Immutep Enters into Second Clinical Trial Collaboration Agreement with Merck KGaA, Darmstadt, Germany, and Pfizer for New Combination Study of its First-in-Class LAG-3 Candidate, Eftilagimod Alpha, and Avelumab to Treat Urothelial Cancer

- New collaboration builds on encouraging clinical data previously reported from INSIGHT-004 in multiple solid tumour indications from the combination of eftilagimod alpha ("efti") and avelumab (BAVENCIO®)
- Expansion into urothelial cancer builds on core strategy to increase target indications for combination approaches with efti to exploit the full potential of this unique LAG-3 candidate
- First patient is expected to be enrolled and dosed in H1 of calendar year 2023

SYDNEY, AUSTRALIA – 29 November 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, is pleased to announce it has signed a Clinical Trial Collaboration and Supply Agreement ("Agreement") with Merck KGaA, Darmstadt, Germany and Pfizer for a new Phase I clinical study in patients with urothelial cancer, called INSIGHT-005.

"We are very pleased to be deepening our collaboration with Merck KGaA, Darmstadt, Germany and Pfizer through this new study in patients with urothelial cancer, the sixth most common cancer in the US, who are in need of treatment options," said Immutep CEO, Marc Voigt. "INSIGHT-005 builds on the encouraging clinical efficacy and safety previously reported from the combination of efti and avelumab in various solid cancers, including deep and durable responses in patients with low or no PD-L1 expression and in indications that typically do not respond to immune checkpoint therapy."

INSIGHT-005 will be an investigator-initiated explorative, open-label study evaluating the safety and efficacy of Immutep's lead product candidate, efti, in combination with avelumab (BAVENCIO®) in up to 30 patients with metastatic urothelial cancer. The study will take place in Germany. The first patient is expected to be enrolled and dosed in H1 of calendar year 2023, after completing the necessary ethics and regulatory steps.

Urothelial cancer is a type of cancer in the bladder or urinary tract. In the US alone, it is estimated there will be 81,180 new cases of bladder cancer in 2022 and an estimated 17,100 people will die of this disease.[1] Avelumab is a checkpoint inhibitor that works by targeting and blocking a protein called PD-L1 on the surface of certain immune cells, activating the cells to find and kill cancer cells. It is approved in more than 60 countries around the world as a monotherapy for first-line maintenance treatment for adult patients with advanced urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy. Avelumab is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer.

[1] US National Cancer Institute: https://seer.cancer.gov/statfacts/html/urinb.html

Efti was previously evaluated in combination with avelumab via the INSIGHT-004 study in patients with advanced solid cancers, including colorectal, pleural mesothelioma, squamous anal cell, cervical, and gastroesophageal carcinomas. Immutep announced final data from INSIGHT-004 in June 2021, reporting encouraging efficacy signals from the combination with a response rate of 41.7% according to RECIST 1.1.

Under the Agreement, Immutep and Merck KGaA, Darmstadt, Germany will jointly fund the INSIGHT-005 study. It will be conducted by the Institute of Clinical Cancer Research, Krankenhaus Nordwest (IKF) as part of the investigator-initiated INSIGHT platform for studies investigating efti in different combination treatments and routes of administration. INSIGHT consists of 5 different arms from stratums A to E (INSIGHT-005 is Stratum E).

For more information on INSIGHT, visit clinicaltrials.gov (INSIGHT identifier NCT03252938).

The study announced today modifies the previously announced protocol for INSIGHT-005 evaluating efti in combination with bintrafusp alfa. The former INSIGHT-005 study did not advance based on previously generated results for bintrafusp alfa in other studies.

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 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 maximize 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.