

Media Release

## Immutep Quarterly Activities Report

- Final Overall Survival data from AIPAC Phase IIb trial reported at the SITC 2021 conference, supporting Immutep's planned Phase III clinical development of efti in combination with paclitaxel in metastatic breast cancer
- Encouraging antitumor activity also reported from TACTI-002 trial of efti in 2<sup>nd</sup> line head and neck squamous cell carcinoma (HNSCC) at SITC 2021
- TACTI-003 Phase IIb study patient recruitment and country/site initiation ongoing
- IMP761 GMP manufacturing advanced

**SYDNEY, AUSTRALIA – 25 January 2022** – [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 31 December 2021.

### Efti Development Program for Cancer

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

Immutep reported final Overall Survival (OS) data from its Phase IIb AIPAC clinical trial evaluating efti in metastatic breast cancer (MBC) in November 2021, as a *late breaker* poster at the Society for Immunotherapy of Cancer (SITC) Annual Meeting.

The late-stage trial showed very encouraging OS data, including a statistically significant and clinically meaningful benefit in three patient predefined subgroups representing a majority of patients. A survival benefit of +7.5 months was observed in patients < 65 years, reflecting a > 50% improvement compared to the control group. A +19.6 month survival benefit was seen in patients with low monocytes, a benefit of > 150% compared to the control group. Lastly, a survival benefit of +4.2 months was reported in luminal B patients, reflecting a > 33% benefit compared to the control group. The data from these subgroups was improved data versus the interim data presented by Immutep in December 2020.

In addition, a statistically significant Quality of Life preservation was demonstrated in the first 6 months from patients in the efti group in the total population. A statistically significant increase in peripheral CD8 T cells in patients in the efti group of the total population was also observed and positively correlated with improved OS.

These final results have given Immutep additional confidence efti can deliver a meaningful clinical improvement for diverse sets of cancer patients, as the Company started its preparations for a larger clinical trial in MBC via its Phase III clinical trial, AIPAC-003.

#### **AIPAC-003 - planned Phase III trial**

In October 2021, Immutep received positive feedback from the European Medicines Agency (EMA) regarding its clinical development program for efti. Immutep has also been interacting with the US FDA and is providing additional information relating to efti's unique mechanism of action as an agonist that leads to T cell expansion and proliferation (rather than all other LAG-3 products in development which are antagonists that block an immune checkpoint). Interactions with the EMA, US FDA and other regulators are ongoing. The feedback from competent authorities, along with insights from a rigorous

engagement process with Key Opinion Leaders and other stakeholders will help Immutep generate a final study design.

#### **TACTI-003 - Phase IIb clinical trial**

During the quarter, Immutep continued recruitment of patients for the TACTI-003 clinical trial. At present, 6 of approximately 154 patients with 1<sup>st</sup> line HNSCC have been enrolled into the trial at active clinical sites. The study is in its start-up phase and additional sites are planned to be initiated in the first quarter of 2022.

Immutep also presented the trial design for TACTI-003 via a poster at the SITC 2021 conference in November 2021. It is a Phase IIb multicentre, open label, randomised and controlled trial. Fast track designation for 1<sup>st</sup> line HNSCC by the US FDA was granted in April 2021.

#### **TACTI-002 (also designated KEYNOTE-PN798) - Phase II clinical trial**

Immutep also reported data from the 2<sup>nd</sup> line HNSCC patients (Part C) of TACTI-002 at the SITC 2021 conference.

Part C is showing encouraging antitumor activity. An encouraging Overall Response Rate (ORR) was reported, with 29.7% of patients responding to the combination therapy of efti and pembrolizumab. In addition, a favourable duration and depth of responses was observed, with 5 Complete Responses and a minimum duration of response extended to > 9 months across all responding patients. The responses continue to be reported in PD-L1 low and high expressors.

During the quarter, Immutep enrolled and dosed the last patient in the expansion stage of Part A (1<sup>st</sup> line non-small cell lung cancer (NSCLC)), completing the recruitment of all cohorts of the TACTI-002 study.

