

ASX/Media Release

**ImmuteP Receives FDA Fast Track Designation for LAG-3 Therapeutic
Eftilagimod Alpha for First Line Non-Small Cell Lung Cancer**

- Fast Track designation has been granted by the US FDA for efti in combination with pembrolizumab in 1st line non-small cell lung cancer
- Based on the encouraging Phase II clinical data for PD-L1 all-comers presented at ASCO 2022
- Marks the second Fast Track designation issued by the FDA for eftilagimod alpha, offering the potential for expedited development and review

SYDNEY, AUSTRALIA – 4 October 2022 – [ImmuteP Limited](#) (ASX: IMM; NASDAQ: IMMP) ("ImmuteP" or "the Company"), a clinical-stage biotechnology company developing novel immunotherapies for cancer and autoimmune disease, today announced the United States Food and Drug Administration (FDA) has granted Fast Track designation to eftilagimod alpha ("efti" or "IMP321") in combination with pembrolizumab for the treatment of 1st line non-small cell lung cancer (NSCLC). Efti is the Company's first-in-class soluble LAG-3 clinical stage candidate which activates antigen presenting cells (APC) to engage both the innate and adaptive immune system to target solid tumors.

"We are pleased to receive this Fast Track designation as it acknowledges efti's unique potential to empower the human immune system against cancer and significantly enhance patient responses to standard-of-care immunotherapy. Efti also offers a chemotherapy-free option for NSCLC patients in need of less toxic and more durable solutions," stated Marc Voigt, CEO of ImmuteP.

"This important designation that efti has now received across two indications, 1st line NSCLC and 1st line HNSCC, enables us to work more closely with the FDA to bring this novel treatment option to cancer patients in the most timely and efficient manner possible. We look forward to providing additional clinical data in 1st line NSCLC later this year," he concluded.

The FDA's Fast Track designation process is designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fill an unmet medical need. ImmuteP will now have access to more frequent interactions with the FDA to discuss efti's development path and, if relevant criteria are met, eligibility for Rolling Review, Accelerated Approval, and Priority Review.

Fast Track designation has been granted for the development of efti in combination with pembrolizumab in 1st line treatment of Stage IIIB/IV NSCLC patients expressing PD-L1 Tumor Proportion Score $\geq 1\%$, not amenable to EGFR/ALK based therapy. The designation is based on the encouraging TACTI-002/KEYNOTE-798 Phase II clinical data in 1st line NSCLC for PD-L1 all-comers shared earlier this year via [an oral presentation at the American Society of Clinical Oncology's \(ASCO\) 2022 Annual Meeting](#).

This represents the second Fast Track designation that efti has received, following receipt of the same designation in April 2021 for efti in combination with pembrolizumab in [1st line treatment of recurrent or metastatic Head and Neck Squamous Cell Carcinoma](#).

About Eftilagimod Alpha (Efti)

Efti is ImmuteP's proprietary soluble LAG-3 clinical stage candidate that is a first-in-class antigen presenting cell (APC) activator for the treatment of cancer, in particular solid tumors. Efti capitalises on LAG3's unique characteristics to activate both innate and adaptive immunity via binding to antigen presenting cells such as dendritic cells, monocytes, and macrophages via MHC II molecules. Activation of APCs leads to expansion of anti-tumor cells, presentation of antigens to the adaptive immune system, and proliferation of CD4+ (helper) and CD8+ (cytotoxic) T cells. Efti's favorable safety profile enables its use in various combination settings, including with anti-PD-[L]1 immunotherapy and/or chemotherapy.

Efti is under evaluation for a variety of solid tumors including non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC) and HER2–/HR+ metastatic breast cancer. Efti has received Fast Track Designation in 1st line recurrent or metastatic HNSCC and in 1st line NSCLC from the United States Food and Drug Administration (FDA).

About ImmuteP

ImmuteP is a clinical stage biotechnology company leading the development of LAG-3 related immunotherapy products for the treatment of cancer and autoimmune disease. The Company is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximise value to shareholders.

ImmuteP's lead product candidate is eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3 fusion protein (LAG-3Ig), which is a first-in-class antigen presenting cell (APC) activator being explored in cancer in multiple clinical trials. ImmuteP is also developing an agonist of LAG-3 (IMP761) for autoimmune disease. Additional LAG-3 product candidates, including antibodies for immune response modulation, are licensed to and being developed by ImmuteP's large pharmaceutical partners.

ImmuteP is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Further information can be found on the Company's website www.immuteP.com or by contacting:

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