Patient Enrolment Completed for EFTISARC-NEO Phase II Trial

- Phase II trial evaluating efti in combination with radiotherapy plus KEYTRUDA® (pembrolizumab) in patients with soft tissue sarcoma reaches enrolment target of 40 patients
- Data updates from EFTISARC-NEO expected in 2025

SYDNEY, AUSTRALIA – January 22, 2025 – 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 patient enrolment has been completed in the investigator-initiated EFTISARC-NEO trial. EFTISARC-NEO is evaluating eftilagimod alpha (efti) in combination with radiotherapy plus KEYTRUDA® (pembrolizumab) in the neoadjuvant setting for patients with resectable soft tissue sarcoma (STS).

The Phase II trial conducted by the Maria Skłodowska-Curie National Research Institute of Oncology (MSCNRIO) in Warsaw, the national reference centre for STS in Poland, has reached its enrolment target of 40 patients.

As previously announced, positive data from EFTISARC-NEO was presented at the Connective Tissue Oncology Society (CTOS) Annual Meeting in November 2024. Among 21 patients available for primary endpoint assessment, the triple combination achieved a greater than three-fold increase in tumour hyalinization/fibrosis (median 50%) at the time of surgical resection as compared to a historical median 15% from radiotherapy alone. This is an early surrogate endpoint at the time of surgery as tumour hyalinization/fibrosis has been associated with improved survival for STS patients.[1,2]

Additionally, the treatment has been safe with no grade ≥3 toxicities related to efti and pembrolizumab.

Data updates from EFTISARC-NEO are expected in 2025. For more information on the trial, please visit clinicaltrials.gov (NCT06128863).

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.

1. Schaefer IM et al. Histologic Appearance After Preoperative Radiation Therapy for Soft Tissue Sarcoma: Assessment of the European Organization for Research and Treatment of Cancer-Soft Tissue and Bone Sarcoma Group Response Score. Int J Radiat Oncol Biol Phys. 2017 Jun 1;98(2):375-383. doi: 10.1016/j.ijrobp.2017.02.087. Epub 2017 Feb 24. PMID: 28463157.

2. Rao SR et al. Extent of tumor fibrosis/hyalinization and infarction following neoadjuvant radiation therapy is associated with improved survival in patients with soft-tissue sarcoma. Cancer Med. 2022 Jan;11(1):194-206. doi: 10.1002/cam4.4428. Epub 2021 Nov 27. PMID: 34837341; PMCID: PMC8704179.

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