

## **ImmuteP Announces Strong Operational Progress in Global TACTI-004 (KEYNOTE-F91) Phase III and Enrolment Continues at Robust Pace**

- *The registrational TACTI-004 Phase III has enrolled 289 patients globally, over 38% of the trial's targeted enrolment*
- *Strong operational progress continues globally with over 120 activated clinical sites and 27 countries having received full regulatory approvals including the United States*
- *Futility analysis remains on track for the first quarter of CY2026 and completion of patient enrolment in the third quarter of CY2026*

**SYDNEY, AUSTRALIA – December 16, 2025** – [ImmuteP Limited](#) (ASX: IMM; NASDAQ: IMMP) ("ImmuteP" or "the Company"), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today reports strong operational progress 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.

The registrational TACTI-004 trial has enrolled 289 patients (over 38% of the trial's targeted enrolment of 756 patients), and enrolment continues at a robust pace. Additionally, the number of activated clinical sites now exceeds 120 and 27 countries have received full regulatory approvals.

This includes the United States where the first of multiple clinical sites has received full regulatory clearance following the recent completion of the [FDA's Project Optimus](#) initiative and subsequent receipt of local and central Institutional Review Board (IRB) approvals.

As announced on 9 October 2025, TACTI-004 had enrolled the necessary 170 patients to conduct the futility analysis that remains on track for the first quarter of CY2026. Furthermore, ImmuteP expects to complete patient enrolment in the third quarter of CY2026.

**ImmuteP Chief Executive Officer, Marc Voigt, said,** "We are very pleased with the strong operational progress of TACTI-004 globally and the robust pace of recruitment. Growing interest in this pivotal trial has been enhanced by the recent licensing deal for efti in emerging markets with Dr Reddy's. The ImmuteP team is excited about further delivering on key milestones ahead, including the futility analysis and completion of patient enrolment."

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 **A**CTive **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 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](http://www.immutep.com).

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

