Primary Endpoint Met in EFTISARC-NEO Phase II Evaluating Neoadjuvant Efti in Soft Tissue Sarcoma and Data Presented at ESMO Congress 2025

- Novel combination including eftilagimod alfa (efti) in neoadjuvant setting drives 51.5% tumour hyalinization/fibrosis in patients with soft tissue sarcoma ($p<0.001$)
- High level of tumour hyalinization/fibrosis, achieved across multiple STS subtypes, over 3-fold greater than historical results from standard-of-care radiotherapy alone
- Data from investigator-initiated Phase II selected for Proffered Paper oral presentation

SYDNEY, AUSTRALIA – October, 20, 2025 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces positive data from the EFTISARC-NEO Phase II trial were shared in a Proffered Paper oral presentation by Katarzyna Kozak, M.D., Ph.D., Maria Sklodowska-Curie National Research Institute of Oncology, Warsaw, Poland, at the 2025 European Society of Medical Oncology (ESMO) Congress in Berlin, Germany.

The investigator-initiated Phase II study evaluating eftilagimod alfa (efti) with radiotherapy plus KEYTRUDA® (pembrolizumab) in the neoadjuvant setting for resectable soft tissue sarcoma (STS) met the primary endpoint and significantly exceeded the study's prespecified 35% tumour hyalinization/fibrosis. In the evaluable patient population (N=38), the novel combination with efti reached a median 51.5% tumour hyalinization/fibrosis ($p<0.001$).

This impressive outcome, over three times greater than 15% from standard-of-care radiotherapy alone based on historical data, may hold significance in terms of future outcomes as tumour hyalinization/fibrosis serves as an early surrogate endpoint correlated with enhanced overall survival and recurrence-free survival in STS patients.[1,2]

These promising results were achieved across multiple STS subtypes and the study proved a very good safety profile for the therapy, with only one grade ≥3 toxicity related to immunotherapy.

Dr. Katarzyna Kozak, said: "The novel combination with neoadjuvant efti has significantly exceeded the originally established target for the trial's primary endpoint in resectable soft tissue sarcoma. These outcomes achieved in a diverse population of multiple STS subtypes further substantiate the hypothesis that efti's unique stimulation of antigen-presenting cells, resulting in a robust adaptive and innate immune response, contributes to modifying the immunosuppressed tumour microenvironment and achieving notable anti-cancer efficacy in soft tissue sarcomas. We hope these findings can help pave a path to a new therapeutic option for the substantial unmet medical need in this challenging indication."

Marc Voigt, CEO of Immutep, noted: "We sincerely thank the principal investigators leading this study, as well as the patients and their families for taking part in this important trial. There is a significant unmet medical need for novel therapies in STS that have the potential to provide better outcomes for patients than the current standard of care radiotherapy."

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]

The EFTISARC-NEO study has been primarily funded with a grant from the Polish government awarded by the Polish Medical Research Agency program. For more information on EFTISARC-NEO, visit clinicaltrials.gov (NCT06128863).

The presentation slides can be found on the Posters & Publications page of Immutep's website.

About Eftilagimod Alfa (Efti)

Efti is a novel immunotherapy that directly activates antigen-presenting cells or APCs (e.g. dendritic cells, monocytes) via the MHC Class II pathway to fight cancer. As an MHC Class II agonist, its activation of APCs engages the adaptive and innate immune system to initiate a broad anti-cancer immune response. This includes priming and activating cytotoxic T cells as well as generating important co-stimulatory signals & cytokines that further boost the immune system's ability to combat cancer.

Efti is under evaluation for a variety of solid tumours including non-small cell lung cancer (NSCLC) in a pivotal Phase III trial called TACTI-004 (KEYNOTE-F91), as well as head and neck squamous cell carcinoma (HNSCC), soft tissue sarcoma, and breast cancer. Its favourable safety profile enables various combinations like with anti-PD-[L]1 immunotherapy, radiotherapy, 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

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