

ASX/Media Release

Immutep Announces Successful Meeting with the FDA on Eftilagimod Alpha plus Chemotherapy for the Treatment of Metastatic Breast Cancer

- Agreement with FDA on Phase II/III trial design positions the Company to exploit eftilagimod alpha's potential to address high unmet need for metastatic breast cancer patients
- Patient population expanded to include patients with triple-negative breast cancer
- Late-stage clinical development efforts remain focused on frontline non-small cell lung cancer (NSCLC) in combination with anti-PD-1 therapy
- Immutep's cash runway extended to the end of the 1st half of calendar year 2024

SYDNEY, AUSTRALIA – 23 December 2022 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, today announces the results of a positive follow-up Type C meeting with the US Food and Drug Administration (FDA) regarding late-stage clinical development plans for its first-in-class soluble LAG-3 protein, eftilagimod alpha ("efti"), in conjunction with standard-of-care chemotherapy for the treatment of metastatic breast cancer (MBC). The Company and the FDA have agreed to an integrated Phase II/III trial design that will help inform a Biologics License Application (BLA).

Based on the encouraging efficacy, favourable safety, and learnings from the randomised AIPAC Phase IIb trial, which administered efti and chemotherapy on different days and ceased chemotherapy at six months, patients will receive efti and paclitaxel on the same day and treatment will continue until disease progression. The patient population has also been expanded to include triple-negative breast cancer (TNBC), an aggressive form of breast cancer with limited treatment options.

Immutep CEO, Marc Voigt, commented: "As recently announced, our late-stage clinical development efforts for efti are now focused on frontline NSCLC in combination with anti-PD-1 therapy, given the large market opportunity and need for more durable and tolerable options. With this said, progress reported to date with the FDA and EMA provides Immutep and its potential partners flexibility for late-stage clinical development of efti plus standard-of-care chemotherapy to address the high unmet need for metastatic breast cancer patients, while maintaining their quality of life as was shown in the AIPAC trial."

Immutep CSO & CMO, Dr. Frédéric Triebel, stated: "We are excited about efti's promise to stimulate the immune system and improve standard-of-care chemotherapy by activating dendritic cells to present antigens from chemo-induced cancer cell death to cytotoxic T cells. Our engagement with regulatory agencies to establish the optimal design of a registrational trial has steadily progressed during the year and we are pleased with the FDA's positive feedback during this follow up meeting. The chosen trial design provides us with a very risk-balanced approach before potentially embarking on the Phase 3 part of this study."

Subject to regulatory and ethic committee feedback, the Phase II portion of the MBC trial is expected to begin during the first quarter of 2023. In addition to the biologically active 30mg dosing for efti, the Company and

FDA have agreed to test 90mg efti dosing in combination with paclitaxel driven predominantly by the excellent safety profile of the AIPAC Phase IIb trial, along with the FDA's Project Optimus initiative in oncology. The trial design has a safety lead in of 6 to 12 patients, given the higher 90mg dosing of efti, followed by 58 patients for the randomised Phase II portion of the trial. Depending on Phase II results and resources, the Phase III portion will follow and be directed to MBC patients most likely to benefit from treatment, taking into consideration the strong overall survival results in pre-specified and post-hoc subgroups from the AIPAC trial.

The Phase II portion of the MBC trial and the initiation of the registrational trial in 1st line NSCLC are included in the budget of the Company and have no impact on its expected cash runway to the end of the 1st half of calendar year 2024.

About Eftilagimod Alpha (Efti)

Efti is Immutep's proprietary soluble LAG-3 clinical stage candidate that is a first-in-class antigen presenting cell (APC) activator for the treatment of cancer, capitalising on LAG-3's unique characteristics to stimulate both innate and adaptive immunity. Efti binds to and activates antigen presenting cells via MHC II molecules leading to expansion and proliferation of CD8+ (cytotoxic) T cells, CD4+ (helper) T cells, dendritic cells, NK cells, and monocytes. It also upregulates the expression of key biological molecules like CXCL10 that further boost the immune system's ability to fight cancer.

Efti is under evaluation for a variety of solid tumours including non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), and HER2-/HR+ metastatic breast cancer. Its favourable safety profile enables various combinations, including with anti-PD-[L]1 immunotherapy and/or chemotherapy. Efti has received Fast Track Designation in 1st line HNSCC and in 1st line NSCLC from the United States Food and Drug Administration (FDA).

About Immutep

Immutep is a clinical stage biotechnology company leading the development of LAG-3 related immunotherapy products for the treatment of cancer and autoimmune disease. The Company 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 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 in multiple clinical trials. The Company is also developing an agonist of LAG-3 (IMP761) for autoimmune disease. Additional LAG-3 product candidates, including antibodies for immune response modulation, are being developed under license 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.