

Immutep quarterly activities report and Appendix 4C Q3 FY23

- **Initiation of integrated Phase II/III AIPAC-003 trial evaluating eftilagimod alpha (efti) and paclitaxel in HER2-neg/low metastatic breast cancer and triple-negative breast cancer**
- **Positive final data reported from patients with second-line non-small cell lung cancer refractory to anti-PD-(L)1 therapies, including overall survival rate of 39 percent at 21 months**
- **Randomised TACTI-003 Phase IIb trial has reached 75 percent enrolment subsequent to quarter end and top line results anticipated in H2 of CY2023**
- **Expansion of INSIGHT-003 evaluating triple combination of efti, pembrolizumab and chemotherapy post encouraging initial safety and efficacy in first-line non-small cell lung cancer**
- **Solid cash position of AUD 55.2 million, with cash runway to the end of FY2024 (June 2024)**
- **Since period end Lis Boyce appointed as Non-Executive Director and Florian D. Vogl, M.D., Ph.D., appointed Chief Medical Officer**

Sydney, Australia, April 27, 2023 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel LAG-3 related immunotherapy treatments for cancer and autoimmune diseases, provides an update on the ongoing development of its product candidates, eftilagimod alpha (efti) and IMP761 for the quarter ended 31st March 2023 (Q3 FY23).

Efti development program for cancer

Immutep made strong progress during the quarter to advance its clinical development strategy to position the company, or a potential partner, to fully exploit efti's broad potential.

AIPAC-003 - Phase II/III trial in metastatic breast cancer (MBC)

In March, Immutep initiated AIPAC-003 (**Active Immunotherapy PAClitaxel**), its integrated Phase II/III trial evaluating efti in combination with paclitaxel for the treatment of HER2-neg/low metastatic breast cancer and triple-negative breast cancer. These two indications account for approx 78 percent of breast cancer cases. The trial commenced following the regulatory approval in the United States and Institutional review Board (IRB) approval in Spain. Immutep anticipates enrolling the first patient in Q2 CY2023.

As a first-in-class soluble LAG-3 protein targeting MHC Class II ligands on antigen-presenting cells (APC), efti is well positioned to improve clinical outcomes from standard-of-care chemotherapy due to its unique mechanism of action. Its activation of APC triggers a broad immune response that includes significant increases in cytotoxic CD8+ T cells armed with chemo-induced tumour antigens to target cancer.

The AIPAC-003 trial employs an integrated clinical design agreed to with the FDA to help inform a potential Biologics License Application (a request for permission to sell a biologic product) and a potential Marketing Authorisation Application with the European Medicines Agency (EMA). This trial design also allows for a risk-balanced approach with the Phase III portion dependent on the Phase II results, among other items.

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

Positive final data on safety and efficacy was reported from Part B of the TACTI-002 trial in patients with second-line non-small cell lung cancer (NSCLC) refractory to anti-PD-(L)1 therapies in a Mini Oral presentation at ESMO's European Lung Cancer Congress (ELCC) 2023. These patients have few therapeutic options, and the addition of efti to pembrolizumab may help these patients by reverting the confirmed anti-PD-(L)1 therapy resistance.

The Company reported encouraging clinical results, including an Overall Survival (OS) rate of 39 percent at 21 months. In addition, 83 percent of patients studied for Tumour Growth Kinetics showed deceleration (50 percent) in tumour growth or shrinkage (33 percent) of target lesions. Responses were confirmed and durable with responders participating in the study for more than 19 months.

The ORR, PFS, and OS were more pronounced in patients with high PD-L1 expression (N=6) or who were secondary resistant (N=25). For patients with greater than or equal to 50 percent PD-L1 TPS expression, median OS was not yet reached, overall response rate (ORR) was 33.3 percent, and 6-month progression-free survival (PFS) was 50 percent. Efti plus pembrolizumab was well tolerated without any new safety signals, and there was no treatment discontinuation due to adverse reactions.

TACTI-003 – Phase IIb clinical trial in first-line HNSCC

In early 2023 Immutep announced it has successfully enrolled over 50 percent of the planned 154 patients into the randomised Phase IIb TACTI-003 trial. Subsequent to quarter end TACTI-003 has reached 75 percent enrolment, and Immutep expects to complete enrolment by mid-year positioning the Company to report top-line results in H2 of CY2023.

Planned Late-Stage trial in first-line NSCLC

Immutep is continuing its preparations for a late-stage trial evaluating efti in first-line NSCLC in combination with anti-PD-1 therapy. The NSCLC program will be shaped by the maturing data from the Company's ongoing TACTI-002 and INSIGHT-003 trials. Current activity is focused on trial design and engagement with regulatory authorities and other stakeholders. The Company obtained US FDA Fast Track designation late last year for this indication.

