

ASX/Media Announcement

Immutep Quarterly Activities Report & Appendix 4C

- Highly encouraging data from efti in ongoing TACTI-002 study
- AIPAC Phase IIb study reported first results
- Limited impact on clinical trials from COVID-19 to date
- Further significant data to be reported throughout 2020

SYDNEY, AUSTRALIA – April 20, 2020 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), 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, as well as its response to the COVID-19 pandemic and its potential business impact.

COVID-19 update

Immutep has welcomed recent guidance from the United States Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”) and other regulators on how to continue ongoing clinical trials during the COVID-19 pandemic. Cancer patients have been recognised by regulators as at risk and vulnerable to COVID-19 infection due to their weakened immune system. The FDA and other regulators are actively helping trial sponsors and hospitals continue critical clinical trials through the pandemic.

For Immutep, the safety and wellbeing of its clinical trial participants and investigators are its absolute priority. The Company is working closely with the clinical sites and regulators to monitor the situation, with the impact to date on treatment of patients being limited. Immutep also continues to work with its Clinical Research Organisation (CRO) partners to verify data remotely and review clinical trial processes according to the new guidance.

The Company anticipates that trial recruitment may slow down for its two actively recruiting trials, TACTI-002 and INSIGHT-004 over the coming months, due to the closure of hospitals in certain countries that have been most affected, such as Spain and the United Kingdom. However, INSIGHT has already recruited 91% of total patients and TACTI-002 has recruited 70% of total patients. Both its AIPAC and TACTI-mel trials are fully recruited.

Immutep is also implementing strategies to account for any impact of the pandemic on its ongoing trial data, related to potential patient infection. These strategies are under constant re-evaluation. As COVID-19 response restrictions are lifted, the Company will conduct an impact analysis to evaluate the overall effects of the pandemic.

The Company's own operations are minimally affected with increased home office work and less travel for the staff.

Eftilagimod alpha Clinical Update

TACTI-002-Phase II clinical trial

In mid-February, ImmuteP reported highly encouraging first data from its ongoing TACTI-002 study of efti in combination with pembrolizumab, an anti-PD-1 therapy. The data showed an Overall Response Rate (ORR) of 47% for patients in Part A, first line non-small cell lung cancer (NSCLC) patients who are receiving the combination treatment of efti with pembrolizumab. This compared very favorably to patients in Part A who are receiving pembrolizumab monotherapy and reported an initial ORR of approximately just 20%.

Trial recruitment continues to progress well, with 76 patients out of up to 109 already enrolled at 12 clinical sites across Australia, Europe, the UK and US. Details of recruitment for each Part are below.

Study – Part*	Stage 1 (N) Actual/target	Stage 2 (N) target
Part A - 1st line NSCLC	17/17	17/19
Part B - 2nd line NSCLC	18/23	-/13
Part C - 2nd line met. HNSCC	18/18	6/19

ImmuteP was selected to provide a poster short talk presentation of new TACTI-002 data as part of the high-impact paper presentation program at the American Association for Cancer Research (AACR) Virtual Annual Meeting, scheduled for 27 and 28 April. In addition, further data will be reported throughout 2020.

AIPAC-Phase IIb clinical trial

In March 2020, ImmuteP reported first results from its randomised, placebo controlled AIPAC trial in metastatic breast cancer. Patients receiving efti showed a positive trend in Progression Free Survival (PFS) rate at the 6-month landmark, with 63% of those who received paclitaxel plus efti being progression-free. This compared favourably to 54% of patients who received paclitaxel plus placebo. The ORR in the efti group was 48.3%, compared to 38.4% in the placebo group.

In addition, analysis on the trial subgroups showed that patients with a low monocyte count at baseline received a remarkable benefit from efti, with a median PFS of 7.29 months, compared to just 5.45 months in the placebo group (Hazard Ratio 0.61). Similarly, patients with a more aggressive, more immunogenic luminal B type also benefitted from efti with a median PFS of 7.29 months, compared to just 5.45 months in the placebo group (Hazard Ratio 0.65). Patients with lower general performance status at baseline also had a median PFS of 7.13 months compared to of 6.67 months in the placebo group (Hazard Ratio 0.76). These interesting subgroups are being discussed with the Company's clinical advisory board as well as other partners and will be investigated further.

Further building upon efti's strong safety profile to date, the combination of efti and paclitaxel chemotherapy was overall safe and well tolerated. For further information please also view the webcast available at www.immutep.com.

Immutep expects to report Overall Survival (OS) and immuno-monitoring results from AIPAC later in 2020. Together with the already reported data, this will inform the Company's future strategy for efti in metastatic breast carcinoma.

In early March 2020, Immutep received approval for its second Investigational New Drug ("IND") application from the United States FDA for efti. The IND enables the Company to initiate a clinical study in metastatic breast cancer patients. It also enables Immutep to further interact with the FDA regarding the use of efti in metastatic breast cancer.

INSIGHT-004 -Phase I clinical trial

Patient recruitment is continuing for Cohort 2 (30 mg efti) of the INSIGHT-004 study with 5 out of 6 patients participating. Cohort 1 is already fully recruited, bringing total recruitment to 11 out of 12 patients. As previously reported, the study is showing encouraging, positive initial activity.

