

Immutep Receives Positive Feedback from the Spanish Medicines Agency for Upcoming TACTI-004 Registrational Trial in Metastatic Non-Small Cell Lung Cancer

SYDNEY, AUSTRALIA – April 17, 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 it has received positive feedback from the Spanish Agency for Medicines and Health Products (AEMPS) Competent Authority regarding the Company’s upcoming TACTI-004 Phase III trial of eftilagimod alpha (“efti”) for first line treatment of metastatic non-small cell lung cancer (1L NSCLC).

Immutep SVP, Regulatory & Strategy, Christian Mueller commented: “We continue to be pleased with our discussions with regulatory bodies around the world regarding our upcoming pivotal TACTI-004 trial and are thankful for the positive feedback and constructive guidance received by AEMPS. Spain, a member of the EMA’s Committee for Medicinal Products for Human Use (CHMP), represents an important region given the relatively large number of institutions that participated in our TACTI-002 Phase II study evaluating efti in combination with anti-PD-1 therapy in first line non-small cell lung cancer.”

The AEMPS is supportive of Immutep moving into a registrational trial in 1L NSCLC and evaluating efti in combination with an anti-PD-1 therapy in a chemotherapy-free regimen or as a triple combination approach that includes chemotherapy. Among the other items discussed at the meeting were general aspects of the trial design, including selection of the control arm and statistics, and the specificities of the patient population.

Additional interactions with regulatory agencies as well as with other stakeholders and potential partners are ongoing in a productive manner.

About Eftilagimod Alpha (Efti)

Efti is Immutep’s proprietary soluble LAG-3 protein and MHC Class II agonist that stimulates both innate and adaptive immunity for the treatment of cancer. As a first-in-class antigen presenting cell (APC) activator, efti binds to MHC (major histocompatibility complex) Class II molecules on APC leading to activation and proliferation of CD8+ cytotoxic T cells, CD4+ helper T cells, dendritic cells, NK cells, and monocytes. It also upregulates the expression of key biological molecules like IFN- γ and CXCL10 that further boost the immune system’s ability to fight cancer.

Efti is under evaluation for a variety of solid tumours including non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), and metastatic breast cancer. Its favourable safety profile enables various combinations, including with anti-PD-[L]1 immunotherapy 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 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. Immunetep 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.immunetep.com.

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