Positive Data from Phase II Trial in Soft Tissue Sarcoma Presented at CTOS 2024 Annual Meeting

- Efti in combination with pembrolizumab and radiotherapy demonstrates significant efficacy in the neoadjuvant setting in patients with soft tissue sarcoma
- Over three-fold increase in tumour hyalinization, the primary endpoint of the study and an important predictor of overall survival, as compared to historical results from radiotherapy alone

SYDNEY, AUSTRALIA – 14 November 2024 – 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 the presentation of new data from EFTISARC-NEO, a Phase II investigator-initiated trial of eftilagimod alpha (efti) in combination with radiotherapy plus KEYTRUDA® (pembrolizumab) for patients with soft tissue sarcoma (STS), at the Connective Tissue Oncology Society (CTOS) 2024 Annual Meeting. Based on preliminary analysis among 21 patients available for primary endpoint assessment, the triple combination therapy demonstrates significant efficacy in the neoadjuvant setting for resectable STS.

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 (Warsaw) and the trial's principal investigators, stated: "Our belief in efti's unique mechanism of action to complement radiotherapy and pembrolizumab in order drive better outcomes for patients with this rare aggressive disease was the foundation of the EFTISARC-NEO trial. These very encouraging results we are presenting today build our confidence in the synergistic effects of this new therapeutic approach and its potential to treat these patients in dire need of more effective therapies. In particular, the high level of hyalinization/fibrosis achieved with this novel combination therapy, three-times above historical results from standard radiotherapy, demonstrates remarkable efficacy in patients with resectable soft tissue sarcomas."

In the neoadjuvant setting for patients with resectable STS, the 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 standard radiotherapy alone. In addition to being the primary endpoint of the EFTISARC-NEO study, the tumour hyalinization/fibrosis rate has also been identified as an important predictor of overall survival for STS patients.[1,2]

The EFTISARC-NEO trial, with a data cut-off of 20 October 2024, also showed 71.4% of patients achieved a pathologic response defined as ≥35% of hyalinization/fibrosis and 9.5% of patients achieved a complete pathologic response. The triple combination therapy is safe with no grade ≥3 toxicities related to efti and pembrolizumab.

Dr. Frédéric Triebel, CSO of Immutep, said: "We are pleased with the strength of these preliminary results in this difficult-to-treat cancer. To see 71.4% of soft tissue sarcoma patients achieving a pathologic response defined as ≥35% of hyalinization/fibrosis combined with low viable tumour cells at 8% is very promising, especially as strong efficacy has been observed in different STS subtypes. We look forward to further evaluation of efti's potential as neoadjuvant immunotherapy to help drive improved clinical outcomes."

The ongoing open-label EFTISARC-NEO Phase II study, conducted by the Maria Skłodowska-Curie National Research Institute of Oncology (MSCNRIO) in Warsaw, is expected to reach the planned enrolment of 40 patients in Q1 CY2025. The trial is primarily funded with an approved grant from the Polish government awarded by the Polish Medical Research Agency program. For more information, visit clinicaltrials.gov (NCT06128863).

The CTOS poster is available on the Posters & Publications section of Immutep's website.

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.

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

1. *Schaefer IM, Hornick JL, Barysauskas CM, Raut CP, Patel SA, Royce TJ, Fletcher CDM, Baldini EH. 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, Lazarides AL, Leckey BL, Lane WO, Visgauss JD, Somarelli JA, Kirsch DG, Larrier NA, Brigman BE, Blazer DG, Cardona DM, Eward WC. 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.*

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