

## ASX Announcement

### IMMUTEP QUARTERLY ACTIVITIES REPORT & APPENDIX 4C

- Very encouraging data for efti from the ongoing Phase II TACTI-002 trial
  - First complete disappearance of target lesion from a patient with second line HNSCC
  - Progression-free survival estimated to be more than 9 months for patients with first line NSCLC
- INSIGHT-004 also reported encouraging first data including partial responses from 4 out of 12 patients
- Cash runway to the end of calendar year 2021, beyond multiple data read-outs

**SYDNEY, AUSTRALIA – July 23, 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, the activity of its partners, and the minimal impacts to the business from the COVID-19 pandemic.

Protecting the health of patients recruited into our clinical trials and our employees continues to be a focus for Immutep during the COVID-19 pandemic. Pleasingly, none of our employees have been infected with the virus. We have also been working closely with the clinical sites and regulators to monitor the situation and make any necessary adjustments to trial protocols to diminish risks to patients.

To date, the Company has not seen a significant impact on the pace of trial recruitment for its two actively recruiting trials: TACTI-002 and INSIGHT-004. TACTI-002 is now 74% recruited and INSIGHT-004 reached full recruitment during the quarter. AIPAC has been fully recruited since June 2019.

#### **Eftilagimod Alpha Clinical Update**

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

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

During the quarter, Immutep has continued to report consistently encouraging findings from its TACTI-002 study. The most recent results presented at ASCO in June reported the first Complete Response (complete disappearance of target lesion) from a patient with second line HNSCC (Part C). The Overall Response Rate according to iRECIST (iORR) of this group is 38.9% and 44% of patients were still under therapy. For patients with first line NSCLC (Part A) progression-free survival (PFS) is estimated to be more than 9 months, which is a very encouraging achievement for patients with such advanced cancer. The iORR for this group is 53% and 71% of patients had tumour shrinkage. Most importantly, responses have been observed regardless of the PD-L1 expression status. The trial continues to report a good safety profile from the combination. Recruitment for Part A of the study has recently been completed, while recruitment is ongoing for Part B (second line NSCLC) and for stage 2 of Part C (second line HNSCC). In total, 81 patients out of up to 109 patients (74%) are already enrolled and participating in the trial.

Further results are expected to be reported throughout calendar year 2020.

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

AIPAC is evaluating efti in combination with paclitaxel, a standard of care chemotherapy, in patients with metastatic breast cancer. Following the read out of PFS data from AIPAC in March 2020, Immutep has continued to explore the favourable results demonstrated in multiple predefined patient subgroups in greater detail. Overall, the PFS results showed that efti provided an improvement for patients compared to the placebo group at the 6-month landmark and an increase in ORR of 48.3% compared to 38.4% in the placebo group.

Importantly, Overall Survival (OS) results are expected to be reported from AIPAC by the end of calendar year 2020.

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

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. It is the 4th arm of the ongoing INSIGHT Phase I clinical trial which is being conducted by trial sponsor, the Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany ("IKF").

In April 2020, INSIGHT-004 reached full recruitment and first data was reported in May 2020. Encouraging early efficacy signals have been observed in a variety of cancer indications and, overall, Partial Responses have been reported in 4 of the 12 patients. Importantly, thus far, the combination treatment of efti and avelumab is safe and well tolerated.

Further data from the study is expected to be reported throughout calendar year 2020.

#### ***Efti Manufacturing***

The Company plans to manufacture two new 200L batches of efti in FY21 which will provide sufficient material to complete the current clinical program. During the quarter, Immutep postponed its efti up-scaling manufacturing program at the WuXi Biologics manufacturing plant (Wuxi, China). The program aims to upscale the manufacturing process from 200L to 2,000L single-use bioreactors to prepare for potential commercial manufacturing and additional registration trials in multiple indications. Immutep will recommence the 2000L manufacturing program as its clinical development program for efti advances.

