Immutep Announces Successful Completion of FDA Project Optimus Requirements

- Confirmation of 30 mg efti as optimal biological dose relevant for Immutep's oncology pipeline and potential future Biological License Applications (BLA)
- Registrational TACTI-004 (KEYNOTE-F91) Phase III trial in first line non-small cell lung cancer now in process of opening clinical sites in the United States

SYDNEY, AUSTRALIA – October 13, 2025 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces that positive and straightforward feedback has been received from the US Food and Drug Administration ("FDA") regarding the successful completion of Project Optimus requirements and agreement on 30 mg as the optimal biological dose for eftilagimod alfa (efti).

Immutep's Chief Development Officer, Christian Mueller, said, "We are very thankful for the FDA's positive feedback and productive discussions over the past few years. The alignment on efti's optimal biologic dose has strategic relevance to our efti oncology programs and is a major de-risking event and building block towards future BLA filings. We are excited to successfully conclude this chapter of efti's clinical development and are intently focused on bringing this novel immunotherapy to market to help address the needs of cancer patients worldwide."

The agreement with the FDA on efti's optimal biological dosing carries strategic importance in the ongoing and future clinical development of this first-in-class immunotherapy, including the global TACTI-004 (KEYNOTE-F91) Phase III trial evaluating efti in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab), and chemotherapy as first-line treatment for advanced or metastatic non-small cell lung cancer (1L NSCLC), regardless of PD-L1 expression. With the conclusion of Project Optimus, this registrational study is now in process of opening sites in the United States.

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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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

U.S. Investors/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 Board of Immutep Limited.