

ASX/Media Release

## Immutep Announces Successful Meeting with FDA on Phase III Design in Non-Small Cell Lung Cancer

- *Final discussion with the FDA, successfully concluding the regulatory preparations for the TACTI-004 Phase III trial design to evaluate efti in combination with KEYTRUDA<sup>®</sup> (pembrolizumab), MSD's anti-PD-1 therapy, and standard chemotherapy in first-line non-small cell lung cancer*
- *TACTI-004 registrational trial will enrol ~750 patients regardless of PD-L1 expression in order to address the entire 1L NSCLC market eligible for anti-PD-1 therapy*

**SYDNEY, AUSTRALIA – 22 July 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 that positive feedback has been received from the US Food and Drug Administration ("FDA") regarding the planned TACTI-004 Phase III trial of eftilagimod alfa ("efti") in combination with KEYTRUDA<sup>®</sup> (pembrolizumab), MSD's anti-PD-1 therapy, and histology-based platinum doublet chemotherapy for the treatment of first-line metastatic non-small cell lung cancer (1L NSCLC), regardless of PD-L1 expression.

The FDA feedback from this Type C meeting, along with feedback previously received from the Paul-Ehrlich-Institut ("PEI") and the Spanish Agency for Medicines and Health Products ("AEMPS"), concludes the preparatory regulatory interactions for the design of this registrational trial. This marks a significant step forward to develop an effective treatment for non-squamous and squamous 1L NSCLC patients who have high, low, or no PD-L1 expression and are eligible for anti-PD-1 therapy.

The TACTI-004 Phase III trial, which will enrol ~750 patients, is based on the positive efficacy and safety data in 1L NSCLC generated from the TACTI-002 Phase II and INSIGHT-003 trials.

"We are pleased with the FDA's feedback as this allows us to successfully conclude our regulatory preparation for the TACTI-004 registrational trial. This represents a key milestone in our late-stage development process for efti centred on potentially driving a new standard of care globally in the treatment of non-small cell lung cancer. We hope to achieve this through efti in combination with KEYTRUDA, which has led to strong efficacy data with a favourable safety profile in 1L NSCLC patients regardless of PD-L1 expression," stated Christian Mueller, Immutep's SVP, Regulatory and Strategy.

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

### **TACTI-004 (Two ACTIVE Immunotherapies-004) Registrational Phase III Trial Design**

TACTI-004 will be a 1:1 randomized, double-blind, multinational, controlled clinical trial to evaluate Immutep's efti in combination with KEYTRUDA and standard chemotherapy compared to the standard-of-care, KEYTRUDA in combination with chemotherapy and placebo in first-line metastatic non-small cell lung cancer (NSCLC), regardless of PD-L1 expression. In this pivotal PD-L1 all comer trial, the dual primary

endpoints will be progression-free and overall survival with a prespecified futility boundary and a pre-planned interim analysis. The trial will be conducted globally and enrol approximately 750 NSCLC patients (including both squamous and non-squamous subtypes).

#### **About Eftilagimod Alfa (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- $\gamma$  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. 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](http://www.immutep.com).

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