

Immutep Achieves 50% Enrolment in Global TACTI-004 (KEYNOTE-F91) Phase III Trial in 1L NSCLC

- *The registrational TACTI-004 trial in first line non-small cell lung cancer (1L NSCLC) has enrolled 378 patients globally, 50% of the trial's targeted enrolment*
- *Futility analysis and completion of patient enrolment remain on track for the first quarter and the third quarter of CY2026, respectively*

SYDNEY, AUSTRALIA – February 06, 2026 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces it has achieved 50% of the patient enrolment target in 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 therapy for advanced/metastatic non-small cell lung cancer (1L NSCLC).

Immutep Chief Executive Officer, Marc Voigt, said, “The excellent pace of enrolment globally in the TACTI-004 trial speaks to the promise of efti and the need for more efficacious therapies in the first line setting for patients with advanced/metastatic non-small cell lung cancer. Our team continues to work hard to bring this innovative cancer immunotherapy to market and looks forward to delivering on additional important upcoming milestones ahead, including the futility analysis in the first quarter and completing patient enrolment in the third quarter this year.”

The combination of efti with KEYTRUDA and chemotherapy has the potential to establish a new standard of care in 1L NSCLC, one of the largest and deadliest indications in oncology, by expanding the number of patients who respond to anti-PD-1 therapy, across all PD-L1 expression levels, along with enhancing clinical outcomes and extending patients’ survival.

The registrational TACTI-004 Phase III has enrolled 378 patients globally and enrolment continues its robust pace. Additionally, over 140 clinical sites are now activated across 27 countries. The futility analysis and completion of patient enrolment remain on track for the first quarter and the third quarter of CY2026, respectively.

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.

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

