

ASX/Media Release

## **ImmuteP Doses First Patient in AIPAC-003 Phase II/III Trial for Metastatic Breast Cancer**

**SYDNEY, AUSTRALIA – 25 May 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 first patient has been enrolled and safely dosed at a European clinical site for its integrated Phase II/III AIPAC-003 trial in metastatic breast cancer.

AIPAC-003 is evaluating eftilagimod alpha ("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 HER2-neg/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. Patients will receive same-day administration of efti + paclitaxel that can continue until disease progression.

**ImmuteP CSO, Prof Frédéric Triebel said:** "Commencing patient dosing for our AIPAC-003 trial of efti is a significant milestone for ImmuteP. Our aim is to improve clinical outcomes, focusing on a robust primary endpoint later in the phase III, overall survival, for patients with standard-of-care chemotherapy. Our previous trial, AIPAC, showed encouraging efficacy and safety results, including a 2.9-month median overall survival benefit and statistically significant median overall survival improvements of between 4.2 to 19.6 months across three pre-specified subgroups. We look forward to seeing how 90mg efti dosing, along with same-day administration of efti plus paclitaxel until disease progression, may build upon these prior results."

AIPAC-003 includes an open-label lead-in of up to 12 patients dosed at 90mg efti, which will be followed by a randomized (1:1) portion of the Phase II consisting of up to 58 evaluable patients who will receive 30mg efti or 90mg efti to determine the optimal biological dose in combination with paclitaxel. Depending on the Phase II results, potential regulatory actions and resources, a randomized, double-blinded, placebo-controlled Phase III portion will then follow. The Phase III will have overall survival as the primary objective and may include a specific patient population.

### **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](http://www.immuteP.com).

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