First Patient Dosed in Immutep's TACTI-004 Phase III Trial in First Line Non-Small Cell Lung Cancer

- First patient safely dosed at Calvary Mater Newcastle Hospital in Australia, marking a significant milestone for Immutep
- Global Phase III with efti will enrol approximately 756 patients at more than 150 clinical sites
- Trial results will inform potential marketing approval application in non-small cell lung cancer, one of the largest indications in oncology

SYDNEY, AUSTRALIA – March 25, 2025 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces the first patient has been successfully dosed in the Company's pivotal TACTI-004 Phase III trial. TACTI-004 will evaluate Immutep's eftilagimod alfa, a first-in-class MHC Class II agonist, in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) and chemotherapy as first line treatment for patients with advanced or metastatic non-small cell lung cancer (1L NSCLC).

Dr. Ina Nordman, who treated the first patient at Calvary Mater Newcastle Hospital in Australia, stated, "We are very excited to participate in this important Phase III trial. Despite advancements in the treatment landscape for non-small cell lung cancer, there remains a high unmet need for new approaches that can safely extend patients' lives. The anti-cancer immune response driven by efti's unique mechanism of action as an MHC Class II agonist in combination with KEYTRUDA has led to strong efficacy across all PD-L1 levels with favourable safety in multiple lung cancer trials. We hope to see this study confirm the promise of this novel combination to provide patients with a powerful new treatment option."

Immutep CEO, Marc Voigt, said, "Dosing the first patient in our pivotal Phase III trial ranks among the most significant milestones in the Company's history. We are excited about the potential of the TACTI-004 study to deliver a new standard-of-care therapy for patients with metastatic or advanced non-small cell lung cancer that includes efti in combination with KEYTRUDA. If successful, the study will result in a clinically meaningful and statistically improved survival benefit and thus could potentially be practice changing."

Immutep CSO, Frédéric Triebel, M.D., Ph.D, commented, "As a result of all global regulatory interactions to date including previous discussion with US FDA under Project Optimus and tolerability issues at 90 mg[1], we are moving forward with 30 mg subcutaneous efti dosing used in previous studies. The ability of 30 mg efti in combination with KEYTRUDA to activate the immune system and fight non-small cell lung cancer regardless of PD-L1 expression has been demonstrated across multiple clinical trials.[2] Importantly, this novel approach has an excellent safety profile while delivering strong efficacy that compares favourably to standard-of-care therapies, including high rates of durable responses and compelling progression-free survival and overall survival."

Recruitment in TACTI-004 is underway at a growing number of activated clinical sites and countries with approvals from all regulatory authorities continues to expand including Australia, Austria, Belgium, Bulgaria, Canada, Germany, Greece, Hungary, India, Ireland, Italy, Latvia, Lithuania, Portugal, Spain, and the United Kingdom. Further regulatory clearances in three additional countries are expected shortly, with the remaining countries anticipated in the weeks and months ahead.

Lung cancer is the leading cause of death among all cancer types and the incidence is set to increase to approximately 3 million cases worldwide by 2030.[3] NSCLC is the most common type of lung cancer representing ~80-85% of all diagnoses.[4] The condition is often diagnosed at a late stage, and less than 30% of patients are alive five years after diagnosis.[5,6] There remains a high unmet need for additional treatment options for people living with NSCLC.

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

About TACTI-004

TACTI-004 (**T**wo **ACT**ive **I**mmunotherapies) is a randomised, double-blind, controlled Phase III study evaluating eftilagimod alfa (efti), a first-in-class MHC Class II agonist, in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) and chemotherapy as first line therapy for patients with advanced or metastatic non-small cell lung cancer with no EGFR, ALK or ROS1 genomic tumour aberrations. The global trial will enrol approximately 756 patients regardless of PD-L1 expression and with non-squamous or squamous tumours at over 150 clinical sites in over 25 countries. Patients will be randomised 1:1 to receive either efti in combination with pembrolizumab and chemotherapy in the treatment arm or pembrolizumab in combination with chemotherapy and placebo in the control arm. The study's dual primary endpoints are progression-free survival and overall survival.

About Immutep

Immutep is a late-stage biotechnology company developing novel immunotherapies for cancer and autoimmune disease. The Company is a pioneer in the understanding and advancement of therapeutics related to Lymphocyte Activation Gene-3 (LAG-3), and its diversified product portfolio harnesses LAG-3's 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.

1. Patients randomised 1:1 in AIPAC-003 Phase II to receive 30mg or 90mg dosing of eft in combination with paclitaxel to determine the optimal biological dose consistent with the FDA's Project Optimus initiative.

2. Immutep's Efti in Combination with KEYTRUDA® Generates Excellent Overall Survival Benefit in Patients with Metastatic Non-Small Cell Lung Cancer, October 2023, and Immutep's Efti Shows Excellent Survival Data from INSIGHT-003 Trial in Non-Small Cell Lung Cancer, November 2024

3. International Agency for Research on Cancer – World Health Organization. Rates of trachea, bronchus and lung cancer.

4. Zappa C & Mousa Non-small cell lung cancer: current treatment and future advances, Transl Lung Cancer Res. 2016 Jun; 5(3): 288–300.

5. Polanco D et al. Prognostic value of symptoms at lung cancer diagnosis: a three-year observational study. J Thorac Dis 2021;13:1485–1494.

6. National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) - https://seer.cancer.gov/statfacts/html/lungb.html

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