A total of 189 patients are now participating in TACTI-002 across Parts A, B, and C at approximately 20 clinical sites in Australia, Europe, and the US. Additional data from TACTI-002, particularly in NSCLC, are planned to be reported in the first half of calendar year 2022. Data from the 114 patients in Part A (1<sup>st</sup> line NSCLC) is expected to inform potential late-stage development of efti in this important indication.

#### **INSIGHT**

INSIGHT is an investigator-initiated Phase I trial at the Institute of Clinical Cancer Research, Krankenhaus Nordwest (IKF) investigating different combination treatments with efti and a different route of administration for efti. INSIGHT consists of 5 different arms from stratum A to E.

##### *INSIGHT-003 – triple combination*

In December 2021, the first five patients were enrolled and safely treated in the INSIGHT-003 study, also referred to as stratum C of INSIGHT. No additional safety signals were observed in the study which is the first time a triple combination therapy consisting of efti and an existing approved standard of care combination of chemotherapy (carboplatin) and an anti-PD-1 therapy has been administered.

Patient recruitment is ongoing with 6 out of a total of 20 patients with various solid tumours now participating in the trial. Interim results are expected to be reported in 2022.

##### *INSIGHT-005 – combination with bintrafusp alpha*

INSIGHT-005, known as stratum E of INSIGHT, will include 12 patients with solid tumours and will evaluate efti in combination with bintrafusp alfa. In the light of the suboptimal results from Merck KGaA's bintrafusp alpha in other studies, this arm of the INSIGHT study is currently under review.

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

The investigator-initiated EAT COVID study is continuing at the University Hospital Pilsen in the Czech Republic. Immutep will provide an update on the trial in due course.

### **IMP761 Development Program for Autoimmune Disease**

During the quarter, Immutep appointed Northway Biotech, an end-to-end biopharmaceutical contract development and manufacturing organisation (CDMO), to manufacture IMP761 ahead of clinical testing.

Northway has commenced development of a GMP-compliant manufacturing process of IMP761 and will manufacture IMP761 in large scale bioreactors. After Immutep completes the required preclinical development evaluations, the material will be used for clinical trials of IMP761. Planning for preclinical and clinical development is ongoing.

### **Intellectual Property**

Immutep was granted two new patents by the Chinese Patent Office, protecting Immutep's intellectual property relating to combined therapeutic preparations comprising efti and either a PD-1 pathway inhibitor or a chemotherapy agent. These new patents follow the grant of corresponding patents in other key global markets announced previously.

### **Financial Summary – Q2 FY22<sup>1</sup>**

Cash receipts from customers for the quarter were \$14k, compared to \$56k in Q1 FY22 (i.e., the quarter ended 30 September 2021).

The net cash used in G&A activities in the quarter was \$0.2 million compared to \$1.0 million in Q1 FY22. The difference compared with the last quarter is mainly due to capital raising expenses included in Q1 FY22. Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter includes \$217k 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 \$4.67 million, compared to \$6.83 million in Q1 FY22. The higher cash outflows in Q1 FY2022 is mainly due to an upfront payment associated with the commencement of the TACTI-003 clinical trial. Total net cash outflows used in operating activities in the quarter was \$6.06 million. In comparison, total net cash outflows from operating activities in Q1 FY22 was \$5.37 million, which was net of the \$3.42m research and development (R&D) tax incentive payment received in cash in Q1 FY22 from the French Government under its Crédit d'Impôt Recherche scheme (CIR).

The Company's cash and cash equivalent balance as at 31 December 2021 was \$99.66 million compared to a balance of \$106.39 million as at 30 September 2021. Immutep's cash balance puts the company in a strong financial position with an estimated cash reach of December 2023.

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<sup>1</sup> All cash amounts shown are in Australian currency, unless noted differently.

### **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 maximise value to shareholders.

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.

Immutep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Further information can be found on the Company's website [www.immutep.com](http://www.immutep.com) or by contacting:

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