Immutep Outlines Focused Development Strategy for Eftilagimod Alfa ("efti")

- *Future registration-directed clinical development of efti is intended to focus on head and neck squamous cell carcinoma (HNSCC) in patients with negative PD-L1 expression (Combined Positive Score (CPS) < 1) and the neoadjuvant setting of soft tissue sarcoma (STS).*
- *Root cause analysis following the discontinuation of TACTI-004 has identified subtle analytical differences between efti manufactured at 200 L scale and efti manufactured at 2,000 L scale. A new manufacturing run of efti at 200 L scale has been contracted.*
- *This development focus reflects a staged risk/benefit approach consistent with prior interactions with the U.S. Food and Drug Administration (FDA), Orphan Drug Designation granted for STS in April 2026, and Fast Track designation for HNSCC.*
- *Preparations for the next clinical trials have commenced, with study start targeted for 2H CY2027, subject to final decisions on trial design, regulatory interactions, manufacturing timelines, partnering and resources.*

SYDNEY, AUSTRALIA – September 11, 2026 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel immunotherapies, today provides an update on its development strategy for eftilagimod alfa ("efti").

Update on Root Cause Analysis

Following the early discontinuation of the TACTI-004 study, Immutep has been conducting a detailed root cause analysis covering clinical, pharmacological and manufacturing aspects. This ongoing root cause analysis has identified structural differences between the efti used in TACTI-004 and the efti used in earlier successful clinical studies. These differences (e.g. a subtle difference in N-glycan structure) are considered potentially relevant given the markedly different immune activation profile observed in TACTI-004 compared to previous trials and the unexpected clinical outcome of the study.

Based on the currently available data from the Root Cause Analysis to date, Immutep believes that the unexpected outcome of TACTI-004 cannot be explained by clinical factors (e.g. suboptimal protocol, substantial imbalance between treatment arms or safety findings) or trial execution factors (e.g. invalid randomisation pattern or general clinical trial conduct). The Company will provide a further update on completion of the root cause analysis.

New Manufacturing Run

Based on the findings from the root cause analysis to date, Immutep has contracted a manufacturing run of efti at 200 L scale. Ten GMP batches of efti have previously been manufactured at 200 L scale and used in successful Phase I and Phase II clinical studies of efti, including TACTI-mel, TACTI-002 and INSIGHT-003. In contrast, TACTI-004 was conducted exclusively with efti manufactured at 2,000 L scale.

Future Clinical Development Focus

Immutep currently intends to focus the registration-directed clinical development of efti on:

- HNSCC in patients with CPS < 1 — based on clinical efficacy data, including mature overall survival data, in a patient population with high unmet need and limited approved treatment options, and for which efti has received Fast Track designation and FDA feedback that the Company considers constructive; and

- the neoadjuvant setting of STS — based on positive Phase II data, including achievement of the primary endpoint, and for which efti received Orphan Drug Designation from the FDA in April 2026.

This focus reflects the compelling clinical data generated to date, the Company's interactions with the FDA, regulatory designations obtained, unmet medical need and substantial market potential in these indications.

Preparations for the next clinical trials have commenced. Subject to final decisions on strategy and trial design, regulatory interactions, manufacturing timelines, partnering and resources, Immutep is targeting study start during 2H CY2027.

Immutep's licensing partner, Dr. Reddy's Laboratories ("DRL"), has been consulted on and is supportive of this approach. The Company is also in preliminary discussions with other parties regarding the proposed development pathway.

Immutep CEO, Marc Voigt, said: "Based on the totality of evidence generated with efti, we believe there is a scientifically and clinically justified path to continue its development. This includes clinical and translational data across multiple tumour types, consistent evidence of immune activation, encouraging results in soft tissue sarcoma and head and neck cancer with CPS < 1, and constructive regulatory interactions. At the same time, we fully recognise the significance of the TACTI-004 outcome. Our root cause analysis remains ongoing, including further investigation of smaller differences identified between product batches. We intend to apply these learnings rigorously and focus future potential development on settings where the clinical evidence, biological rationale, time-to-market and unmet medical need are most compelling."

Other Programs

Immutep's LAG-3 portfolio extends beyond efti. Development of IMP761, the Company's agonist anti-LAG-3 antibody for autoimmune disease, continues in line with previously disclosed plans.

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 and cytokines that further boost the immune system's ability to combat cancer.

Efti's favourable safety profile has enabled various combinations, including with anti-PD-[L]1 immunotherapy, radiotherapy, and/or chemotherapy. Efti has received Fast Track designation in 1st line HNSCC and in 1st line NSCLC, and Orphan Drug Designation in STS, from the United States Food and Drug Administration (FDA).

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.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding anticipated clinical development, regulatory progress and potential benefits of eftilagimod alfa (efti) and IMP761. These forward-looking statements are based on current expectations, estimates and projections, and involve known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from those expressed or implied in such statements.

Factors that could cause actual results to differ materially include risks associated with clinical trial outcomes, the ongoing root cause analysis, manufacturing, the ability to reach agreement with regulators on trial design and registrational pathways, the outcome of partnering discussions, and the Company's ability to obtain additional funding and to advance its product candidates. Additional risks are described in the Company's most recent Annual Report on Form 20-F and subsequent filings with the U.S. Securities and Exchange Commission and in announcements lodged with the ASX. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this release. Immutep undertakes no obligation to update or revise such statements, except as required by applicable law.

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