ASX/Media Release

Immutep receives FDA and IRB approval in the US for Phase IIb TACTI-003 trial in HNSCC

- Regulatory steps completed with the competent authority (FDA) and institutional review board (IRB) approval received in the United States to commence TACTI-003
- Patient recruitment into the trial is expected to begin within this quarter with European and Australian sites expected to follow

SYDNEY, AUSTRALIA – 6 July 2021 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel LAG-3 related immunotherapy treatments for cancer and autoimmune disease, announces it has completed all the necessary competent authority steps with the US Food and Drug Administration (FDA) and has received IRB approval to commence its phase IIb TACTI-003 trial in the United States. Patient recruitment for the TACTI-003 trial is expected to begin within this quarter.

TACTI-003 will evaluate the Company's lead product candidate, eftilagimod alpha ("efti" or "IMP321"), in combination with MSD's KEYTRUDA® (pembrolizumab) as a first line therapy in approximately 154 patients with Head and Neck Squamous Cell Carcinoma (HNSCC). It is a randomised, controlled clinical study that will take place across Australia, Europe and the United States of America in up to 35 clinical sites.

Immutep was granted Fast Track designation for efti to treat 1st line HNSCC patients by the US FDA in early April 2021.

Pending approval by the European and Australian competent authorities and ethics committees, Immutep expects to broaden its recruitment sites into these regions.

Commenting on the start of the TACTI-003 trial, Immutep CSO and CMO Frédéric Triebel said: "We are delighted to start our new TACTI-003 trial in 1st line HNSCC patients to evaluate efti in combination with pembrolizumab vs pembrolizumab monotherapy. Results we reported from this therapeutic combination earlier in June at ASCO in the 2nd line setting were robust, with sustained and durable responses. We look forward to deepening these results with a larger group of 1st line HNSCC patients in TACTI-003."

About TACTI-003

TACTI-003 is a Phase IIb clinical trial in 1st line Head and Neck Squamous Cell Carcinoma (HNSCC). It will evaluate efti in combination with MSD's KEYTRUDA® (pembrolizumab) as a first line therapy in unresectable recurrent or metastatic HNSCC patients with PD-L1 negative and PD-L1 positive (CPS ≥1) tumors. It will be a randomised, controlled clinical study in approximately 154 first line HNSCC patients and will take place across Australia, Europe and the United States of America in up to 35 clinical sites.

The study will evaluate the safety and efficacy of efti in combination with pembrolizumab, compared to pembrolizumab alone in 1st line metastatic or recurrent HNSCC patients with PD-L1 positive (CPS ≥1) tumors (cohort A), and determine the efficacy and safety of efti plus pembrolizumab in patients with PD-L1 negative tumors (CPS <1) (cohort B). According to the current plans, about 130 patients in cohort A will be randomised 1:1 to receive either efti plus pembrolizumab or pembrolizumab alone. Subjects in cohort B (up to 24 patients) will receive a combination of efti and pembrolizumab.

The primary endpoint of the study is the Overall Response Rate (ORR) according to RECIST 1.1. and iRECIST will be used for treatment decisions. Secondary endpoints include OS and Progression Free Survival (PFS).

About Immutep
Immutep is a globally active biotechnology company that is a leader in the development of LAG-3 related immunotherapeutic products for the treatment of cancer and autoimmune disease. Immutep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximize value to shareholders. Immutep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Immutep's current lead product candidate is eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3 fusion protein (LAG-3Ig), which is a first-in-class antigen presenting cell (APC) activator being explored in cancer and infectious disease. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease. Additional LAG-3 products, including antibodies for immune response modulation, are being developed by Immutep's large pharmaceutical partners.

Further information can be found on the Company's website www.immutep.com or by contacting:

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