Separately, Immutep's partner in China, EOC Pharma, has started upscaling manufacturing for efti to 2,000L.

#### **IMP761 Preclinical Update**

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. The Company's manufacturing partner for IMP761, Batavia Biosciences, reported significant progress in the cell line development of IMP761,

delivering a pharmaceutical-grade, stable CHO cell line that produces sufficient yields for clinical development. The program is now working on the completion of the cell line development.

## **Partner Updates**

### ***EOC Pharma***

Immutep's partner and Chinese licensee, EOC Pharma, is evaluating efti (designated as EOC202 in China) in patients with metastatic breast cancer in a Phase I study in China, called EOC202A1101.

During the quarter, EOC Pharma confirmed its plans to continue advancing efti through clinical trials following its analysis of the PFS data, including subgroup analysis, from Immutep's Phase IIb AIPAC study, detailed above. This includes manufacturing scale up work, also detailed above.

### ***CYTLIMIC***

CYTLIMIC is evaluating efti in two Phase I clinical trials as part of a therapeutic vaccine, known as CYT001, in patients with advanced or metastatic solid cancer.

In June 2020, CYTLIMIC reported interim results from its second Phase I study in the neoadjuvant setting before surgery, called YCP02, showing that tumour cell death and infiltration of CD8 T cells into hepatocellular carcinoma surgical samples was observed in 6 out of 9 patients.

### ***GSK***

Clinical Proof-of-Concept data is expected in 1H of calendar year 2021 from GSK's ongoing Phase II trial of GSK'781 in ulcerative colitis.

## **Financials**

Cash receipts from customers for the quarter were \$0.13 million, compared to \$0.22 million in Q3 FY2020. Cash receipts from government grants and tax incentives for the quarter were \$5.1 million, compared to nil in Q3 FY2020.

The net cash used in G&A activities in the quarter was \$0.36 million compared to \$0.49 million in Q3 FY2020. G&A costs for the quarter includes \$171K in payment of Non-Executive Director's fees and Executive Director's salary.

Total net cash inflows from operating activities in the quarter was \$0.12 million. In comparison, total net cash outflows used in the operating activities in Q3 FY2020 were \$6.09 million.

The net cash used in Research and Development activities in the last quarter was \$3.77 million, compared to \$4.71 million in Q3 FY2020. R&D expenditure is expected to continue to decline further over the remaining two 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.

In April 2020, Immutep raised A\$12 million before transaction costs via a Placement. The proceeds are being used to continue the LAG-3 related programs, including the ongoing clinical development of efti and the development of IMP761.

The cash balance as at 30 June 2020 was \$26.3 million compared to a balance of \$16.1 million as at 31 March 2020. The Company's cash runway is expected to extend beyond several significant data catalysts to the end of calendar year 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 immunotherapies 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 the NASDAQ (IMMP) in the United States.

Immutep's current lead product candidate is eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3lg fusion protein which is a first-in-class antigen presenting cell (APC) activator. Efti is currently in a Phase IIb clinical trial known as AIPAC which is evaluating efti in combination with chemotherapy for the treatment of metastatic breast cancer (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 (clinical trials.gov identifier NCT03252938); and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT02676869).

