

ASX/Media Release (Code: ASX: IMM; NASDAQ: IMMP)

# Immutep Presents Positive New Data from Ongoing TACTI-mel Study at Society for Immunotherapy of Cancer (SITC) 2018 Annual Meeting

**SYDNEY, AUSTRALIA – November 12, 2018 –** <u>Immutep Limited</u> (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, today announced new positive interim data from its TACTI-mel Phase I clinical trial, presented at the 33<sup>rd</sup> Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in Washington, D.C., U.S.

The TACTI-mel study is evaluating the use of eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3Ig fusion protein based on the LAG-3 immune control mechanism, in combination with anti-PD-1 therapy KEYTRUDA<sup>®</sup> (pembrolizumab) for unresectable or metastatic melanoma.

In an oral presentation, Prof. Adnan Khattak, Consultant Medical Oncologist at Fiona Stanley Hospital and a principal investigator of the on-going TACTI-mel study, showed efficacy and safety data from 18 patients in part A, the dose escalation part of the study, and first safety data from 6 patients in part B.

In part A, dose escalation, combination therapy started after four cycles of KEYTRUDA<sup>®</sup> monotherapy. In part B, patients were treated with the combination from the first day of treatment i.e. receiving efti from day one, cycle one with KEYTRUDA<sup>®</sup>.

The efficacy data from part A was encouraging and supportive of previously disclosed response rates with a 33% Overall Response Rate (ORR) when measured from start of the combination at cycle 5 of KEYTRUDA<sup>®</sup>. The ORR was 61% when measured from the start of KEYTRUDA<sup>®</sup> monotherapy treatment in an explorative analysis measuring from cycle 1, day 1. A disease control rate of 66% was reported from the combination treatment. The patient population was partly pre-treated before the start of KEYTRUDA<sup>®</sup>, suboptimally responding to KEYTRUDA<sup>®</sup> and the majority had increased risk factors.

In both parts (A and B), combination therapy has been well tolerated with no dose-limiting toxicities and local erythema and injection site reactions as the most common side effects. Importantly the safety data of part B supports the dose scheduling of the Company's planned Phase II TACTI-002 clinical study in collaboration with MSD.

Dr. Frédéric Triebel, Immutep's Chief Scientific Officer and Chief Medical Officer, also commented "We were honored to have been selected for an oral presentation of the data which further supports our hypothesis that combining efti with a checkpoint inhibitor results in a combinatory therapeutic benefit to patients, pushing the accelerator and releasing the brake of the immune system. The data also highlights the excellent safety profile of efti, when combined with an anti-PD-1 therapy."

Prof. Adnan Khattak commented, "We are very pleased with the responses we have observed in this patient population. These patients had a sub-optimal response to pembrolizumab monotherapy. However, after



participating in the TACTI-mel study, we have seen good responses in these patients, with a very encouraging overall response rate."

The data was also presented in a poster presentation titled "Results from a Phase I dose escalation trial (TACTI-mel) with the soluble LAG-3 protein (IMP321, eftilagimod alpha) together with pembrolizumab in unresectable or metastatic melanoma."

The trial design of the Company's planned Phase II TACTI-002 clinical study in collaboration with MSD was presented at SITC in a poster titled, "A Multicenter, Phase II Study in Patients With First Line NSCLC, or Recurrent PD-X Refractory NSCLC or With Recurrent HNSCC Receiving Eftilagimod Alpha in Combination With Pembrolizumab (TACTI-002)".

Dr. Frédéric Triebel, Immutep's Chief Scientific Officer and Chief Medical Officer, commented, "We are looking forward to the initiation of TACTI-002 later this year and I believe the clinical trial collaboration and supply agreement that we entered into with MSD earlier this year, as well as the recently announced agreement with Merck KGaA and Pfizer Inc., further supports the development of efti in combination with PD-1 and PD-L1 therapeutics."

The TACTI-mel poster and presentation, along with the TACTI-002 poster are available on Immutep's website under the "Investor & Media" tab at <u>www.immutep.com/investors-media/presentations</u>.

# About the TACTI-mel clinical trial

The ongoing TACTI-mel (Two ACTive Immunotherapies in melanoma) Phase I clinical trial is a multi-center, open-label, dosing escalating (1, 6 or 30 mg of eftilagimod alpha or "efti") study evaluating the combination of efti with pembrolizumab, in unresectable or metastatic melanoma patients that have had either a suboptimal response or had disease progression with pembrolizumab monotherapy (clinicaltrials.gov identifier NCT 02676869).

In Part A of the study, the combination therapy starts at treatment cycle 5 (of pembrolizumab) for 6 months and consists of three cohorts of six patients. Part B is an expansion of the initial study by an additional cohort of 6 patients that receive 30 mg of efti in combination with pembrolizumab starting at cycle 1 and with a treatment duration of 12 months.

### 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's current lead product 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 NCT 02614833); a Phase II clinical trial referred to as TACTI-002 (Two ACTive Immunotherapies) to evaluate a combination of Efti with KEYTRUDA<sup>®</sup> (pembrolizumab) in several different solid tumours (clinicaltrials.gov identifier NCT03625323); a planned Phase I clinical trial referred to as INSIGHT-004 to evaluation a combination of Efti with avelumab<sup>\*</sup> (clinical trials.gov identifier NCT03252938) and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT 02676869). Additional LAG-3 products, including antibodies, for immune response modulation in autoimmunity and cancer are being developed by Immutep's large pharmaceutical partners. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

Immutep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

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

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