Press Release
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Immutep achieves 50 percent enrollment milestone in randomised Phase IIb TACTI-003 trial for first-line head and neck cancer

Sydney, Australia, January 4th 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 that it has enrolled and randomised over 50 percent of the planned 154 patients in the TACTI-003 Phase IIb trial. TACTI-003 is evaluating Immutep's first-in-class soluble LAG-3 protein eftilagimod alpha ("efti"), in combination with MSD's (Merck and Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA (R) (pembrolizumab) as 1st line treatment of recurrent or metastatic head and neck squamous cell carcinoma (1L HNSCC).

Marc Voigt, CEO of Immutep stated: "We are pleased to reach this important milestone and extend our sincere appreciation to our investigators, clinical team, partners, and most importantly patients, that have participated in this study. As clinical evidence showing the compelling benefits of combining efti with immune checkpoint therapies such as pembrolizumab continues to grow, we are increasingly excited about efti's potential to safely deliver superior clinical outcomes and meaningfully expand the population of cancer patients that respond to treatment."

The 1:1 randomised, controlled multinational TACTI-003 trial is currently accruing patients at over 25 centers in the United States, Australia, and Europe, and is expected to be fully recruited by mid-2023. Based largely on the promising data in 2nd line HNSCC from the Phase II TACTI-002 trial (KEYNOTE-798), including encouraging overall response rates regardless of PD-L1 expression and five complete responses (CR), eftilagimod alpha was granted Fast Track designation by the FDA in April 2021 for treatment of 1L HNSCC.

As recently announced, the Independent Data Monitoring Committee (IDMC) for the TACTI-003 trial reviewed initial safety data and recommended continuing the trial with no modifications. The IDMC also reviewed initial efficacy data, although this was not the primary focus of the analysis.

HNSCC is the sixth most common cancer by incidence worldwide, with 890,000 new cases and 450,000 deaths reported in 2018.1,2,3 HNSCC is an aggressive, genetically complex, and difficult to treat cancer.4 Furthermore, HNSCC is associated with high levels of psychological distress and compromised quality of life (QOL).5 As such, HNSCC patients are in need of improved treatment options.
KEYTRUDA(R) is a registered trademark of Merck Sharp and Dohme LLC, a subsidiary of Merck and Co., Inc., Rahway, NJ, USA.

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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(R) (pembrolizumab) as a 1st line therapy in metastatic or recurrent HNSCC patients with PD-L1 negative and PD-L1 positive (CPS ≥1) tumours. It is 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).

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: