

**Immutep announces expansion of triple combination therapy in first-line non-small cell lung cancer**

- **Expanding INSIGHT-003 trial evaluating efti with standard-of-care combination of anti-PD-1 therapy and chemotherapy to 50 patients**
- **Expansion based on safety and strong initial efficacy results**
- **Data updates expected throughout CY2023 and a cost-efficient approach through investigator-initiated trial will further inform options related to 1L NSCLC development**
- **Clinical data to date shows efti uniquely positioned to address entire NSCLC patient population through both chemo-free IO-IO and IO-IO-chemo triple combinations**

**Sydney, Australia, March 30, 2023 – 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 it has signed an agreement to expand the INSIGHT-003 trial evaluating the combination of eftilagimod alpha ("efti"), a soluble LAG-3 protein and first-in-class MHC class II agonist, in conjunction with standard-of-care combination of anti-PD-1 therapy and chemotherapy in first-line non-small a lung cancer (1L NSCLC).

INSIGHT-003 recently reached its initial enrolment target of 20 patients and will now be expanded to 50 patients across multiple sites. This expansion is based on favourable safety and strong initial efficacy results presented at SITC 2022. Additional data from INSIGHT-003 is expected throughout calendar year 2023.

Prof. Dr. Salah-Eddin Al-Batran of the Institute of Clinical Cancer Research IKF and lead investigator noted: "We're thrilled to expand the trial population for this triple combination therapy, which has demonstrated promising efficacy and safety in first-line non-small cell lung cancer patients. We have seen the previous findings that are indicative of powerful synergies of efti's immune system stimulation with anti-PD-(L)1 therapies and separately with chemotherapy across various solid tumors. As we continue to gather clinical data throughout the year, we eagerly anticipate discovering how this synergy translates in the INSIGHT-003 study, which combines all three modalities."

Initial results from the triple combination of efti, an anti-PD-1 therapy and chemotherapy in patients with 1L NSCLC show that the therapy is well-tolerated and provides promising early signals of therapeutic activity with an ORR of 72.7 percent and a Disease Control Rate (DCR) of 90.9 percent. Additionally, 82 percent of the eleven evaluable patients had a PD-L1 Tumour Proportion Score (TPS) of less than 50 percent and this group reported an encouraging 66.7 percent ORR and 88.9 percent DCR.

Patients with low to negative PD-L1 expression represent two-thirds of the 1L NSCLC patient population and are less responsive to anti-PD-(L)1 therapy compared to patients with a PD-L1 TPS of greater than or equal to 50 percent. Unlike many dual immuno-oncology combinations (IO-IO) that focus solely on high PD-L1 expressing patients, compelling clinical results to date suggest that efti may be uniquely positioned to address the entire NSCLC patient population regardless of PD-L1 expression through chemo-free IO-IO combinations or IO-IO chemo triple combinations as INSIGHT-003 is evaluating.

In addition to the Company's late-stage clinical development efforts focused on 1L NSCLC with the combination of efti and anti-PD-1 therapy (IO-IO), the expansion of INSIGHT-003 will further inform planning for registrational studies. Importantly, this multi-center investigator-initiated trial will generate valuable data in a cost-efficient manner.

Immutep CEO, Marc Voigt, said: "We are grateful for the long-standing support of Dr. Al-Batran and the entire team at IKF. Our valuable relationship with this world-class institution has uncovered many positive attributes of efti and continues to help us cost-effectively advance this novel immunotherapy for patients with advanced solid tumours, including 1st line non-small cell lung cancer."

**ENDS**

**About INSIGHT-003**

INSIGHT-003 is an investigator-initiated study conducted by the Institute of Clinical Cancer Research IKF. It is being run as the third arm (Stratum C) of the ongoing Phase I INSIGHT trial with Prof. Dr. Salah-Eddin Al-Batran as lead investigator. The study is evaluating a triple combination therapy in front-line non-small cell lung cancer patients consisting of efti administered subcutaneously in conjunction with an existing approved standard-of-care combination of anti-PD-1 therapy (pembrolizumab) and chemotherapy (carboplatin and pemetrexed) delivered intravenously. The trial will assess the safety, tolerability, and initial efficacy of the combination.

**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 is an agonist to major-histocompatibility index (MHC) Class II on antigen presenting cells (APCs) that binds to and uniquely activates these APCs via MHC II leading to activation/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- $\gamma$  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](http://www.immutep.com).