ASX/Media Release

Immutep Announces Independent Data Monitoring Committee Positive Recommendation to Continue TACTI-003 Trial as Planned

SYDNEY, AUSTRALIA – 26 October 2022 – 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 that the Independent Data Monitoring Committee (IDMC) for the randomised, controlled Phase IIb TACTI-003 trial has reviewed initial safety data and recommended continuing the trial with no modifications.

TACTI-003 is evaluating eftilagimod alpha ("efti" or "IMP321"), in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) as a 1st line therapy in approximately 154 patients with head and neck squamous cell carcinoma (HNSCC).

The IDMC safety analysis included 47 patients enrolled in either cohort A or cohort B of the TACTI-003 trial. Subjects in cohort A (CPS ≥1) are randomized 1:1 to receive either efti plus pembrolizumab or pembrolizumab alone. Subjects in cohort B (CPS <1) receive a combination of efti and pembrolizumab. The IDMC also reviewed initial efficacy data, although this was not the primary focus of the analysis.

Immutep's CSO and CMO Dr. Frédéric Triebel said, "We are very pleased with the IDMC's recommendation. While early, this represents positive affirmation of the decision to move TACTI-003 into the 1st line setting for head and neck squamous cell carcinoma patients following the robust results and durable responses that efti in combination with pembrolizumab achieved in the 2nd line setting. Notably, the encouraging antitumour activity previously attained spanned the entire spectrum of PD-L1 expression, which is important as the majority of patients have lower PD-L1 levels and are in need of new approaches to fight cancer."

Currently, 53/154 patients (approximately 34%) have been recruited into the TACTI-003 trial, and recruitment is accelerating as further sites have been activated in Europe and the United States. Based largely on the promising data from Immutep's Phase II TACTI-002 trial (KEYNOTE-798) in 2nd line HNSCC, Immutep was granted Fast Track designation by the FDA for efti in combination with pembrolizumab in April 2021 for 1st line treatment of recurrent or metastatic HNSCC. This designation provides Immutep with access to more frequent meetings and communications with the FDA, and potentially enables Rolling Review of a Biologic License Application. In addition, Fast Track designation may provide Accelerated Approval and Priority Review if relevant criteria are met, for efti in HNSCC.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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, capitalising on LAG-3's unique characteristics to stimulate both innate and adaptive immunity. Efti binds to and activates antigen presenting cells via MHC II molecules

leading to expansion 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 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 TACTI-003
TACTI-003 is a Phase IIb clinical trial in 1st line head and neck squamous cell carcinoma (HNSCC). The study will evaluate efti in combination with MSD's KEYTRUDA® (pembrolizumab) as a 1st line therapy in metastatic or recurrent HNSCC patients with PD-L1 negative and PD-L1 positive (CPS ≥1) tumours. It will be a randomised, controlled clinical study in approximately 154 patients and will take place across Australia, Europe and the United States of America in up to 35 clinical sites.

The study will evaluate the safety and efficacy of efti in combination with pembrolizumab, compared to pembrolizumab alone in 1st line metastatic or recurrent HNSCC patients with PD-L1 positive (CPS ≥1) tumours (cohort A), and determine the efficacy and safety of efti plus pembrolizumab in patients with PD-L1 negative tumours (CPS <1) (cohort B). According to the current plans, about 130 patients in cohort A will be randomised 1:1 to receive either efti plus pembrolizumab or pembrolizumab alone. Subjects in cohort B (up to 24 patients) will receive a combination of efti and pembrolizumab. The primary endpoint of the study is Overall Response Rate (ORR) according to RECIST 1.1. Secondary endpoints include Overall Survival (OS) and Progression Free Survival (PFS). For more information about the Phase IIb trial, visit clinicaltrials.gov (NCT04811027).

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. 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 or by contacting:

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