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 June 2020

| <b>Consolidated statement of cash flows</b>               | <b>Current quarter<br/>\$A'000</b> | <b>Year to date (12<br/>months)<br/>\$A'000</b> |
|---|------------------------------------|---|
| <b>1. Cash flows from operating activities</b>            |                                    |   |
| 1.1 Receipts from customers                               | 128                                | 7,737   |
| 1.2 Payments for  |                                    |   |
| (a) research and development                              | (3,774)                            | (19,868)  |
| (b) product manufacturing and operating costs             | -                                  | -   |
| (c) advertising and marketing                             | (101)                              | (468)   |
| (d) leased assets   | -                                  | -   |
| (e) staff costs   | (899)                              | (3,672)   |
| (f) administration and corporate costs                    | (357)                              | (2,791)   |
| 1.3 Dividends received (see note 3)                       | -                                  | -   |
| 1.4 Interest received                                     | 32                                 | 229   |
| 1.5 Interest and other costs of finance paid              | -                                  | -   |
| 1.6 Income taxes paid                                     | -                                  | -   |
| 1.7 Government grants and tax incentives                  | 5,091                              | 7,599   |
| 1.8 Other (provide details if material)                   | -                                  | -   |
| <b>1.9 Net cash from / (used in) operating activities</b> | <b>120</b>                         | <b>(11,234)</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)                                | (19)  |
| (d) investments   | -                                  | -   |
| (e) intellectual property                                 | -                                  | -   |
| (f) other non-current assets                              | -                                  | -   |

| <b>Consolidated statement of cash flows</b> |   | <b>Current quarter<br/>\$A'000</b> | <b>Year to date (12<br/>months)<br/>\$A'000</b> |
|---|---|------------------------------------|---|
| 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>(19)</b>                                     |

|             |   |               |               |
|-------------|---|---------------|---------------|
| <b>3.</b>   | <b>Cash flows from financing activities</b>   |               |               |
| 3.1         | Proceeds from issues of equity securities (excluding convertible debt securities)       | 12,000        | 22,031        |
| 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 | (679)         | (1,475)       |
| 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)                           | (20)          | (78)          |
| <b>3.10</b> | <b>Net cash from / (used in) financing activities</b>                                   | <b>11,301</b> | <b>20,478</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                             | 16,117 | 16,568   |
| 4.2       | Net cash from / (used in) operating activities (item 1.9 above)              | 120    | (11,234) |
| 4.3       | Net cash from / (used in) investing activities (item 2.6 above)              | (1)    | (19)     |

| <b>Consolidated statement of cash flows</b> |  | <b>Current quarter<br/>\$A'000</b> | <b>Year to date (12<br/>months)<br/>\$A'000</b> |
|---|--|------------------------------------|---|
| 4.4   | Net cash from / (used in) financing activities (item 3.10 above) | 11,301                             | 20,478  |
| 4.5   | Effect of movement in exchange rates on cash held                | (1,215)                            | 529   |
| <b>4.6</b>                                  | <b>Cash and cash equivalents at end of period</b>                | <b>26,322</b>                      | <b>26,322</b>                                   |

| <b>5.</b>  | <b>Reconciliation of cash and cash equivalents</b><br>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | <b>Current quarter<br/>\$A'000</b> | <b>Previous quarter<br/>\$A'000</b> |
|------------|---|------------------------------------|-------------------------------------|
| 5.1        | Bank balances   | 10,989                             | 5,843                               |
| 5.2        | Call deposits   | 1,805                              | 2,059                               |
| 5.3        | Bank overdrafts   | -                                  | -                                   |
| 5.4        | Other (term deposit)  | 13,528                             | 8,215                               |
| <b>5.5</b> | <b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>  | <b>26,322</b>                      | <b>16,117</b>                       |

| <b>6.</b>   | <b>Payments to related parties of the entity and their associates</b>                   | <b>Current quarter<br/>\$A'000</b> |
|---|---|------------------------------------|
| 6.1   | Aggregate amount of payments to related parties and their associates included in item 1 | 171                                |
| 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> |   |                                    |

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

| <b>7. Financing facilities</b>  | <b>Total facility amount at quarter end \$A'000</b> | <b>Amount drawn at quarter end \$A'000</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>   |   |  |
| 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)  | 120            |
| 8.2 Cash and cash equivalents at quarter end (item 4.6)  | 26,322         |
| 8.3 Unused finance facilities available at quarter end (item 7.5)  | -              |
| 8.4 Total available funding (item 8.2 + item 8.3)  | 26,322         |
| 8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>  | N/A            |
| <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.

23 July 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.