Immutep Announces Initiation of TACTI-004 Phase III Trial in First Line Non-Small Cell Lung Cancer

SYDNEY, AUSTRALIA – December 10, 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 initiation of the pivotal TACTI-004 Phase III clinical trial for the treatment of first-line metastatic non-small cell lung cancer (1L NSCLC).

"The receipt of regulatory approval from the Australian Therapeutic Goods Administration to commence the TACTI-004 trial is a significant milestone for Immutep and marks its transformation into a Phase III company. This also represents a key step towards potentially establishing a new standard of care for patients with metastatic NSCLC. We are confident based on the strength of eftilagimod alfa's data that it can make a meaningful difference in cancer patients' lives, and we eagerly anticipate enrolling the first patient into this important study during the first quarter of 2025," said Marc Voigt, CEO of Immutep.

Immutep has successfully completed regulatory submissions to the vast majority of the more than 25 countries that will be part of the global TACTI-004 trial. Australia represents the first approval by all regulatory authorities including ethics committees and Institutional Review Boards (IRB). The Company also anticipates full approval in the United Kingdom shortly as it has received clearances from the Medicines and Healthcare products Regulatory Agency (MHRA) and the Research Ethics Committee (REC). Additional approvals from multiple countries are expected in the weeks and months ahead.

The registrational TACTI-004 Phase III trial will evaluate eftilagimod alfa, a soluble LAG-3 protein that activates dendritic cells, in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) and chemotherapy compared to KEYTRUDA in combination with chemotherapy and placebo in ~750 metastatic 1L NSCLC patients, regardless of PD-L1 expression. The 1:1 randomized, double-blind, multinational, controlled study, with dual primary endpoints of progression-free survival and overall survival, will include over 150 clinical sites in over 25 countries across the globe.

The Company expects to enrol the first patient in Q1 of CY2025.

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

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.

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