

ASX/Media Release

Immutep Reaches Enrolment Target for INSIGHT-003 Trial in 1st Line NSCLC

- 20 patients with 1st line non-small cell lung cancer (1L NSCLC) now enrolled in the first triple combination therapy study of efiti with standard-of-care combination of anti-PD-1 therapy and chemotherapy
- Promising initial efficacy results showing a 72.7% response rate and 90.9% disease control rate reported at SITC 2022
- Additional data is expected throughout calendar year 2023 and will further inform our next steps in 1L NSCLC

SYDNEY, AUSTRALIA – 6 February 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 diseases, today announces the investigator-initiated INSIGHT-003 trial has reached its enrolment target of 20 patients with 1L NSCLC. INSIGHT-003 is the first trial evaluating Immutep’s lead product candidate, efitilagimod alpha (“efiti” or “IMP321”) as part of a triple combination therapy with standard-of-care anti-PD-1 therapy and chemotherapy.

Immutep’s CSO & CMO Dr Frederic Triebel said, “The promising initial efficacy and favourable safety results reported in November 2022 from this first triple combination approach instils more confidence in the flexibility of our novel immunotherapy, efiti to be combined with various therapeutics and safely drive superior patient outcomes. We are pleased to have reached our enrolment target and look forward to reporting as the results mature further. Additional data from INSIGHT-003 will help further inform our next steps in 1st line NSCLC.”

In a poster presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting 2022, initial results in 1L NSCLC patients show the triple combination therapy is well-tolerated and provides promising early signals of therapeutic activity with an Objective Response Rate (ORR) of 72.7% (8/11) and a Disease Control Rate (DCR) of 90.9% (10/11). Nine patients had a PD-L1 Tumour Proportion Score (TPS) of <50% and this group reported an encouraging ORR of 66.7% and DCR of 88.9%. Patients with a PD-L1 of <50% represent approximately two-thirds of the 1L NSCLC patient population and are less responsive to anti-PD-1 therapy compared to patients with a PD-L1 TPS of ≥50%.

Additional data from INSIGHT-003 is expected to be presented throughout calendar year 2023. For more information on the study, please see the poster titled ‘*Feasibility of efitilagimod alpha (soluble LAG-3 protein) combined with standard-of-care-therapy in advanced non-small-cell lung cancer (NSCLC). Initial results from INSIGHT 003*’ in the [Posters & Publications section](#) of Immutep’s website.

About INSIGHT-003

INSIGHT-003 is an investigator-initiated study conducted by the Institute of Clinical Cancer Research IKF at Krankenhaus Nordwest in Frankfurt. 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 efi 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 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.

Australian Investors/Media:

Catherine Strong, Citadel-MAGNUS
+61 (0)406 759 268; cstrong@citadelmagnus.com

U.S. Investors/Media:

Chris Basta, VP, Investor Relations and Corporate Communications
+1 (631) 318 4000; chris.basta@immutep.com

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