2021).	465	465
	-Payment for the finance lease liability under AASB 16)	(61)	(229)
3.10	Net cash from / (used in) financing activities	14,122	52,685

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	51,698	26,322
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,708)	(17,673)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(24)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	14,122	52,685
4.5	Effect of movement in exchange rates on cash held	485	(717)
4.6	Cash and cash equivalents at end of period	60,593	60,593

5. Reconciliation of cash and cash equivalents	Current quarter \$A'000	Previous quarter \$A'000
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		
5.1 Bank balances	20,533	9,000
5.2 Call deposits	31,313	22,311
5.3 Bank overdrafts	-	-
5.4 Other (provide details if material)		
-Term deposit	8,282	20,387
-Restricted cash (Advance payment from shareholder for SPP)	465	-
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	60,593	51,698

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	128
6.2 Aggregate amount of payments to related parties and their associates included in item 2	-
<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>	
The amount at 6.1 includes payment of Non-Executive Directors' fees and Executive Directors' salary.	

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<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>		
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)	(5,708)
8.2 Cash and cash equivalents at quarter end (item 4.6)	60,593
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	60,593
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	10.62
<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.

13 July 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.