ASX/Media Release

Immutep Completes Patient Enrolment of the AIPAC Phase IIb Clinical Trial in Metastatic Breast Cancer

- 226 patients with metastatic breast cancer have been enrolled in the AIPAC study
- Combination of eftilagimod alpha, an antigen presenting cell (APC) activator, administered in combination with chemotherapy is designed to boost the T-cell immune responses against tumours
- Read-out of progression-free survival (PFS) primary endpoint expected to occur in Q1 of calendar year 2020

SYDNEY, AUSTRALIA – June 25, 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 it has completed patient enrolment of the Phase IIb Active Immunotherapy PAClitaxel (AIPAC) clinical trial in HER2-negative/ Hormone Receptor positive (HR^+) metastatic breast cancer (MBC).

The AIPAC study has enrolled 226 patients at more than 30 clinical trial sites across Germany, the UK, France, Hungary, Belgium, Poland and the Netherlands. The trial is evaluating Immutep's lead product candidate, eftilagimod alpha (efti or IMP321), in combination with paclitaxel, a standard of care chemotherapy, as a chemo-immunotherapy combination in patients with HR^+ MBC not eligible for human epidermal receptor 2 (HER2) therapies. This combination is designed to boost the immune response against tumour cells compared to chemotherapy plus placebo. Apoptotic tumour cells induced by chemotherapy release antigenic tumour debris which are then captured by APCs. Boosting the APC network with efti increases cytotoxic T-cell responses which complements the direct cytotoxic effect of the chemotherapy.

The primary endpoint of the AIPAC study is PFS according to RECIST as evaluated by blinded independent central readers. Additional efficacy endpoints include PFS by local read, overall response rate (ORR) and overall survival (OS). The Company expects to report PFS data, together with ORR data, in Q1 of calendar year 2020.

AIPAC is a potentially pivotal clinical trial, meaning it could serve as a basis to pursue appropriate regulatory approval pathways for efti with, for example, the European Medicines Agency (EMA) or the U.S. Food and Drug Agency (FDA), subject to sufficient and clinically meaningful data from the trial and regulatory interactions. Before AIPAC started, the Company received scientific advice from the EMA and is currently exploring ways to bridge its research efforts in HR^+ MBC to the United States.

Metastatic breast cancer, also called stage IV breast cancer, is the most advanced stage of breast cancer where it has spread beyond the breast to other organs in the body, most often the bones, lungs, liver or brain. It is estimated that each year there are over 800,000 new cases worldwide of MBC that are HER2 negative and HR positive[1]. Paclitaxel is a taxane-based standard of care chemotherapy that is widely used for patients in the EU and United States with this cancer.

[1] GlobalData PharmaPoint: HER2-Negative/HR+ and Triple Negative Breast Cancer – Global Drug Forecast and Market Analysis to 2025, December 2016

Immutep CEO Marc Voigt commented: "The completion of recruitment for our Phase IIb AIPAC study is an important milestone for Immutep as this is our largest and most advanced clinical trial. As the first PFS data read-out is event-driven, the timeline for reporting remains on track for early in 2020. We sincerely thank our principal investigators, the patients and their families for being part of this study.

MBC is a serious medical condition where patients have a median life expectancy of approximately two years from the start of first line chemotherapy. This means there is a clear high unmet medical need for new therapies that may deliver improved outcomes compared to current standard of care therapies."

AIPAC Principal Investigator Dr Hans Wildiers added: "By combining efti with chemotherapy, we hope to boost the body's immune response against tumour cells and improve treatment outcomes compared to giving chemotherapy alone. Most studies in metastatic breast cancer, including immune therapy, are focusing on blocking the PD-1/PD-L1 checkpoint pathway, but results have been disappointing in this type of hormone sensitive metastatic breast cancer. With efti, we hope to activate the immune system more efficiently in hormone sensitive metastatic breast cancer, the most frequent breast cancer subtype. Through the AIPAC study, we are leading the search for effective immune therapy in this subtype."

Immutep CSO and CMO, Dr Frederic Triebel said: "APC activators are a new class of drug products that could nicely complement the action of standard of care, either chemotherapy or immune checkpoint inhibitors. Despite recent positive announcements including preliminary anti-CD40 agonist mAb data in a difficult-to-treat "cold tumor" indication such as advanced pancreatic carcinoma, this new class of IO drug products has not yet been validated in a pivotal trial in terms of efficacy. We hope that the results of the AIPAC trial will unequivocally demonstrate the value of APC activators in combined advanced cancer therapies."

About AIPAC

Active Immunotherapy PAClitaxel (AIPAC) is a Phase IIb clinical trial in HER2-negative/ HR positive metastatic breast cancer. Based on Immutep's LAG-3 technology, the study evaluates the combination of the Company's lead product candidate, eftilagimod alpha (efti, LAG-3Ig or IMP321), and a taxane-based chemotherapy, called paclitaxel, as an immunotherapy. This combination is aimed at boosting the immune response against tumour cells compared to chemotherapy alone. In AIPAC, 226 hormone receptor positive metastatic breast cancer patients are randomised 1:1 to treatment A (paclitaxel chemotherapy plus placebo) or treatment B (paclitaxel chemotherapy plus eftilagimod alpha) for six months. Thereafter, patients will pass over to the maintenance phase with efti alone.

The primary endpoint of the study is progression-free survival (PFS). The Company expects to report first PFS data in Q1 of calendar year 2020.

For more information regarding the AIPAC trial, visit clinicaltrials.gov (identifier NCT02614833) and https://www.ncbi.nlm.nih.gov/pubmed/30977393).

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; 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 Phase I clinical trial being conducted 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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