ASX/Media Release

Immutep Announces Expansion of TACTI-002 Collaboration Trial

- Additional 74 patients with 1st line non-small cell lung cancer (NSCLC) to be enrolled, more than tripling patient numbers in this indication
- Follows encouraging interim data from 1st line NSCLC patients
- First Patient is expected to be enrolled in the expanded trial by the end of 2020
- Separately, Immutep has initiated planning for a new randomized, controlled Phase II trial in 1st line Head and Neck Squamous Cell Carcinoma (HNSCC) advancing efti into late stage clinical trials in this indication

SYDNEY, AUSTRALIA – 19 November 2020 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) announces it is advancing clinical development for its lead product candidate eftilagimod alpha ("efti" or "IMP321") through the expansion of its ongoing TACTI-002 study and a new Phase II trial.

TACTI-002 Expansion with Merck & Co, Inc., Kenilworth, NJ, USA
Immutep has expanded its collaboration trial with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada) to include an additional 74 patients with 1st line NSCLC (Part A), the most advanced part of its ongoing Phase II TACTI-002 clinical trial evaluating efti with MSD's KEYTRUDA® (pembrolizumab, an anti PD-1 treatment). The expansion extends Immutep's existing clinical trial collaboration and supply agreement with MSD (announced on 12 March 2018).

Additional clinical sites will be added to the existing 12 study centres across Australia, Europe, and the US and the first patient is expected to be enrolled in the expanded trial by the end of 2020. The additional 74 patients in Part A will receive the same treatment regimen and dosing schedule.

The expansion follows the encouraging interim data presented at SITC as announced on 10th November 2020 including an Overall Response Rate (ORR) of 39.4% in evaluable patients (n=36), Disease Control Rate of 66.7% and two complete responses (complete disappearance of all lesions) from 1st line NSCLC patients enrolled in Part A. In addition, efti plus pembrolizumab continues to be safe and well tolerated with no new safety signals reported so far.

Immutep CEO, Marc Voigt said: "We are excited to expand our collaboration trial with MSD, one of the world's leading immuno-oncology companies. The interim results reported from 1st line NSCLC patients have been consistently encouraging and signal good efficacy, particularly for low PD-L1 expressing patients who do not typically respond to immune checkpoint therapy. Not only does this give us great confidence expanding the TACTI-002 trial, but it also validates our strategy to form and grow multiple collaborations with innovative large pharma companies, such as MSD, that are seeking to augment the efficacy of their existing approved products, like Keytruda."

Immutep Commences Planning for New Phase II Clinical Trial in Head and Neck Cancer
Separately, Immutep has commenced planning for a new Phase II, randomised, controlled clinical study in approximately 160 1st line HNSCC patients. Patients will be 1:1 randomised to receive efti in combination with an anti-PD-1 treatment, or anti-PD-1 monotherapy. The trial is intended to take place across clinical sites in the United States, Australia and Europe.

Immutep CEO, Marc Voigt said: "Efti has shown very encouraging results in head and neck cancer in the 2nd line setting with PD-X naïve patients as demonstrated by the results reported at SITC. This has given us great confidence to explore it as a therapy in the commercially more relevant 1st line therapy setting and we have initated planning for a new randomized clinical study. We hope to share additional details in the near future. This advances our development program into later stage clinical development."

About the TACTI-002 Trial

TACTI-002 (Two ACTive Immunotherapies) is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada). The study is evaluating the combination of efti with MSD's KEYTRUDA® (pembrolizumab) in up to 183 patients with second line head and neck squamous cell carcinoma or non-small cell lung cancer in first and second line.

The trial is a Phase II, Simon's two-stage, non-comparative, open-label, single-arm, multicentre clinical study that is taking place in study centres across Australia, Europe, and the US.

Patients participate in one of the following:

- Part A - First line Non-Small Cell Lung Cancer (NSCLC), PD-X naive
- Part B - Second line NSCLC, PD-X refractory
- Part C - Second line Head and Neck Squamous Cell Carcinoma (HNSCC), PD-X naive

TACTI-002 is an all comer study in terms of PD-L1 status, a well-known predictive marker for response to pembrolizumab monotherapy especially in NSCLC and HNSCC. PD-L1 expression is typically reported in three groups for NSCLC: < 1%, 1-49% and ≥ 50% (Tumour Proportion Score or TPS) and in HNSCC: < 1%, 1-19% and ≥ 20% (Combined Positive Score or CPS). Patients with a high PD-L1 status are typically more responsive to anti-PD-1 therapy such as pembrolizumab, whereas those with low PD-L1 status are overall significantly less responsive. Pembrolizumab monotherapy is registered in the US and the EU for first line NSCLC patients with a TPS score ≥ 1% (US) and ≥ 50% (EU), reflecting 65% and 30% of all first line NSCLC patients, respectively. Pembrolizumab monotherapy is registered in the US (regardless of PD-L1 expression) and EU (≥ 50% TPS score) for second line HNSCC patients.

More information about the trial can be found on Immutep's website or on ClinicalTrials.gov (Identifier: NCT03625323)

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:

Australian Investors/Media:
Catherine Strong, Citadel-MAGNUS
+61 (0)406 759 268; cstrong@citadelmagnus.com

U.S. Media:
Tim McCarthy, LifeSci Advisors
+1 (212) 915.2564; tim@lifesciadvisors.com

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