Immutep Presents Data from Safety Lead-in Phase of AIPAC-003 at ESMO Breast 2024

- Confirmed complete response in a patient with metastatic breast cancer refractory to several lines of therapy achieved during combination treatment with 90mg efti and paclitaxel
- Ongoing complete response has been maintained since the patient started treatment with efti monotherapy
- Efti + paclitaxel combination continues to be well tolerated with a favourable safety profile
- First-ever 90mg dosing leads to higher maximum concentration of efti, as well as pharmacologically active level up to 96 hours after administration
- Data from randomized Phase II portion of study expected in CY2024

SYDNEY, AUSTRALIA – May 15, 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 encouraging efficacy, safety, and pharmacodynamic data from the safety lead-in of the AIPAC-003 Phase II/III trial presented at the European Society for Medical Oncology (ESMO) Breast Cancer 2024 Congress. This lead-in represents the first ever 90mg dosing of eftilagimod alpha ("efti"), a soluble LAG-3 protein and MHC Class II agonist, given in combination with weekly paclitaxel.

Efficacy

The poster titled *"Testing a higher dose (90 mg s.c.) of eftilagimod alpha, a soluble LAG-3 protein, in metastatic breast cancer patients receiving weekly paclitaxel in AIPAC-003"* details positive results in six metastatic breast cancer (MBC) patients, who exhausted endocrine therapy including cyclin-dependent kinase 4/6 (CDK4/6) inhibitors. The data shows a confirmed 50% overall response rate, including one complete response and two partial responses, and a 100% disease control rate, with three patients having stable disease as best overall response per RECIST 1.1.

Complete Response Patient Case Study

The patient with a confirmed complete response (CR) was diagnosed with triple-negative breast carcinoma (TNBC) in 2019 and has failed multiple lines of therapy including a CDK 4/6 inhibitor for ER+/PR+ metastasis. During the immuno-oncology (IO)-chemotherapy treatment of efti and paclitaxel, this patient achieved a partial response (PR) that subsequently turned into a CR. This patient's ongoing CR has been maintained since stopping paclitaxel and being treated with efti monotherapy.

Safety & Pharmacodynamic Effects

The lead-in has also shown that the first-ever 90mg efti dosing in combination with weekly paclitaxel continues to be well tolerated with a favourable safety profile. As of the data cut-off (April 3), no dose-limiting toxicities and no treatment-emergent adverse events of grade 3 or higher severity were recorded.

The 90mg efti dosing leads to a higher maximum concentration of efti in the blood as compared to lower efti doses in past clinical trials, and efti remains detectable at a pharmacologically active level ($\geq$1 ng/mL) up to 96 hours after administration. Pharmacodynamic effects also showed an increase of circulating levels of immune cells such as CD8 & CD4 T cells and plasma Th1 biomarker levels. All patients in the AIPAC-003 safety

lead-in had a ≥1.4-fold change in interferon-gamma (IFN-γ) and ~83% had a ≥1.4-fold change in CXCL10 after a single 90mg efti dose.

Dr. Serafin Morales Murillo, University Hospital Arnau de Vilanova, Lleida, Spain, and AIPAC-003 investigator stated, "It is encouraging to see the high efti dose of 90mg with weekly paclitaxel continue to be safe and well tolerated in these metastatic breast cancer patients. It is also positive at this early stage to see high response and disease control rates, including a complete response, in these patients who have unfortunately all seen their cancers progress after endocrine therapy including CDK 4/6 inhibitors. We are looking forward to further data emerging from this study."

The randomized Phase II portion of the trial, which will include up to 58 evaluable patients, is underway and focused on whether 90mg efti dosing is more efficacious than 30mg dosing. This portion of the trial has enrolled 35 patients to date. Importantly, the determination of the optimal dose in AIPAC-003 is directly tied to the FDA's Project Optimus initiative and is relevant for the entire efti program.

Further data updates in terms of safety and efficacy from AIPAC-003 are expected in CY2024. The ESMO Breast 2024 poster will be available on the Posters & Publications section of Immutep's website.

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