

## Media Release

### Immutep Quarterly Activities Report

- New interim TACTI-002 data from 2<sup>nd</sup> line metastatic non-small cell lung carcinoma (NSCLC) patients shows encouraging early overall survival rate of 73.7% at the six-month landmark
- Constructive feedback from the US FDA regarding the clinical development program for efti in metastatic breast cancer (MBC)
- New interim data for 1<sup>st</sup> line NSCLC patients from TACTI-002 to be reported in a prestigious Oral Presentation at ASCO in June 2022
- Phase IIb TACTI-003 patient recruitment advancing
- Strong cash and cash equivalent balance as at 31 March 2022: \$87.2 million
- Distinguished Australian businesswoman, Lucy Turnbull AO, re-joins Board as Non-executive Director (NED), following the passing of NED Grant Chamberlain

**SYDNEY, AUSTRALIA – 29 April 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 March 2022 (Q3 FY22).

#### **Efti Development Program for Cancer**

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

Immutep will report new biomarker and multivariate analysis data from the Phase IIb AIPAC trial in a poster presentation at ESMO's Breast Cancer Congress in May 2022. The trial evaluated efti in combination with paclitaxel chemotherapy in 227 patients with HER2-negative/HR positive metastatic breast cancer (HR+ MBC). Final Overall Survival results were reported in November 2021 showing a statistically significant survival benefit in multiple patient subgroups.

##### ***AIPAC-003 - planned registrational trial***

In March 2022, Immutep received constructive feedback from the US Food and Drug Administration (FDA) regarding its clinical development program for efti in MBC. The FDA has supported Immutep's view to continue exploring efti in MBC in a new registrational trial, based on previously reported clinical data, including the final Overall Survival data from the Phase IIb AIPAC trial. The planned new registrational trial, AIPAC-003, will be based on Immutep's completed Phase IIb AIPAC trial, but with an optimised design and for patients who are likely to benefit most from the treatment.

The FDA advice follows feedback from the European Medicines Agency (EMA) regarding the efti program received in Q2 of FY22. Additional regulatory interactions are ongoing, including with the FDA and EMA.

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

Recruitment of 1<sup>st</sup> line head and neck squamous cell carcinoma (HNSCC) patients into the TACTI-003 trial continued in Q3 FY22. 21 patients out of approximately 154 have been enrolled into the trial. To date, 21 sites have been activated out of 30 sites. TACTI-003 is a Phase IIb multicentre, open label, randomised and controlled trial. It was granted fast track designation for 1<sup>st</sup> line HNSCC by the US FDA in 2021.

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

ImmuteP reported new interim data from patients with 2<sup>nd</sup> line metastatic NSCLC from the Phase II TACTI-002 trial in a poster presentation at ESMO's European Lung Cancer Congress (ELCC) in March 2022. Efti, in combination with pembrolizumab, is showing an encouraging early overall survival rate of 73.7% at the six-month landmark, along with promising interim disease control and tumour growth kinetics. These early signs are supportive that efti may boost the body's immune system to enable pembrolizumab to work more effectively in NSCLC patients that have progressive disease after 1<sup>st</sup> line treatment with anti-PD-1 or anti-PD-1 plus chemotherapy.

As announced yesterday, new interim data for 1<sup>st</sup> line NSCLC patients from TACTI-002 has been selected for a prestigious Oral Presentation at the American Society of Clinical Oncology's (ASCO) 2022 Annual Meeting.

In addition, the Phase IIb TACTI-003 trial design will be presented in a Trial-in-Progress Poster Presentation. ASCO's 2022 Annual Meeting will take place in-person and online from 3-7 June 2022 in Chicago, United States.

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

Patient recruitment is ongoing for INSIGHT-003 which is an investigator-initiated Phase I trial taking place at the Institute of Clinical Cancer Research, Krankenhaus Nordwest (IKF), Germany. Already 10 out of a total of 20 patients with various solid tumours are now participating in the trial. The study is evaluating a triple combination therapy consisting of efti and an existing approved standard of care combination of chemotherapy (carboplatin) and an anti-PD-1 therapy. Interim results from the study are expected to be reported in 2022.

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

ImmuteP is continuing the required preclinical development evaluations of IMP761 prior to entering clinical trials. In addition, the Company's contract development and manufacturing organisation partner, Northway Biotech is progressing development of a GMP-compliant manufacturing process of IMP761 to prepare the materials needed for the clinical trials.

### **Intellectual Property**

In February 2022, ImmuteP was granted a new Australian patent protecting its intellectual property for therapeutic preparations comprising efti and an anti-PD-1 or anti-PD-L1 antibody, such as pembrolizumab, nivolumab, avelumab, durvalumab or atezolizumab.

The Company and its out-licensing partner for IMP701, Novartis, were granted a new patent by the Japanese Patent Office for LAG525 (IMP701) for the treatment of cancer. The new patent protects pharmaceutical compositions comprising LAG525 in a specific dose and for use in a defined treatment regimen. The

compositions may also be administered in combination with a second agent such as an anti-PD-1 antibody, an anti-PD-L1 antibody or a chemotherapeutic agent. LAG525 (INN: ieramilimab) is a humanised form of Immutep's IMP701 antibody.

During the quarter, Immutep was also granted a new patent for its preclinical autoimmune candidate, IMP761, by the Russian Federal Service for Intellectual Property, known as Rospatent. The patent protects IMP761 and related methods of use in inflammatory and autoimmune disease for the territory of the Russian Federation.

## **Corporate Update**

### ***Board Changes***

Immutep was deeply saddened by the sudden and unexpected passing of Non-Executive Director Grant Chamberlain in January 2022. Mr Chamberlain was a well-respected and much liked member of the Immutep team. The Board and staff of Immutep extend their sincere condolences to his family and friends.

The Company welcomed distinguished Australian businesswoman, philanthropist and former local government politician, Lucy Turnbull AO as a Non-executive Director of Immutep in February 2022. Ms Turnbull re-joined Immutep's Board having previously served as its Chairman from October 2010 to November 2017, stepping down from the role due to professional and personal commitments at the time.

### ***Financial Summary***

Cash receipts from customers for the quarter were \$8k, compared to \$14k in Q2 FY22 (i.e., the quarter ended 31 December 2021).

The net cash used in G&A activities in the quarter was \$1.6 million compared to \$0.2 million in Q2 FY22. The difference compared with the last quarter is mainly due to the prepayment of certain annual expenses. Payments to Related Parties for the quarter includes \$127k 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 \$8.13 million, compared to \$4.67 million in Q2 FY22. The higher cash outflows in Q3 FY22 were mainly due to increased efti and IMP761 contract manufacturing activities. Total net cash outflows used in operating activities in the quarter were \$10.95 million. In comparison, total net cash outflows from operating activities in Q2 FY22 were \$6.06 million.

The Company's cash and cash equivalent balance as at 31 March 2022 was \$87.20 million compared to a balance of \$99.66 million as at 31 December 2021. Immutep's higher than planned cash balance puts the company in a strong financial position with an expected cash reach based on current estimates of early 2024.

### **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](http://www.immutep.com) or by contacting:

#### **Australian Investors/Media:**

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

#### **U.S. Media:**

Tim McCarthy, LifeSci Advisors  
+1 (212) 915.2564; [tim@lifesciadvisors.com](mailto:tim@lifesciadvisors.com)