ASX/Media Release

First Patient Dosed in Trial Evaluating Efti and the Anti-PD-L1 Therapy BAVENCIO® in Metastatic Urothelial Cancer

SYDNEY, AUSTRALIA – 04 January 2024 – 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 first patient has been enrolled and safely dosed in the INSIGHT-005 Phase I trial. The investigator-initiated study jointly funded with Merck KGaA, Darmstadt, Germany, will evaluate eftilagimod alpha ("efti") in combination with BAVENCIO® (avelumab) in up to 30 patients with metastatic urothelial carcinoma.

This chemotherapy-free immuno-oncology (IO) combination has already shown promising signals of efficacy and a favorable safety profile in advanced solid tumors, including several IO insensitive indications, in the INSIGHT-004 Phase I trial. Encouragingly, responses were achieved even in cancer patients with low and negative PD-L1 expression, who typically would not be expected to respond to anti-PD-(L)1 therapy.

INSIGHT-005 looks to build on these clinical results and is focused on an area of high unmet need: metastatic urothelial carcinoma patients that are not eligible for platinum-based chemotherapy or progressing during or after platinum-based chemotherapy. The trial will assess the safety and efficacy of efti and avelumab, an anti PD-L1 monoclonal antibody owned by Merck KGaA, Darmstadt, Germany, that is widely recognized in international guidelines as the standard of care for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are progression-free following platinum-based chemotherapy.

Immutep CSO, Frédéric Triebel, M.D., Ph.D., "Immunotherapy has made great strides in improving clinical outcomes for patients with bladder cancer, including avelumab that has set a new standard of care for many metastatic urothelial carcinoma patients, and we are pleased to commence patient enrollment in the INSIGHT-005 study that we hope will build upon this progress. The chemotherapy-free IO combination utilizing efti and avelumab has already generated encouraging efficacy and safety in difficult-to-treat advanced solid tumors, and this trial will help further elucidate how efti's unique immune system activation may complement and enhance the ability of immune checkpoint inhibitors like avelumab to fight cancer."

INSIGHT-005 will be conducted by the Institute of Clinical Cancer Research IKF at Krankenhaus Nordwest in Frankfurt and other German cancer centers, including Helios Klinikum Bad Saarow with Dr. Med. Daniel Pink, as part of the investigator-initiated INSIGHT platform for studies investigating efti in different combination treatments and routes of administration. INSIGHT currently consists of 5 different arms from stratums A to E (INSIGHT-005 is Stratum E).

Urothelial carcinoma is the most common type of bladder cancer. For 2023, it was estimated there would be 82,290 new cases of bladder cancer and 16,710 deaths in the US alone.[1]

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 first line HNSCC and in first 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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[1] US National Cancer Institute: https://seer.cancer.gov/statfacts/html/urinb.html

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