Immutep's Efti with Radiotherapy & KEYTRUDA® (pembrolizumab) Meets Primary Endpoint in Phase II for Soft Tissue Sarcoma

- Novel combination with efti has met the trial's primary endpoint of tumour hyalinization/fibrosis in the neoadjuvant setting for patients with resectable soft tissue sarcoma
- Detailed results are planned for presentation at a future medical meeting

SYDNEY, AUSTRALIA – May 26, 2025 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces the investigator-initiated EFTISARC-NEO Phase II trial evaluating eftilaginod alpha (efti) with radiotherapy plus KEYTRUDA® (pembrolizumab) in the neoadjuvant setting for resectable resectable soft tissue sarcoma (STS) has met its primary endpoint. The novel combination significantly exceeded the study's prespecified median of 35% tumour hyalinization/fibrosis versus 15% for historical data from radiotherapy alone in patients with resectable soft tissue sarcoma (STS).

Tumour hyalinization/fibrosis is an early surrogate endpoint at the time of surgical resection that has been associated with improved overall survival and recurrence-free survival for STS patients.[1,2] The trial's investigators at the Maria Skłodowska-Curie National Research Institute of Oncology (MSCNRIO) in Warsaw, the national reference centre for STS in Poland, plan to present detailed results from the study at a future medical meeting.

Katarzyna Kozak, M.D., Ph.D., and Paweł Sobczuk, M.D., Ph.D., medical oncologists at the Department of Soft Tissue/Bone Sarcoma and Melanoma at MSCNRIO and the trial's principal investigators, said: "It is very encouraging to see the chemotherapy-free combination with efti far exceed the ambitious target we initially set for the trial's primary endpoint in resectable soft tissue sarcoma. These results support our belief that efti's activation of antigen-presenting cells, and in turn a broad adaptive and innate immune response, helps transform the immunosuppressed tumour microenvironment of soft tissue sarcomas leading to strong anti-cancer efficacy. There remains a very high unmet need in this aggressive orphan cancer indication and we look forward to presenting detailed results at a medical meeting later this year."

As previously announced at the Connective Tissue Oncology Society (CTOS) Annual Meeting in November 2024, the combination therapy demonstrated significant efficacy with a median of 50% tumour hyalinization/fibrosis in a preliminary analysis of 21 patients with resectable STS available for primary endpoint assessment. The EFTISARC-NEO study, which is primarily funded with a grant from the Polish government awarded by the Polish Medical Research Agency program, subsequently completed enrolment of 40 patients in January 2025.

STS is an orphan disease with high unmet medical need and a poor prognosis for patients. The incidence of STS varies in different regions globally. In the United States, the number of new STS cases in 2025 is estimated to be ~13,520 with ~5,420 deaths, according to the American Cancer Society.[3]

For more information on EFTISARC-NEO, visit clinicaltrials.gov (NCT06128863).

About Eftilagimod Alfa (efti)

Efti is Immutep's proprietary soluble LAG-3 protein and MHC Class II agonist that stimulates both innate and adaptive immunity for the treatment of cancer. As a first-in-class antigen presenting cell (APC) activator, efti

binds to MHC (major histocompatibility complex) Class II molecules on APC leading to activation 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 late-stage biotechnology company developing novel immunotherapies for cancer and autoimmune disease. The Company is a pioneer in the understanding and advancement of therapeutics related to Lymphocyte Activation Gene-3 (LAG-3), and its diversified product portfolio harnesses LAG-3's 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.

3. American Cancer Society statistics: https://www.cancer.org/cancer/types/soft-tissue-sarcoma/about/key-statistics.html

Australian Investors/Media:
Catherine Strong, Sodali & Co.
+61 (0)406 759 268; catherine.strong@sodali.com

U.S. 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 CEO of Immutep Limited.