Immutep Quarterly Activities Report

- Phase II TACTI-002 trial met its primary objective in 1st line non-small cell lung cancer (NSCLC) patients, with 38.6% Overall Response Rate and favourable anti-tumour activity
- Biomarker and multivariate analysis data from the completed Phase IIb AIPAC trial reported, confirming efti is activating the immune system and helping patients live longer
- Four world leading oncologists join the Clinical Advisory Board
- Well-funded with ~$80 million in cash, giving Immutep an expected cash runway into early CY2024

SYDNEY, AUSTRALIA – 28 July 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 30 June 2022 (Q4 FY22).

Efti Development Program for Cancer

AIPAC - clinical trials

New biomarker and multivariate analysis data from the Phase IIb AIPAC trial was reported at ESMO's Breast Cancer Congress in May 2022. The AIPAC trial evaluated efti in combination with paclitaxel chemotherapy in 227 patients with HER2-negative/HR positive metastatic breast cancer (HR+ MBC). While the final Overall Survival results from this trial were reported in November 2021, the biomarker analysis reported highly valuable additional insights.

The analysis showed a statistically significant increase in innate and adaptive immune response biomarkers (monocyte and CD8+ T cell counts and serum CXCL10 levels) and absolute lymphocyte count (ALC) was observed in the efti group, but not in the placebo group. These improved immune parameters correlated with improved overall survival of the patients, confirming efti is activating the immune system and helping patients live longer.

In addition, an observed early rise in ALC in patients treated with efti may provide clinicians with a potential predictor of improved survival, helping them to determine early on if continued treatment with efti is beneficial. The exploratory analysis also identified six patient subgroups that showed improvements in Overall Survival (OS). These subgroups are therefore relevant for patient population selection for future late-stage studies in breast cancer.

Regulatory interactions are ongoing for the further clinical development program for efti in MBC, including with the US Food and Drug Administration (FDA) and European Medicines Agency (EMA). This follows feedback from the EMA regarding the efti program received in October 2021 and the FDA in March 2022.

In light of the exciting 1st line NSCLC data from TACTI-002 (discussed below) Immutep is reviewing clinical plans for MBC and NSCLC in order to potentially prioritize one indication.

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

New data from 1st line NSCLC patients (Part A) from TACTI-002 was reported in a prestigious Oral Presentation at the American Society of Clinical Oncology's (ASCO) 2022 Annual Meeting in June 2022. The data showed TACTI-002 met its primary objective for 1st line NSCLC patients in this PD-L1 all-comer trial.

Immutep reported an Overall Response Rate of 38.6% to the combination of efti plus pembrolizumab and favourable anti-tumour activity. Encouraging responses were demonstrated in all PD-L1 status groups, including patients who were PD-L1 negative or PD-L1 low, both groups were less likely to respond to anti-PD-1 monotherapy. Immutep also reported improving secondary endpoints, Disease Control Rate (DCR) and interim median Progression Free Survival (PFS), across all PD-L1 expression levels. Efti continues to be safe and well tolerated, with a safety profile consistent with previously reported studies for pembrolizumab monotherapy. The results are supportive of continued late-stage clinical development of efti in 1st line NSCLC.

New interim data from 2nd line NSCLC patients (Part B) has been selected for a poster presentation at the IASLC 2022 World Conference on Lung Cancer (WCLC 2022) taking place in August 2022 in Vienna, Austria. WCLC is the world's largest international gathering of clinicians, researchers and scientists in the field of lung cancer and thoracic oncology.

TACTI-003 - Phase IIb clinical trial

Recruitment is ongoing for 1st line head and neck squamous cell carcinoma (HNSCC) patients for Immutep's TACTI-003 trial, with 39 patients out of approximately 154 enrolled to date across the now 24 active trial sites.

TACTI-003 is a Phase IIb multicentre, open label, randomised and controlled trial. It was granted fast track designation for 1st line HNSCC by the US FDA in 2021. Immutep presented the trial design for TACTI-003 at the American Society of Clinical Oncology's (ASCO) 2022 Annual Meeting held in June. Recruitment and trial updates are expected to be reported throughout the remainder of 2022 and into 2023.

INSIGHT-003 - triple combination

Patient recruitment is ongoing for the INSIGHT-003 investigator-initiated trial, with 13 out of a total of 20 patients already enrolled. INSIGHT-003 focuses on a patient population with NSCLC adenocarcinomas and evaluates a triple combination therapy consisting of efti and an existing approved standard of care combination of chemotherapy (carboplatin, pemetrexed) and an anti-PD-1 therapy. Interim results from the study are expected to be reported in Q4 2022. The trial is being conducted by the Institute of Clinical Cancer Research (IKF) at Northwest Hospital, Frankfurt, Germany.

