ASX/Media Release

Immutep Completes Recruitment of Initial Cohort in 1st Line NSCLC Patients for TACTI-002 Trial

• Recruitment for 2nd line (PD-1 refractory) NSCLC and 2nd line HNSCC cohorts of the TACTI-002 trial, conducted in collaboration with MSD, are ongoing
• Initial data from the TACTI-002 study expected mid-2019

SYDNEY, AUSTRALIA – June 13th, 2019 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, announces that 17 patients have been enrolled into the first cohort of the first line non-small cell lung cancer (NSCLC) arm (Part A) of the Phase II TACTI-002 clinical trial. This completes patient recruitment of the initial cohort of the study Part A. TACTI-002 is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada).

Patient enrollment for TACTI-002 commenced in early 2019, with the first patient being dosed in March 2019.

Under the Simon’s two-stage design, the initial cohort of first line NSCLC patients may be enlarged by a further 19 patients, if a pre-defined number of responses are observed. Ten study centers are now recruiting patients into the trial across the U.S., Europe and Australia, with three additional sites expected to commence recruitment in the coming months.

Dr Frederic Triebel, Immutep CSO and CMO, commented, “Efti has a unique mode of action. As an antigen presenting cell activator, it is successful in activating dendritic cells that process and present antigens for recognition by the T cell receptor on T lymphocytes. Efti is the only antigen presenting cell activator targeting MHC class II molecules currently in clinical development, setting it apart from other immunoncology therapies in the landscape.

It is very encouraging that we are achieving such positive traction with recruitment for our TACTI-002 study of efti, which commenced dosing patients just over three months ago. We expect to report the first data from this trial in mid-2019.”

Recruitment is ongoing for the initial cohorts of the 2nd line NSCLC and 2nd line HNSCC of the Phase II TACTI-002 clinical trial. These cohorts may also be enlarged if a pre-defined number of responses are observed.

About TACTI-002 Phase II 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 Immutep’s lead product candidate eftilagimod alpha (“efti” or “IMP321”) with MSD’s KEYTRUDA® (or pembrolizumab, an anti-PD-1 therapy) in up to 109 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, multi centre clinical study that is taking place in up to 13 study centres across the U.S., Europe and Australia.

About Immutep

Immutep is a globally active biotechnology company that is a leader in the development of 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-3Ig fusion protein based on the LAG-3 immune control mechanism. This mechanism plays a vital role in the regulation of the T cell immune response. Efti is currently in a Phase IIb clinical trial as a chemoimmunotherapy for metastatic breast cancer termed AIPAC (clinicaltrials.gov identifier NCT02614833); a Phase II clinical trial being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada) referred to as TACTI-002 (Two ACTive Immunotherapies) to evaluate a combination of efti with KEYTRUDA® (pembrolizumab) in several different solid tumours (clinicaltrials.gov identifier NCT03625323); a planned Phase I clinical trial in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. referred to as INSIGHT-004 to evaluate a combination of efti with avelumab (clinical trials.gov identifier NCT03252938); and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT02676869).

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

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