

Immutep Announces Update for TACTI-004 (KEYNOTE-F91) Phase III Trial in First Line Non-Small Cell Lung Cancer

- *Global Phase III trial has enrolled and randomised over 170 patients, reaching an important milestone as this is above the amount needed to conduct the futility analysis*
- *Over 100 clinical sites across 24 countries now activated and open for recruitment*
- *Futility analysis remains on track for completion in the first quarter of CY2026*

SYDNEY, AUSTRALIA – October 09, 2025 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces a patient enrolment update for the TACTI-004 (KEYNOTE-F91) Phase III trial evaluating eftilagimod alfa (efti) in combination with MSD’s (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) and chemotherapy as first line treatment for advanced or metastatic non-small cell lung cancer (1L NSCLC).

This registrational Phase III trial has enrolled and randomised over 170 patients, reaching an important milestone as this is above the amount necessary to conduct the futility analysis. Additionally, the number of activated clinical trial sites continues to expand at a strong pace and there are now over 100 active clinical sites across 24 countries globally.

The futility analysis will be assessed by an independent data monitoring committee (IDMC) based on the data of a predefined number of patients with sufficient follow-up (minimum 12 weeks) and predefined criteria for efficacy. The trial remains on track for the IDMC to conduct the futility analysis in the first quarter of CY2026.

Immutep Chief Executive Officer, Marc Voigt, said, “We are very pleased with the pace of enrolment in our pivotal Phase III trial that we believe has the potential to change the treatment landscape in non-small cell lung cancer, one of the largest indications in oncology with over two million diagnoses annually worldwide. The trial remains on track for key milestones ahead including futility analysis in early 2026.”

Immutep CMO, Stephan Winckels, M.D., Ph.D., added, “Our engagement with the principal investigators and physicians in the lung cancer community at medical conferences throughout the year, including WCLC 2025 last month, has consistently resulted in constructive feedback. Notably, their favourable assessments of the trial design and of efti as an innovative immunotherapy—capable of safely increasing response rates and improving efficacy in non-small cell lung cancer patients regardless of PD-L1 expression—provide a strong basis for ongoing positive enrolment trends.”

The TACTI-004 trial follows positive efficacy and safety results from two previous studies, TACTI-002 and INSIGHT-003, which tested efti with KEYTRUDA in 1L NSCLC. With in total over 165 patients enrolled, both trials demonstrate that efti enhances anti-PD-1 therapy regardless of PD-L1 expression levels. The novel combination of these two immunotherapies has led to high response rates and strong progression-free survival (PFS). Both trials show these responses and PFS



translate into significantly improved overall survival, addressing a high unmet need for these patients.

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 2030.¹ NSCLC is the most common type of lung cancer representing ~80-85% of all diagnoses.² The condition is often diagnosed at a late stage, and less than 30% of patients are alive five years after diagnosis.^{3,4} 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 (**Two ACTive Immunotherapies**) 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 Eftilagimod Alfa (Efti)

Efti is a novel immunotherapy that directly activates antigen-presenting cells or APCs (e.g. dendritic cells, monocytes) via the MHC Class II pathway to fight cancer. As an MHC Class II agonist, its activation of APCs engages the adaptive and innate immune system to initiate a broad anti-cancer immune response. This includes priming and activating cytotoxic T cells as well as generating important co-stimulatory signals & cytokines that further boost the immune system's ability to combat cancer.

Efti is under evaluation for a variety of solid tumours including non-small cell lung cancer (NSCLC) in a pivotal Phase III trial called TACTI-004 (KEYNOTE-F91), as well as head and neck squamous cell carcinoma (HNSCC), soft tissue sarcoma, and breast cancer. Its favourable safety profile enables various combinations like with anti-PD-[L]1 immunotherapy, radiotherapy, and/or chemotherapy. Efti has received Fast Track designation in first line HNSCC and in first line NSCLC from the United States Food and Drug Administration (FDA).

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. International Agency for Research on Cancer – World Health Organization. Rates of trachea, bronchus and lung cancer.
2. Zappa C & Mousa Non-small cell lung cancer: current treatment and future advances, *Transl Lung Cancer Res.* 2016 Jun; 5(3): 288–300.
3. Polanco D et al. Prognostic value of symptoms at lung cancer diagnosis: a three-year observational study. *J Thorac Dis* 2021;13:1485–1494.
4. 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 CEO of Immutep Limited.

