

ASX/Media Release

## Immutep Receives Positive Feedback from FDA on Late-Stage Clinical Development of Eftilagimod Alpha in Non-Small Cell Lung Cancer

**SYDNEY, AUSTRALIA – 16 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 it has received positive feedback from the US Food and Drug Administration (FDA), regarding the Company's late-stage clinical development plans for its first-in-class soluble LAG-3 protein and MHC Class II agonist, eftilagimod alpha ("efti"), for the treatment of 1st line non-small cell lung cancer (NSCLC).

The FDA is supportive of a registrational trial to evaluate efti in combination with an anti-PD-1 therapy based on the encouraging data from the Phase II TACTI-002, Part A (N=114) in 1st line NSCLC patients, no matter their level of PD-L1 expression, [presented in a late-breaking oral abstract presentation](#) at the 37th Annual Society of Immunotherapy of Cancer (SITC) Meeting in November 2022.

Among the items discussed at the meeting were the toxicological package and general aspects of the trial design, including statistics and potential patient population with a focus on 1st line NSCLC patients with a Tumor Proportion Score (TPS) PD-L1 of  $\geq 1\%$  for which efti plus pembrolizumab has already [received Fast Track designation](#). This trial will be named TACTI-004 (Two **ACTIVE** Immunotherapies).

**Immutep CEO, Marc Voigt, commented:** "In light of our compelling clinical data that efti has generated in combination with anti-PD-1 therapy, this meeting with the FDA is a critical step in our late-stage development process for 1st line non-small cell lung cancer. We are thankful for the positive feedback as we continue moving forward with our unique immuno-oncology approach for the many cancer patients impacted by this difficult disease."

**Immutep CSO, Dr. Frédéric Triebel, stated:** "We are very pleased with our constructive dialogue with the FDA establishing a clear path forward for efti in front line non-small cell lung cancer. These interactions represent an important milestone within Immutep's three main clinical programs targeting cancers that affect large patient populations, positioning efti to make a significant impact for the many patients in need of more effective, tolerable, and durable immunotherapy."

### 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- $\gamma$  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 HER2–/HR+ 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 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-3lg), which is a first-in-class antigen presenting cell (APC) activator being explored in cancer in multiple clinical trials. The Company 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.

Further information can be found on the Company’s website [www.immutep.com](http://www.immutep.com) or by contacting:

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