

ASX/Media Release

ImmuteP Announces Completion of the Safety Lead-In and Opening of the Randomized Phase II of the AIPAC-003 Phase II/III Trial in Metastatic Breast Cancer

- *No safety or tolerability issues in open-label, safety lead-in phase evaluating the higher 90mg dose of efti in combination with weekly paclitaxel in the first 6 patients*
- *Good safety profile allows for lead-in phase to be closed early and the randomized Phase II portion of study will now proceed*

SYDNEY, AUSTRALIA – 06 November 2023 – [ImmuteP Limited](#) (ASX: IMM; NASDAQ: IMMP) ("ImmuteP" or "the Company"), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, today announces the open-label safety lead-in of its integrated AIPAC-003 Phase II/III trial evaluating for the very first time 90mg of eftilagimod alpha (efti) in combination with paclitaxel has been completed with no safety or tolerability issues.

Six patients with metastatic breast cancer receiving this immuno-oncology chemotherapy (IO-chemo) combination, after exhaustion of all endocrine/CDK4/6 based therapies, tolerated the therapy very well and there were no dose limiting toxicities, as confirmed by the independent Data Monitoring Committee (IDMC) appointed for the trial. The IDMC recommended proceeding to the randomised Phase II portion of the trial.

The randomised (1:1) Phase II portion of the study will now open to include up to 58 evaluable patients with metastatic breast cancer receiving either 30mg efti or 90mg efti to determine the optimal biological dose. The evaluation of 90mg efti dosing in combination with paclitaxel is driven by efti's excellent safety profile, along with the [FDA's Project Optimus](#) initiative in oncology. Importantly the determination of the optimal biological dose is relevant for the whole efti program across all disease indications.

The [integrated Phase II/III AIPAC-003 trial](#) is evaluating efti, ImmuteP's soluble LAG-3 protein and first-in-class MHC Class II agonist, in combination with standard-of-care paclitaxel for the treatment of metastatic hormone receptor positive (HR+), HER2-negative or HER2-low breast cancer and triple-negative breast cancer. It will take place at approximately 17 clinical sites across Europe and the United States of America. For more information on the trial, please visit clinicaltrials.gov ([NCT05747794](#)).

About Eftilagimod Alpha (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 1st line HNSCC and in 1st line NSCLC from the United States Food and Drug Administration (FDA).

About Immutep

Immutep is a clinical-stage biotechnology company developing novel LAG-3 immunotherapy for cancer and autoimmune disease. We are pioneers in the understanding and advancement of therapeutics related to Lymphocyte Activation Gene-3 (LAG-3), and our diversified product portfolio harnesses its unique 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.