



Press Release
Media Contacts:
IB Communications
Tel +44 (0)20 89434685
immunetep@ibcomms.agency

Immutep Receives Approval to Initiate INSIGHT-005 Trial Evaluating Eftilagimod Alpha and Anti-PD-L1 Therapy BAVENCIO(R)

Investigator-initiated study jointly funded with Merck KGaA, Darmstadt, Germany, will evaluate dual immuno-oncology (IO) combination of eftilagimod alpha and BAVENCIO(R) in metastatic urothelial cancer

Trial builds on strategy to cost-efficiently increase target indications for IO-IO combination approaches utilizing eftilagimod alpha in areas of high unmet need

Sydney, Australia, 1 May 2023 – Immutep Limited (ASX: IMM; NASDAQ: IMMP), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, today announces it has received regulatory approval from the Paul-Ehrlich-Institut ("PEI"), German Federal Institute for Vaccines and Biomedicines, to initiate INSIGHT-005, an investigator-initiated, open-label Phase I trial evaluating the safety and efficacy of eftilagimod alpha ("efti") in combination with BAVENCIO(R) (avelumab) in up to 30 patients with metastatic urothelial carcinoma.

Urothelial carcinoma is the most common type of bladder cancer. For 2023, it is estimated there will be 82,290 new cases of bladder cancer and 16,710 deaths in the US alone[1]. Patients not eligible for platinum-based chemotherapy or progressing during or after platinum-based chemotherapy represent an area of high unmet need and will be enrolled in the trial.

"We are excited to get this important trial underway. In addition to possibly bringing a new chemo-free treatment option to patients with advanced urothelial cancer, we hope to further build upon the encouraging clinical data we have seen to date combining efti and avelumab in other challenging cancers. Efti's unique activation of antigen-presenting cells to fight cancer has shown a benefit with avelumab, and we believe this dual IO-IO approach has broad potential to drive superior clinical outcomes across a variety of indications, including bladder cancer where avelumab monotherapy has regulatory approval," said Immutep CEO, Marc Voigt.

BAVENCIO is a checkpoint inhibitor owned by Merck KGaA, Darmstadt, Germany, that works by targeting and blocking a protein called PD-L1 on the surface of cancer cells and certain immune cells, activating the cells to find and kill cancer cells. It is approved 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 in more than 60 countries around the world.

Efti, a soluble LAG-3 protein and novel MHC Class II agonist, was previously evaluated in combination with BAVENCIO in patients with advanced solid tumours in the INSIGHT-004 Phase I trial. Encouragingly, deep and durable responses were achieved in patients with low or negative PD-L1 expression as well as immunooncology insensitive tumours.

INSIGHT-005 will be conducted by the Institute of Clinical Cancer Research IKF at Krankenhaus Nordwest in Frankfurt 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 stratum A to E (INSIGHT-005 is Stratum E).

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

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.

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