Immutep Receives FDA Orphan Drug Designation for Eftilagimod Alfa in Soft Tissue Sarcoma

SYDNEY, AUSTRALIA – April 15, 2026 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a clinical-stage biotechnology company targeting cancer and autoimmune diseases, today announces that the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for eftilagimod alfa ("efti") for the treatment of Soft Tissue Sarcoma (STS), a rare cancer with significant unmet medical need.

The FDA's Orphan Drug Designation program is designed to encourage development of therapies for rare diseases affecting fewer than 200,000 people in the United States. Benefits of ODD may include regulatory support, potential tax credits, fee exemptions, and seven years of market exclusivity upon approval.

This designation recognises the potential therapeutic relevance of efti in STS, supported by encouraging clinical data from the investigator-initiated Phase II EFTISARC-NEO trial which has been evaluating efti in combination with radiotherapy and KEYTRUDA® (pembrolizumab) in the neoadjuvant setting in patients with resectable soft tissue sarcoma. In 38 evaluable patients, the study met its primary endpoint, demonstrating a median tumour hyalinization/fibrosis of 51.5%, significantly exceeding the pre-specified target of 35% and historical benchmarks of ~15% with radiotherapy alone.[1]

These results were observed across multiple sarcoma subtypes and were supported by translational data showing immune activation consistent with efti's mechanism of action, with a favourable safety profile and no delays to planned surgery.[2]

CEO of Immutep, Marc Voigt said: "We are pleased that the FDA has recognised the potential of efti for patients with soft tissue sarcoma, a rare and difficult to treat cancer. As previously communicated, the Company is currently undertaking a comprehensive review and analysis following the discontinuation of its Phase III TACTI-004 trial and the outcome will influence the decision regarding any potential future clinical trial with efti. The FDA's designation, based on very encouraging data from the EFTISARC-NEO trial, provides us with a potential direct step forward into a late-stage study in the neoadjuvant setting for STS."

About Immutep

Immutep is a clinical-stage biotechnology company developing novel immunotherapies for cancer and autoimmune diseases. 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. ESMO Congress 2025 Proffered Paper presentation, "EFTISARC-NEO: A phase II study of neoadjuvant eftilagimod alpha, pembrolizumab and radiotherapy in patients with resectable soft tissue sarcoma".

2. CTOS 2025 Annual Meeting Oral Presentation, "Primary endpoint and translational correlates from EFTISARC-NEO: Phase II trial of neoadjuvant eftilagimod alfa (efti), pembrolizumab and radiotherapy in patients with resectable soft tissue sarcoma".

Australian Investors/Media:
Eleanor Pearson, Sodali & Co.
+61 2 9066 4071; eleanor.pearson@sodali.com

U.S. Investors/Media:
Matthew Beck, astr partners
Ph: +1 (917) 415-1750; matthew.beck@astrpartners.com

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