Potential new trials for efti in cancer

Due to the positive data from efti presented at ASCO 2022 and other conferences, Immutep has been approached for potential new investigator-initiated trials as well as other potential collaborations for efti in various indications and combinations; we are currently assessing these opportunities. It is very encouraging to see the increased level of industry interest and willingness to support and fund further trials for efti in cancer because of the growing body of positive data generated from efti clinical trials thus far.

At this stage, discussions with various parties are incomplete and still subject to negotiation. Once an agreement is reached, the Company will provide further details in a market announcement.

IMP761 Development Program for Autoimmune Disease

Preclinical development steps are continuing for IMP761, prior to advancing the candidate into clinical trials. This includes development of a GMP-compliant manufacturing process for IMP761. The GMP manufacturing at 200 litre scale is ongoing. IMP761 is Immutep's immunosuppressive agonist antibody to LAG-3 which will be tested to treat the causes of autoimmune disease, such as inflammatory bowel disease, rheumatoid arthritis, and multiple sclerosis, rather than merely treating the symptoms.

Partnering Updates

CYTLIMIC

Immutep signed clinical collaboration, service and supply agreements with the Japanese biotech, CYTLIMIC (an affiliate of NEC) in 2019 to support its development of a therapeutic cancer vaccine. CYTLIMIC has been conducting studies of CYT001, its lead cancer vaccine which comprises peptides designed using artificial intelligence from the HSP70 and GPC-3 proteins, plus two adjuvants, efti and Hiltonol. Based on a comprehensive business evaluation, CYTLIMIC has determined to dissolve the company and to transfer its own patents and licensing rights to NEC accordingly. Investigations into CYT001 will not be continuing whilst NEC assesses the future of this cancer vaccine program.

EAT COVID

Conducted and funded by the University Hospital Pilsen, Czech Republic, the Phase II EAT COVID study was evaluating the Company's lead product candidate efti in hospitalised patients with COVID-19. The study aimed to boost a patient's immune response to prevent development of severe COVID-19 symptoms that require intensive care and can lead to respiratory failure and death. While independently reviewed safety run-in data prompted the Company to initiate enrolment for the randomised portion of the study in January 2021, recruitment into the trial has been slow. Accordingly, Immutep has decided to discontinue the supply of efti for this trial and to terminate the collaboration with the University Hospital Pilsen. Immutep only incurred minimal costs for this investigator-initiated trial.

Intellectual Property

During the quarter, Immutep and its partner Novartis AG were granted a new patent for ieramilimab (Novartis code: LAG525), a humanised LAG-3 antagonist antibody derived from Immutep's IMP701 antibody, by the Eurasian Patent Office. The patent protects ieramilimab in the member states of the Eurasian Patent Convention, namely Armenia, Azerbaijan, Belarus, Kirgizstan, Kazakhstan, Moldova, Russia, Tajikistan and Turkmenistan. The expiry date of the new patent is 13 March 2035.

Corporate Update

Clinical Advisory Board

Immutep was delighted to welcome four world leading oncologists to its Clinical Advisory Board (CAB) during the quarter:

- Scott Antonia, M.D., Ph.D. of the Duke Cancer Institute Center for Cancer Immunotherapy
- Leisha A Emens, M.D., Ph.D. Professor of Medicine at the UPMC Hillman Cancer Center
- Martin Forster, M.D., Ph.D., Associate Professor at University College London (UCL)
- Hans Wildiers, M.D., Ph.D. of the University Hospital Leuven, Belgium

The CAB serves as a strategic resource for advancing Immutep's pipeline of LAG-3 programs, including efti, especially in NSCLC and MBC.

Financial Summary

Overall, the financial performance for the quarter ended 30 June 2022 (i.e. Q4 FY22) was very pleasing. Cash receipts from customers Q4 increased to $96k, compared to $8k in the previous quarter (i.e. Q3 FY22).

The net cash used in G&A activities in the quarter was $361k compared to $1.6 million in Q3 FY22. The decrease compared with the last quarter is mainly due to the inclusion of certain annual expense prepayments in the previous quarter.

Payments to Related Parties for the quarter includes $189k 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 $7.62 million, compared to $8.13 million in Q3 FY22. The lower cash outflows in Q4 FY22 were mainly due to the decrease of efti and IMP761 contract manufacturing payments. The cash outflow for clinical trial activities increased compared with Q3 FY 22 and were in line with increased activity in TACTI-003. Total net cash outflows used in operating activities in the quarter was $9.28 million compared to $10.95 million in Q3 FY22.

The Company's cash and cash equivalent balance as at 30 June 2022 was approximately $80 million compared to a balance of $87 million as at 31 March 2022. Immutep's higher than planned cash balance continues to put the Company in a strong financial position with an expected cash reach based on current estimates of early calendar 2024. The company will continue to manage its strong cash balance carefully as it reviews its overall clinical strategy, particularly in light of the various potential opportunities for the development of efti in cancer.

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. 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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