ASX/Media Release

Immutep Completes Enrollment in TACTI-003 Phase IIb Trial of Efti and KEYTRUDA® in First Line Metastatic or Recurrent Head and Neck Squamous Cell Carcinoma

- *A total of 171 head and neck squamous cell carcinoma (HNSCC) patients enrolled in randomised, multicentre Phase IIb trial evaluating efti in combination with pembrolizumab*
- *Efti has FDA Fast Track designation for first-line treatment of HNSCC*

SYDNEY, AUSTRALIA – November 9, 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 completion of patient enrollment in the TACTI-003 (KEYNOTE-PNC-34) Phase IIb trial evaluating eftilagimod alpha (efti), its proprietary soluble LAG-3 protein and MHC Class II agonist, in combination with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) as first-line treatment of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC).

The Phase IIb trial enrolled 171 patients at over 30 centres across the United States, Europe, and Australia to evaluate the safety and efficacy of efti in combination with pembrolizumab in patients with PD-L1 positive (Combined Positive Score [CPS] ≥1) tumors (Cohort A) and in patients with PD-L1 negative tumors (Cohort B).

A total of 138 patients with recurrent or metastatic HNSCC whose tumours express PD-L1 (CPS ≥1) have been enrolled into the 1:1 randomized Cohort A of the trial evaluating the safety and efficacy of 30mg of efti in combination with 400mg of KEYTRUDA® given every six weeks compared to 400mg of KEYTRUDA® alone. Patients in Cohort A whose tumors express PD-L1 (CPS ≥1) are also stratified by CPS 1-19 and CPS ≥20, and the clinical results for these three CPS groups will be evaluated.

Additionally, 33 patients with recurrent or metastatic HNSCC were enrolled into Cohort B to determine the efficacy and safety of the same combination therapy in patients with PD-L1 negative tumours (CPS <1). These patients are not expected to respond to KEYTRUDA® monotherapy, with a typical Overall Response Rate of up to 5%, and therefore were not randomized.[1] Due to a higher number of patients with negative PD-L1 expression (CPS <1) who were eligible for and allocated to Cohort B and the number of patients in screening at the time of achieving the trial's enrollment goal, the trial enrolled 171 patients.

The primary endpoint of the study is Overall Response Rate of evaluable patients according to RECIST 1.1. Secondary endpoints include Overall Survival, Overall Response Rate according to iRECIST, Progression Free Survival, and Duration of Response. The primary analysis according to the trial protocol will be performed after all subjects have completed at least three cycles of treatment (18 weeks in total) or discontinued the trial, and all relevant data for the primary endpoint has been collected, cleaned, and analysed. The Company expects to report data from the trial in H1 CY2024.

Dr. Frédéric Triebel, CSO of Immutep, said: "The completion of patient enrollment in TACTI-003 represents an important milestone in the clinical development of efti. We hope to build upon the encouraging data

previously seen combining efti with the anti-PD-1 KEYTRUDA® in the second line HNSCC setting. Dr Florian Vogl, our CMO who joined Immutep earlier this year, will oversee the completion of this important trial."

Dr. Florian Vogl, CMO of Immutep, added: "We are very excited to have completed patient enrollment in this randomised, multi-national trial and look forward to sharing data in the first half of 2024. Head and neck squamous cell carcinomas represent a difficult-to-treat, heterogenous cancer and an area of high unmet need. Our results in the second line setting provide optimism for the potential of efti in combination with pembrolizumab in the first-line treatment of these aggressive tumours."

Head and neck squamous cell carcinoma (HNSCC) is the sixth most common cancer by incidence worldwide, with 890,000 new cases and 450,000 deaths reported in 2018.[2,3,4] It is an aggressive, genetically complex, and difficult to treat cancer.[5] Furthermore, HNSCC is associated with high levels of psychological distress and compromised quality of life (QOL).[6] As such, HNSCC patients need improved treatment options.

Eftilagimod alpha was granted Fast Track designation by the FDA in April 2021 for treatment of first-line HNSCC. For more information about the Phase IIb trial, visit clinicaltrials.gov (NCT04811027).

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 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.