The INSIGHT-004 is being conducted as the 4th arm of the INSIGHT trial and evaluates the combination of efti with avelumab in 12 patients with advanced solid malignancies.

TACTI-mel-Phase I clinical trial

Immutep is preparing a clinical study report for its TACTI-mel trial which reported positive final efficacy data in late 2019. The study showed deep and durable responses to the combination of efti and pembrolizumab in patients with metastatic melanoma. 12 patients (50%) reported a decrease of $\geq 75\%$ in the target lesions and 9 patients (38%) were treated for ≥ 12 months.

IMP761 Preclinical Update

Since the end of the quarter, Immutep has reported significant progress in the cell line development of its IMP761 immunosuppressive product candidate. A pharmaceutical-grade, stable CHO cell line has been developed that produces significantly high product yields of IMP761. Immutep will complete its preparations for the Good Manufacturing Practice (GMP) process compliance development phase, ahead of potential clinical testing of the compound in autoimmune disease.

Partner Updates

EOC Pharma

Following the recent APIAC results, Immutep discussed the analysis of the reported PFS data (including subgroup analysis) with its Chinese partner for efti, EOC Pharma. Subsequently, EOC confirmed it plans to continue advancing efti (designated as EOC202 in China) in metastatic breast cancer.

CYTLIMIC

At the end of the quarter, Immutep's partner, CYTLIMIC reported positive results from its YNP01 phase I clinical trial which is evaluating the combination immunotherapy of a HSP70 derived peptide, a GPC3 derived peptide, Immutep's IMP321 (efti) and Hiltonol in patients with advanced or metastatic solid cancer.

The results showed that approximately 70% of patients showed an immune response to each peptide. Further notable results were observed at the recommended dose (which has been adopted in CYTLIMIC's Investigator-Initiated Phase I Trial CRESCENT1), including a significant reduction of lymphocyte population expressing an exhaustion marker in the peripheral blood and an overall survival of 18 months or more in 5 out of 11 patients.

The results were published in the scientific peer-reviewed journal, *Cancer Immunology, Immunotherapy*.

Financials

Cash receipts for the quarter were \$0.22 million, compared to \$7.28 million in Q2 FY2020. Q2 FY2020 was boosted by a milestone payment of £4 million from GSK related to the first patient being dosed in GSK'S Phase II clinical trial evaluating GSK2831781 in ulcerative colitis.

The net cash used in G&A activities in the quarter was \$0.49 million compared to \$1.43 million in Q2 FY2020. The decrease reflected a return to normalised levels, after the Company prepaid some annual corporate expenses related to the 2020 calendar year in Q2. G&A costs for the quarter includes \$136K in payment of Non-Executive Director's fees and Executive Director's salary.

Total net cash outflows related to operating activities in the quarter was \$6.09 million. In comparison, total net cash inflows in Q2 FY2020 were \$1.22 million.

The net cash used in Research and Development activities in the last quarter was \$4.71 million, compared to \$6.19 million in Q2 FY2020. R&D expenditure is expected to continue to decline further over the remaining three quarters of this calendar year as almost all patients in the AIPAC Phase IIb clinical trial have completed the treatment and moved into the follow-up phase.

The cash balance as at 31 March 2020 was \$16.1 million compared to a balance of \$20.5 million as at 31 December 2019. Immutep's cash position gives the Company an expected cash runway beyond multiple upcoming data catalysts in 2020 and into the beginning of CY 2021.

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[®] (or 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 or by contacting:

Australian Investors/Media:

Catherine Strong, Citadel-MAGNUS
+61 (0)406 759 268; cstrong@citadelmagnus.com

U.S. Media:

Garth Russell, LifeSci Advisors
+1 (646) 876-3613; garth@lifesciadvisors.com

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 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	217	7,609
1.2 Payments for		
(a) research and development	(4,707)	(16,094)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(127)	(367)
(d) leased assets	-	-
(e) staff costs	(1,022)	(2,773)
(f) administration and corporate costs	(488)	(2,410)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	37	197
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	2,508
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(6,090)	(11,330)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(6)	(18)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

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)	-	-
2.6	Net cash from / (used in) investing activities	(6)	(18)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	10,031
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	(5)	(796)
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)	(82)	(82)
3.10	Net cash from / (used in) financing activities	(87)	9,153

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	20,516	16,568
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,090)	(11,330)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(18)

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)	(87)	9,153
4.5	Effect of movement in exchange rates on cash held	1,784	1,744
4.6	Cash and cash equivalents at end of period	16,117	16,117

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	5,843	12,833
5.2	Call deposits	2,059	101
5.3	Bank overdrafts	-	-
5.4	Other (term deposit)	8,215	7,582
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	16,117	20,516

6. Payments to related parties of the entity and their associates

6.1 Aggregate amount of payments to related parties and their associates included in item 1

6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current quarter \$A'000
136
-

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

The amount at 6.1 includes payment of Non-Executive Director's fees and Executive Director's salary.

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

7. Financing facilities

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.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
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)	(6,090)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	16,117
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	16,117
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	2.65

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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:

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:

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:

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.

20 April 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.