**ASX/Media Release**

# IMMUTEP QUARTERLY ACTIVITIES REPORT & APPENDIX 4C

**Highlights**

- Encouraging efti data reported from phase IIb AIPAC and phase II TACTI-002 clinical trials
- TACTI-002 study expanded in lung cancer
- New phase II trial in head and neck cancer announced
- EOC Pharma starts new phase II study in metastatic breast cancer
- Robust operational and financial position, with $54.9 million in cash as at 31 December 2020, providing cash runway beyond the end of calendar year 2022

**SYDNEY, AUSTRALIA – 22 January 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.

"Immutep has entered calendar year 2021 in a very strong financial and operational position, following the encouraging clinical results announced for our lead product candidate, efti, last year. We have increasing confidence in efti and accordingly, three new efti trials or trial extensions with up to 386 patients in different cancer indications were announced or started in the quarter.

We advanced our business development activity with MSD and signed a new LAG-3 agreement with LabCorp. Our engagement with regulatory bodies has continued and our IP position has been significantly strengthened; in addition, we are upscaling the manufacturing of efti to prepare for the future. Immutep is advancing strongly towards another step change in calendar year 2021," said Marc Voigt, CEO of Immutep.

## Eftilagimod Alpha Updates

Following a succession of very encouraging clinical trial results for efti reported throughout 2020, Immutep prioritised the process of scaling up the drug candidate's manufacturing, increasing the process from 200L to 2,000L capacity bioreactors. Manufacturing is taking place at the WuXi Biologics manufacturing plant in Mashan, Wuxi, China. The major scale up steps are taking place throughout 2021.

### *AIPAC - Phase IIb clinical trial*

Immutep reported first Overall Survival (OS) data (based on approximately 60% of patient events) from the AIPAC phase IIb trial in a spotlight presentation at the San Antonio Breast Cancer Symposium 2020 in December. The results included a promising and improving overall trend in OS with a median survival benefit of +2.7 months from efti plus chemotherapy, compared to chemotherapy plus placebo.

In addition, a statistically significant OS benefit was observed in the efti group in key pre-defined patient groups. In patients under 65 years of age, a +7.1 months survival benefit was observed in the efti group which reported a median OS of 21.9 months vs. 14.8 months in the placebo group, reflecting nearly 50% longer survival. Similarly, in patients with a low starting monocyte count, a +9.4 months survival benefit was

observed in the efti group, with a median OS of 22.4 months vs. 12.9 months in the placebo group, 74% longer. Importantly there was a statistically significant increase of cytotoxic CD8 T-Cells in the efti arm versus the control arm and patients with those increased cells had, in general, a better OS. It is the first time that an antigen presenting cell activator (APC activator) has delivered meaningful OS data in a randomised, double blind setting.

The proportion of patient events has advanced to ~ 68% currently and Immutep is on track to report final OS data and Overall Response Rates (ORR) by mid calendar year 2021.

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

In November 2020, Immutep presented very encouraging results from its TACTI-002 phase II trial of efti at the Society for Immunotherapy of Cancer's (SITC) Congress. TACTI-002 is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada) and is called Keynote-798 by MSD.

More mature ORRs for Parts A and C were reported at SITC and continued to be very favourable. Immutep reported a 39.4% ORR in patients with 1$^{st}$ line Non-small Cell Lung Cancer (NSCLC) and 43.5% in patients with 2$^{nd}$ line head and neck squamous cell carcinoma (HNSCC), on an evaluable patient basis. Five patients (two with 1$^{st}$ line NSCLC and three with 2$^{nd}$ line HNSCC) reported a complete disappearance of all lesions, known as a Complete Response.

First data from patients with 2$^{nd}$ line NSCLC (Part B) who are PD-1 resistant was also reported at SITC. This group showed encouraging efficacy for low PD-L1 expressing patients who do not typically respond to immune checkpoint (PD-L1) therapy.

Following the encouraging results presented at SITC, Immutep and MSD expanded the TACTI-002 study by 74 additional patients with 1$^{st}$ line NSCLC, creating a stage 3 for Part A. Recruitment for this new stage opened in late December 2020.

In addition, Immutep completed recruitment of 2$^{nd}$ line HNSCC patients for Part C of the trial in early January 2021.

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

***Phase II Clinical Trial in Head and Neck Cancer***

The encouraging results reported by Immutep at SITC in patients with 2nd line HNSCC prompted the Company to announce its intention to run a new randomised, controlled phase II clinical study in approximately 160 1st line HNSCC patients which is a more commercially relevant indication. Patients will be 1:1 randomised to receive efti in combination with an anti-PD-1 treatment, or anti-PD-1 monotherapy. The trial is intended to take place across clinical trial sites in the United States, Australia and Europe.

Immutep is continuing planning for this new trial and will announce further details in due course.

***TACTI-mel - Phase I clinical trial***

The results of Immutep's phase I TACTI-mel trial were recently published in the peer-reviewed Journal for ImmunoTherapy of Cancer. TACTI-mel evaluated efti in combination with pembrolizumab in metastatic melanoma patients.

***EAT COVID – Phase II clinical trial***

The University Hospital Pilsen in the Czech Republic has commenced an investigator-initiated randomised phase II clinical trial evaluating efti in up to 110 hospitalised patients with COVID-19. Recruitment of patients commenced in October 2020.

