ASX/Media Release

Immutep's Efti in Combination with Pembrolizumab Achieves Excellent Initial Overall Survival Benefit in 1st Line Non-Small Cell Lung Cancer

- Immuno-oncology combination of eftilagimod alpha (efti) and the leading anti-PD-1 therapy generates meaningful long-term survival in non-small cell lung cancer patients in Phase II TACTI-002 trial
- Initial median Overall Survival of 25 months in non-small cell lung cancer patients with ≥1% PD-L1 expression, a key area of focus for future development of efti
- Result is above reported rates of anti-PD-1 monotherapy and various immune checkpoint inhibitor combinations with and without chemotherapy
- Based on compelling initial results, the Data Monitoring Committee recommends extending overall survival follow-up collection to show mature 3-year and potentially 5-year rates
- More mature Overall Survival data and additional efficacy and safety results to be presented at a major medical conference in H2 CY2023

SYDNEY, AUSTRALIA – 17 May 2023 – 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 that efti, a soluble LAG-3 protein and first-in-class MHC Class II agonist, in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) achieved robust initial Overall Survival (OS) in 1st line non-small cell lung cancer (1L NSCLC) patients in the Phase II TACTI-002 trial.

This immuno-oncology (IO) investigational combination, without the use of chemotherapy, led to excellent initial survival results in the overall intent-to-treat (ITT) 1L NSCLC patient population (N=114), regardless of PD-L1 expression status. Importantly, an initial median OS of 25 months has been attained in those 1L NSCLC patients (N=58) who have a PD-L1 Tumor Proportion Score (TPS) of ≥1%, a key area of focus for efti's future clinical development and for which Fast Track designation was granted in October 2022.

Notably, the median 25.0-month OS compares favourably to reported historical results for patients with the same PD-L1 TPS of ≥1% from registration trials of:

- anti-PD-1 monotherapy (16.4-month median OS); and
- combinations of anti-PD-1 with chemotherapy (15.8-to-23.3-month median OS) or with anti-CTLA-4 (17.1-month median OS).

Based on the exceptional survival data with a minimum follow-up of now 14 months, the Data Monitoring Committee recommends extending the OS follow-up collection to show mature 3-year and potentially 5-year survival rates of this novel IO-IO combination.

Collectively, the breadth of efficacy and safety data emerging from the large number of 1L NSCLC patients in the Phase II TACTI-002 trial offers compelling evidence of efti's substantial impact in safely stimulating the patients' immune response to fight cancer. These initial OS results are supported by a strong interim median Duration of Response of 21.6 months in the ITT population (N=114), including over one-third of patients with negative PD-L1 expression (N=32), and the high 48.3% response rate achieved with efti in combination with pembrolizumab in 1L NSCLC patients with a PD-L1 TPS of ≥1% (N=58), as reported in a late-breaking oral abstract presentation at the Society for Immunotherapy of Cancer (SITC) Meeting in 2022.

Dr Martin Forster of the UCL Cancer Institute and University College London Hospital NHS Foundation, London, UK, and TACTI-002 Investigator, said: "These initial overall survival results from the TACTI-002 trial are clinically meaningful and build upon the strength of the efficacy data emerging from this exciting novel investigational combination of efti with pembrolizumab. Importantly, the favourable safety profile of this immunotherapy regimen has continued, and to see these deep and durable responses without any additional toxicity from what would be expected from anti-PD-1 monotherapy is very encouraging."

"Efti's clinical results achieved to date in combination with pembrolizumab are increasingly robust and continue to justify the attention given to this novel IO-IO combination through invitations to make oral presentations at two prestigious conferences, ASCO and SITC, last year. We now are showing excellent initial overall survival, which is the gold standard benchmark within oncology, across the entire intent-to-treat population of 1st line NSCLC patients in our Phase II trial. For non-small cell lung cancer patients with ≥1% PD-L1 expression, a key focus for future development and for which efti in combination with pembrolizumab has Fast Track status, the survival benefit is impressive. We look forward to presenting more mature data at a major medical conference later this year," said Marc Voigt, Immutep's CEO.

"This new data adds to the body of evidence that efti's novel activation of antigen-presenting cells provides a powerful boost to the immune system, which furthers the potential of immune checkpoint inhibitors. Fundamentally, efti is leading to a significant systemic expansion of memory cytotoxic T cells that anti-PD-(L)1 therapies can act upon. Indeed, the combination of efti plus anti-PD-1 leads to a superior median OS of 25.0-months as compared to 17.1-months for the registered IO-IO combination of anti-PD-1 plus anti-CTLA-4, with much less toxicity. Perhaps most importantly, as the only MHC Class II agonist in clinical development today, efti is generating this profound immune response across a variety of solid tumour indications, even with low PD-L1 expression, in a unique and safe manner," noted Frédéric Triebel, M.D., Ph.D, Immutep's CSO.

Lung cancer is the second most common cancer. Non-small cell lung cancer accounts for approximately 80-85% of all lung cancers, impacting an estimated 1.87 million people annually, and is the highest cause of death among all cancers [1-3].

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About Eftilagimod Alpha (Efti)

Efti is Immutep's proprietary soluble LAG-3 protein and MHC Class II agonist that stimulates both innate and adaptive immunity for the treatment of cancer. As a first-in-class antigen presenting cell (APC) activator, efti binds to MHC (major histocompatibility complex) Class II molecules on APC leading to activation 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 IFN-γ and 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 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 the TACTI-002 Trial

TACTI-002 (Two ACTive Immunotherapies) is being conducted in collaboration with Merck & Co., Inc., Rahway, NJ, USA (known as "MSD" outside the United States and Canada). The study is evaluating the combination of eftilagimod alpha (efti) with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with second line head and neck squamous cell carcinoma or non-small cell lung cancer in first and second line. The trial is a Phase II, Simon's two-stage, non-comparative, open-label, single-arm, multicentre clinical study that is taking place in study centres across Australia, Europe, and the US.

Patients participate in one of the following:

- Part A - first line Non-Small Cell Lung Cancer (NSCLC), PD-X naïve
- Part B - second line NSCLC, PD-X refractory
- Part C – second line Head and Neck Squamous Cell Carcinoma (HNSCC), PD-X naïve

TACTI-002 is an all-comer study in terms of PD-L1 status, a well-known predictive marker for response to pembrolizumab monotherapy especially in NSCLC and HNSCC. More information about the trial can be found on Immutep's website or on ClinicalTrials.gov (Identifier: NCT03625323).

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 patients in need and to maximise value for shareholders. For more information, please visit www.immutep.com.

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This announcement was authorised for release by the Board of Immutep Limited.

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[1] The Global Cancer Observatory, Lung Cancer Fact Sheet
[2] American Cancer Society, About Lung Cancer
[3] CDC, Lung Cancer Statistics