INSIGHT-003 – Phase I in first-line NSCLC

In February, the investigator-initiated INSIGHT-003 trial reached its enrolment target of 20 patients with first-line NSCLC for this first triple combination therapy study of efti with standard-of-care combination of anti-PD-1 therapy and chemotherapy. INSIGHT-003 has been now extended to include a total of 50 patients. The expansion of INSIGHT-003 will further inform planning for registrational studies.

IMP761 development program for autoimmune diseases

During the first quarter, our preclinical development continued for IMP761, including preparations to begin the toxicology study. As the first immunosuppressive agonist antibody to LAG-3 acting upstream on activated T cells to target the root cause of self-antigen-specific T cell-induced disease, IMP761 is a potential game-changer in how autoimmune diseases are treated. The Company currently anticipates that clinical development will begin in the first half of CY2024.

Intellectual property

During the quarter, Immutep was granted three new patents directed to efti. The first is a United States patent drawn to methods of treating cancer with a combination of efti and chemotherapy, where the efti is administered in a dose of more than 6 mg. This is the third United States patent granted from this family.

The second patent is an Indian patent that protects Immutep's intellectual property relating to combined preparations of efti with a PD-1/PD-L1 therapy for the treatment of cancer or infection. The third patent is an Australian patent which relates to a potency assay for release testing of efti. The assay is used in Immutep's commercial-scale (2,000L) manufacturing process. This new Australian patent follows the grant of a similar patent in South Korea in 2022.

Board and management changes

On 11 April, Lis Boyce was appointed as Non-Executive Director replacing Lucy Turnbull, who re-joined the board after the sudden and untimely death of Grant Chamberlain in January 2022. The Board is grateful to Lucy for stepping in under such tragic circumstances and for her boundless energy and valued insights.

Ms Boyce is a highly experienced corporate lawyer and currently a partner at Piper Alderman. She has extensive experience in the Life Sciences and Healthcare sectors as well as in capital raisings, strategic collaborations, commercial contracts and mergers and acquisitions. Lis is currently deputy chair of AusBiotech's AusMedtech Advisory Group and a member of AusBiotech's State Committee for NSW.

On 26 April, Immutep announced that it expanded its leadership team with the appointment of Florian D. Vogl, M.D., Ph.D., MSc., as Chief Medical Officer (CMO) with effect from 1 May 2023. Dr. Vogl has over a decade of experience in the biopharmaceutical industry with extensive clinical development expertise in the field of oncology. Most recently, he was CMO of Cellectia Biotech where he focused on delivering new treatments to patients with cancer and autoimmune disorders that had limited therapeutic options. Prior to Cellectia, Dr. Vogl held senior management roles in Europe and the United States, including Head of Clinical Development Europe at Rainier Therapeutics, Senior Global Medical Leader, Oncology Development at Novartis, and as Early Development Leader, Oncology Pipeline at Amgen.

Dr. Vogl assumes the CMO role from Frédéric Triebel, M.D., Ph.D., who previously acted as both Chief Scientific Officer (CSO) and CMO of Immutep. Dr. Triebel's foremost focus will be on his responsibilities as CSO and as a member of Immutep's Board.

Financial summary

Immutep continued to focus on prudent cash management during the past quarter (Q3 FY23). The Company remains well funded with a cash runway extending to the end of FY24.

Cash receipts from customers in the quarter increased to AUD 30k, compared to AUD 8k in Q2 FY23. The net cash used in G&A activities in the quarter was AUD 1.12million compared to AUD 734k in Q2 FY23. Payments to Related Parties, detailed in Item 6 of the Appendix 4C cash flow report for the quarter, includes AUD 257k in payments for Non-Executive Director's fees and Executive Director's remuneration.

The net cash used in R&D activities in the quarter was AUD 11.52 million, compared to AUD 5.87 million in Q2 FY23. The increase was mainly due to the increased clinical trial and manufacturing activities.

Total net cash outflows used in operating activities in the quarter were AUD 14.17 million compared to AUD 7.02 million in Q2 FY23.

Immutep's cash and cash equivalent balance at 31 March 2023 was approximately AUD 52.2 million, giving the Company an expected cash reach based on current estimates to June 2024. Immutep will continue to manage its solid cash balance carefully as it pursues its overall clinical development strategy.

More information about Appendix 4C - Quarterly Cash Flow Report you can find [here](#).

About Immutep

Immutep is a clinical-stage biotechnology company developing novel LAG-3 immunotherapy for cancer and autoimmune disease. We are pioneers in the understanding and advancement of therapeutics related to Lymphocyte Activation Gene-3 (LAG-3), and our diversified product portfolio harnesses its unique ability to stimulate or suppress the immune response. Immutep is dedicated to leveraging its expertise to bring innovative treatment options to market for patients in need and to maximise value for shareholders. For more information, please visit www.immutep.com