

Immutep Announces Site Expansion for INSIGHT-003 Phase I Trial

SYDNEY, AUSTRALIA – November 22, 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 that the INSIGHT-003 trial has been expanded to four sites across Germany including the University Clinic of Ruhr Universität Bochum and the Lung Clinic Cologne-Merheim. This site expansion will support faster enrolment in this cost-efficient, investigator-initiated study evaluating eftilagimod alpha (efti) in combination with the anti-PD-1 therapy KEYTRUDA[®] (pembrolizumab) and doublet chemotherapy for first line treatment of non-squamous non-small cell lung cancer (NSCLC).

The strength of the early clinical data in this first-in-man triple combination study led to its increase to 50 patients. The extension opened in mid-2023 and 29 patients have been enrolled to date. With the addition of the new sites, the trial is expected to complete recruitment in 1H CY2024.

As [presented at ESMO Congress 2023](#), the triple combination in INSIGHT-003 achieved a 70.6% overall response rate and 10.9-month median progression-free survival¹ in patients with PD-L1 Tumor Proportion Score (TPS) of <50%, who are typically less responsive to anti-PD-1 therapy. This compares favourably to data in the same patient population, including a response rate of 40.8%, from a registrational trial of anti-PD-1 and doublet chemotherapy.²

Furthermore, the triple combination is well tolerated, and the addition of efti does not appear to increase the toxicity of KEYTRUDA[®] and carboplatin/pemetrexed, building upon the favourable safety profile of efti that has been established across multiple clinical trials to date.

About INSIGHT-003

INSIGHT-003 is an investigator-initiated study conducted by the [Frankfurt 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 doublet chemotherapy (carboplatin and pemetrexed) delivered intravenously. The trial will assess the safety, tolerability, and initial efficacy of the combination.

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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KEYTRUDA[®] is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

1. According to RECIST1.1 (data cut-off of August 1, 2023).

2. Journal of Clinical Oncology 2020 38:14, 1505-1517, Updated Analysis From KEYNOTE-189: Pembrolizumab or Placebo Plus Pemetrexed and Platinum for Previously Untreated Metastatic Nonsquamous Non-Small-Cell Lung Cancer

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