

ImmuteP's Efti with KEYTRUDA® (pembrolizumab) & Chemotherapy Achieves High Response Rates in First-Line Non-Small Cell Lung Cancer

- Novel combination achieves 60.8% response rate and 90.2% disease control rate in first-line non-small cell lung cancer (1L NSCLC)
- Notably, ~92% of all evaluable patients have PD-L1 TPS <50%, including 43% with PD-L1 below 1 (TPS <1%), who represent an area of high unmet need
- Data demonstrates significant improvement in response rates compared to historical controls, and safety continues to be favourable
- Multi-centre INSIGHT-003 is evaluating the same immunotherapy/chemotherapy combination used in the pivotal TACTI-004 Phase III in 1L NSCLC
- Additional data from INSIGHT-003 is planned for presentation at a medical conference later this year

SYDNEY, AUSTRALIA – May 15, 2025 – [ImmuteP Limited](#) (ASX: IMM; NASDAQ: IMMP) (“ImmuteP” or “the Company”), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces that a 60.8% response rate and 90.2% disease control rate, according to RECIST1.1, has been achieved in the investigator-initiated INSIGHT-003 trial as of the data-cut off date of 06 May 2025. INSIGHT-003 is evaluating eftilagimod alpha (efti) in combination with the anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) and doublet chemotherapy as first-line treatment for patients with advanced or metastatic non-squamous non-small cell lung cancer (1L NSCLC).

Marc Voigt, CEO of ImmuteP, stated, “Our level of confidence in efti driving a new standard of care for patients with non-small cell lung cancer via our pivotal TACTI-004 trial continues to rise with the strength of the data from INSIGHT-003 and TACTI-002. Across two trials we have now efficacy data from 165 patients with 1L NSCLC who have been treated with efti and KEYTRUDA, either with or without chemotherapy. In multi-national settings, efti has generated consistent and remarkable improvements in response rates. In particular, the interim ORR data in patients with PD-L1 expression below 50% in the ongoing INSIGHT-003 trial, who represent over two-thirds of the 1L NSCLC patient population, is very encouraging.”

Majority of Patients have PD-L1 TPS <50%

Notably, ~92% of all evaluable patients (N=51) in the INSIGHT-003 study have PD-L1 TPS <50%. This includes 49% of patients with PD-L1 Tumour Proportion Score (TPS) of 1-49% and 43% of patients with PD-L1 TPS <1%, as shown in the table below.

Strong Response Rates Across All PD-L1 Expression Levels

Data from all evaluable patients demonstrates significant improvement of Overall Response Rate (ORR) according to RECIST 1.1 across all levels of PD-L1 expression compared to historical control from a registrational trial of anti-PD-1 and doublet chemotherapy in non-squamous 1L NSCLC¹:

- 75.0% ORR versus 62.1% ORR in patients with high PD-L1 expression (TPS ≥50%)
- 64.0% ORR versus 49.2% ORR in patients with low PD-L1 expression (TPS 1-49%)
- 54.5% ORR versus 32.3% ORR in patients with negative PD-L1 expression (TPS <1%)

The 60.8% response rate regardless of PD-L1 expression (TPS 0-100%) represents a substantial improvement compared to historical control of 48.0%.¹ The relative outperformance is particularly strong given the

registrational trial has four times as many patients with high PD-L1 expression (~32% of patients versus ~8% in INSIGHT-003), who have the highest response rates.

Importantly, in patients with TPS <50% (N=47), who have a high unmet need and represent over two-thirds of the 1L NSCLC patient population, the triple combination with efti achieved a 59.6% response rate as compared to historical control of 40.8%.¹

INSIGHT-003 Overall Response Rate & Disease Control Rate, according to RECIST1.1

PD-L1 Expression Levels	TPS 0-100% (N=51)	TPS <1% (N=22)	TPS 1-49% (N=25)	TPS <50% (N=47)	TPS ≥50% (N=4)
ORR %	60.8	54.5	64.0	59.6	75.0
DCR %	90.2	86.4	92.0	89.4	100

Safety

Safety continues to be favourable for the triple combination in 1L NSCLC with no new safety signals.

Next Steps

Additional data updates from this trial are expected to be presented at a medical conference in 2025 and beyond.

About INSIGHT-003

INSIGHT-003 is an investigator-initiated study conducted by the [Frankfurt Institute of Clinical Cancer Research IKF](#) and several other German centres. It is being run as the third arm (Stratum C) of the ongoing Phase I INSIGHT trial with Prof. Dr. Salah-Eddin Al-Batran as lead investigator. The study is evaluating a triple combination therapy in front-line non-small cell lung cancer patients consisting of efti administered subcutaneously in conjunction with an existing approved standard-of-care combination of anti-PD-1 therapy (pembrolizumab) and chemotherapy (carboplatin and pemetrexed) delivered intravenously. The trial will assess the safety, tolerability, and initial efficacy of the combination.

About Eftilagimod Alfa (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 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. Shirish Gadgeel et al., Updated Analysis From KEYNOTE-189: Pembrolizumab or Placebo Plus Pemetrexed and Platinum for Previously Untreated Metastatic Nonsquamous Non-Small-Cell Lung Cancer. JCO 38, 1505-1517(2020). DOI:10.1200/JCO.19.03136

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