Press Release
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Immutep announces positive final data in second-line metastatic NSCLC patients refractory to anti-PD-(L)1 therapy at European Lung Cancer Congress 2023

- **Efti plus pembrolizumab achieved mOS of 9.9 months and a 39 percent OS rate at 21 months, which compare favourably to typical 6-9 months mOS and a 10-15 percent OS rate for standard-of-care chemotherapy**
- **83 percent of patients studied for Tumour Growth Kinetics showed deceleration of tumour growth or shrinkage of tumours, previously increasing under PD-(L)1 monotherapy or in combination with chemotherapy**
- **ORR of 8.3 percent, DCR of 33.3 percent, and 6-month PFS rate of 25 percent in all-comer PD-L1 patient population, with most of these PD-X refractory patients (75 percent) having negative or low PD-L1 expression**
- **ORR of 33.3 percent, 6-month PFS of 50 percent, and mOS not yet reached for patients with high PD-L1 expression**
- **Combination of efti plus pembrolizumab well tolerated in this difficult-to-treat patient population without any new safety signals**

Sydney, Australia, March 31, 2023 – Immutep Limited (ASX: IMM; NASDAQ: IMMP), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, today announces positive final data from Part B of the TACTI-002 Phase II trial in 2nd line metastatic non-small cell lung cancer (NSCLC) patients refractory to anti-PD-(L)1 therapy via a Mini Oral presentation at ESMO's European Lung Cancer Congress (ELCC) 2023.

The presentation by Margarita Majem, M.D., Ph.D., Department of Medical Oncology, Hospital de la Santa Creu i Sant Pau, titled "Final data from a phase II study (TACTI-002) of eftilagimod alpha (soluble LAG-3) & pembrolizumab second-line metastatic NSCLC patients resistant to PD-1/PD-L1 inhibitors" discusses how eftilagimod alpha, a soluble LAG-3 protein, targets a subset of MHC class II molecules found on antigen-presenting cells (e.g., dendritic cells, monocytes) to mediate their activation and subsequent CD8+ T cell activation/proliferation. This unique stimulation of antigen-presenting cells (APC) leads to a broad anti-tumour immune response, and the addition of efti to pembrolizumab may help refractory second-line NSCLC patients that have few therapeutic options by reverting their anti-PD-(L)1 resistance.

Dr. Majem stated, "In this difficult-to-treat patient population, these clinical results beneficially show that subcutaneous administration of eftilagimod alpha in combination with pembrolizumab is safely stimulating a broad immune response that may revert resistance to anti-PD-X therapy. The data supports further clinical investigation of eftilagimod alpha in combination with pembrolizumab for patients with anti-PD-(L)1 refractory non-small cell lung cancer that have limited treatment options."

All patients (N=36) had confirmed progression (e.g., two consecutive scans) after standard-of-care first-line treatment with anti-PD-X therapy, including 67 percent that received anti-PD-X therapy and chemotherapy (72 percent when excluding non-evaluable patients). In these PD-X refractory, 2L metastatic NSCLC patients, the chemo-free combination of efti plus pembrolizumab achieved a median Overall Survival (mOS) of 9.9 months and a 39 percent OS rate at 21 months, which compare favourably to typical 6-9 months mOS and a 10-15 percent OS rate at 21 months for standard-of-care chemotherapy.

Additionally, Tumour Growth Kinetics (TGK) analysis looking at the difference of the sum of the largest diameters of target lesions in the pre-and post-baseline setting was performed on patients with data available on the same lesions from prior failed therapy and post-baseline (N=24). 83.3 percent of patients showed shrinkage (33 percent) or deceleration of tumour growth (50 percent). Notably, 36 percent, 39 percent, and 16.7 percent of patients had a PD-L1 Tumour Proportion Score (TPS) of less than 1 percent, 1-49 percent, and greater than or equal to 50 percent, respectively, and 8.3 percent of patients were not evaluable for PD-L1 expression.

Efti plus pembrolizumab had an ORR of 8.3 percent , a DCR of 33 percent, and a 6-month PFS rate of 25 percent in the all-comer PD-L1 patient population, with most of these PD-X refractory patients (75 percent) having negative or low PD-L1 expression. The ORR, PFS, and OS were more pronounced in

patients with high PD-L1 expression (N=6) or who were secondary resistant (N=25). For patients with greater than or equal to 50 percent PD-L1 TPS expression, mOS was not yet reached, ORR was 33.3 percent, and 6-month PFS was 50 percent. Efti plus pembrolizumab was well tolerated without any new safety signals, and there was no treatment discontinuation due to adverse reactions.

Immutep CSO and CMO, Dr Frederic Triebel, noted: "The maturation of data across all three indications in the all-comer TACTI-002 trial, namely first-line non-small cell lung cancer, second-line head and neck cancer, and second-line PD-X refractory non-small cell lung cancer, has continued to strengthen our belief that combining immunotherapies that harness the power of both innate and adaptive immunity may be very effective in fighting cancer. Efti's unique targeting and activation of antigen-presenting cells has shown a promising benefit with checkpoint inhibitors that target T cells, and we believe the combination of efti and pembrolizumab has significant potential to safely improve outcomes for cancer patients."

Immutep CEO, Marc Voigt, concluded, "These encouraging results and overall survival trends in patients refractory to PD-1/PD-L1 containing therapy, which have confirmed progression via two consecutive scans, offers a potential therapeutic pathway for many in dire need of new options. As we assess this potential, we continue to focus our late-stage clinical development of efti in combination with anti-PD-1 therapy in first-line non-small cell lung cancer and first-line head and neck cancer and look forward to providing more details on both as the year progresses."

The Mini Oral presentation will be available on the Posters & Publications section of Immutep's website.

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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 that stimulates both innate and adaptive immunity for the treatment of cancer. 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 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 market for patients in need and to maximise value for shareholders. For more information, please visit www.immutep.com.