Initial results from the safety run in of the trial are expected to be reported in early 2021 with initial interim efficacy results in 2021.

**IMP761 Update**

IMP761, a LAG-3 agonist antibody, is Immutep's preclinical candidate for autoimmune disease. The Company is continuing cell line and other preclinical development for IMP761 in preparation for clinical trials.

**Partner Updates**

***EOC Pharma - Phase II clinical trial***

EOC Pharma announced its plans to conduct a new trial in December 2020, following Immutep's announcement of encouraging first OS data from its Phase IIb study, AIPAC (see above).

Approximately 152 patients will participate in EOC Pharma's clinical trial which evaluates efti in combination with chemotherapy and is fully funded by EOC. EOC Pharma is the exclusive licensee of efti for the Chinese market. The ethics committee of the leading clinical site has already approved the study.

***GlaxoSmithKline***

As announced today, GSK has 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. GSK is conducting further reporting, assessment and analyses of the efficacy and safety data and evaluating the biology to determine next steps for the GSK2831781 development program. Immutep's collaboration with GSK remains in place and GSK2831781 continues to be under an exclusive license with GSK. The discontinuation of the GSK trial has no impact on Immutep's three other product candidates all of which have different mechanisms of action, including its lead product candidate eftilagimod alpha. Immutep's cash runway is also unimpacted.

***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.

Immutep's other licensing partnerships with Novartis and CYTLIMIC continue to progress well.

**Intellectual Property**

During the quarter, Immutep was granted a new US patent for efti in combination with a PD-1 pathway inhibitor, such as pembrolizumab or nivolumab. The Company was also granted a new European patent for its pre-clinical candidate IMP761 and a new Australian patent for LAG525, a humanised form of Immutep's IMP701 antibody which is out-licensed to Novartis.

**Financial Summary – Q2 FY21**

Cash receipts from customers for the quarter was $336k, compared to $23k in Q1 (i.e. the quarter ended 30 September 2020). Cash receipts from government grants and tax incentives for the quarter was $34k, compared to $126k in Q1.

The net cash used in G&A activities in the quarter was $1.82 million compared to $0.35 million in Q1. The significant increase compared with last quarter is mainly due to the prepayment of certain annual expenses. G&A costs for the quarter includes $248k in payment of Non-Executive Director's fees and Executive Director's remuneration.

Total net cash outflows used in operating activities in the quarter was $5.58 million. In comparison, total net cash outflows from the operating activities in Q1 was $3.34 million.

The net cash used in Research and Development activities in the quarter was $3.18 million, compared to $2.10 million in Q1. Year to date cash flow used in R&D activities for the 6 months from July to December 2020 was $5.3 million compared to $11.4 million for the 6 months from July to December 2019; the decline is mainly due to the declining AIPAC expenses since almost all patients in the AIPAC Phase IIb clinical trial have completed the treatment and moved into the follow-up phase.

In November 2020, the Company successfully raised $29.57 million via a placement which was supported by high-quality institutional investors in Australia and offshore.

In December 2020, the Company received $10.66 million from the exercise of warrants over American Depository Shares.

The cash and cash equivalent balance as at 31 December 2020 was $54.9 million compared to a balance of $22.7 million as at 30 September 2020.

Immutep is in an excellent financial condition with a cash runway beyond end of calendar year 2022 and beyond several significant data read-outs. Its cash position is currently at its strongest since it started the LAG-3 developments.

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 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** | **Quarter ended ("current quarter")** |
| 90 009 237 889 | 31 December 2020 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (6 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | 336 | 359 |
| 1.2 | Payments for | | |
| | (a) research and development | (3,178) | (5,272) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | (106) | (228) |
| | (d) leased assets | - | - |
| | (e) staff costs | (900) | (1,836) |
| | (f) administration and corporate costs | (1,817) | (2,167) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 28 | 51 |
| 1.5 | Interest and other costs of finance paid | (2) | (8) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 34 | 160 |
| 1.8 | Other (provide details if material) | 26 | 26 |
| **1.9** | **Net cash from / (used in) operating activities** | **(5,579)** | **(8,915)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | (5) | (5) |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | (7) | (7) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 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** | **(12)** | **(12)** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | 29,572 | 29,572 |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of options | 10,661 | 10,661 |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | (1,481) | (1,481) |
| 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) | (33) | (129) |
| **3.10** | **Net cash from / (used in) financing activities** | **38,719** | **38,623** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 22,711 | 26,322 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (5,579) | (8,915) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (12) | (12) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 months) $A'000 |
|---|---|---|---|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | 38,719 | 38,623 |
| 4.5 | Effect of movement in exchange rates on cash held | (959) | (1,138) |
| **4.6** | **Cash and cash equivalents at end of period** | **54,880** | **54,880** |

| 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 | 8,243 | 5,647 |
| 5.2 | Call deposits | 24,448 | 1,417 |
| 5.3 | Bank overdrafts | - | - |
| 5.4 | Other (term deposit) | 22,189 | 15,647 |
| **5.5** | **Cash and cash equivalents at end of quarter (should equal item 4.6 above)** | **54,880** | **22,711** |

| 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 | 248 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | - |

*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 Directors' fees and Executive Directors' remuneration.

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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) | (5,579) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 54,880 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 54,880 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 9.84 |

*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.*

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:

*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.*

## 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 January 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.