Immutep to Present New Data from AIPAC-003 Phase II at the 2025 San Antonio Breast Cancer Symposium

- Immunotherapy-chemotherapy combination of eftilagimod alfa (efti) and paclitaxel led to strong objective response rates and immune activation in heavily pretreated metastatic breast cancer patients
- AIPAC-003 has resulted in successful completion of FDA's Project Optimus requirements and selection of 30 mg as efti's optimal biological dose

SYDNEY, AUSTRALIA – December 2, 2025 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces new data from the AIPAC-003 trial will be presented at the 2025 San Antonio Breast Cancer Symposium (SABCS) taking place in San Antonio, Texas, from December 9-12, 2025.

The Phase II study randomised female participants (N=66) with HR+ and HER2-negative/HER2-low metastatic breast cancer (MBC) resistant to endocrine-based therapy (ET) including cyclin-dependent kinase 4/6 (CDK4/6) inhibitors or metastatic triple-negative breast cancer (mTNBC) not eligible for PD-(L)1-based therapy. Patients were randomised 1:1 to receive either 30 or 90 mg eftilagimod alfa (efti) in combination with paclitaxel to determine the optimal biological dose (OBD) consistent with the FDA's Project Optimus initiative.

Both efti dosing levels on top of weekly paclitaxel in heavily pretreated metastatic breast cancer patients, who received a median of three prior lines of systemic therapy, led to strong objective response rates (ORR) and disease control rates (DCR) of 41.9% and 87.1% (30 mg efti) and 48.5% and 78.8% (90 mg efti), respectively, in the evaluable population (N=64). Time to onset of response (TTR) was comparable at 2.0 months (30 mg) versus 1.9 months (90 mg).

Additionally, both dosing levels elicited the desired pharmacodynamic (PD) response in line with efti's mechanism of action with substantial increases in immune activation biomarkers including absolute-lymphocyte count (ALC) and interferon-gamma (IFN-γ). Data cut-off date for efficacy results was 15 September 2025.

Dr. Nuhad Ibrahim, Professor, Department of Breast Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center noted, "Evaluating two biologically active doses allowed us to integrate clinical response data with meaningful pharmacodynamic readouts. In keeping with Project Optimus principles, the study generated rigorous comparative data in heavily pretreated metastatic breast cancer patients showing consistent efficacy measures and immune-activation signals across both arms, reinforcing efti's novel mechanism of action and the clinical potential of this immunotherapy-chemo combination."

Tolerability at 90 mg was suboptimal including dose-limiting toxicities (DLT) and a higher proportion of local injection site reactions (LISR). In line with FDA guidance/advice and as previously reported on 13 October 2025, 30 mg of efti administered subcutaneously has been defined as the OBD.

Marc Voigt, CEO of Immutep said, "We are pleased to conclude this important phase of efti's clinical development and are fully committed to advancing this novel immunotherapy to address the needs of cancer patients globally, especially in light of our ongoing Phase III in 1st line NSCLC. This study holds significant importance in satisfying FDA's Project Optimus requirements and defining efti's OBD across our entire oncology clinical pipeline and potential future combinations with new therapeutic agents such as ADCs and bispecifics as well as for a potential future Biological Licence Application."

The AIPAC-003 trial has resulted in the successful completion of the FDA's Project Optimus requirements and agreement on 30 mg as efti's OBD carries strategic importance in ongoing and future clinical programs in oncology. This includes the global TACTI-004 (KEYNOTE-F91) Phase III trial evaluating 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), regardless of PD-L1 expression, which is now in the process of opening sites in the United States.

Details on the SABCS 2025 presentation are as follows:

Title: Optimal biological dose of eftilagimod alpha, a soluble LAG-3 protein, in metastatic breast cancer patients receiving weekly paclitaxel in AIPAC-003
Presenter: Dr. Nuhad Ibrahim, Professor, Department of Breast Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center
Presentation number: PS1-09-16
Abstract number: 315
Date and time: Wednesday, December 10th at 12:30-2:30 p.m. CST

The poster presentation is available on the Posters & Publications section of Immutep's website.

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.