

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

# New Data from Ongoing TACTI-mel Study in Unresectable or Metastatic Melanoma Presented at the 4<sup>th</sup> Annual ICI Europe Summit

SYDNEY, AUSTRALIA – November 27, 2018 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), announces new data from its ongoing TACTI-mel Phase I clinical trial is being presented at the 4<sup>th</sup> Annual ICI Europe Summit in Berlin, Germany by Dr. Frédéric Triebel, Immutep's Chief Scientific Officer and Chief Medical Officer. The study is evaluating the combination of eftilagimod alpha ("efti" or "IMP321"), Immutep's lead product candidate, in combination with anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in 24 patients with unresectable or metastatic melanoma.

The multi-center, open-label clinical trial includes four cohorts of six patients each testing different dosages of efti, including 1 milligram (mg), 6 mg and 30 mg, in combination with pembrolizumab. This latest data includes more mature data from the first three cohorts (part A, the dose escalation part of the study) where the combination treatment begins at cycle 5 of pembrolizumab treatment and the first efficacy data from the fourth cohort (part B) where the combination treatment is administered to patients from the beginning of cycle 1, day 1 of pembrolizumab treatment.

Key findings from part B (n=6) were as follows:

- High risk patient population with 100% M1c status, 83 % elevated LDH and 50% ECOG 1;
- 5 out of 6 patients had at least one CT scan post study start; 1 patient died before first staging (not drug related);
- After 3 months, 3 out of 6 patients experienced a partial response, a 50% overall response rate ("ORR") according to immune related response criteria ("irRC");
- The current disease control rate for this group is 66% (4/6);
- No dose limiting toxicity ("DLT") or new safety signal have been observed when the combination treatment (efti plus pembrolizumab) is administered to patients beginning cycle 1, day 1 of pembrolizumab treatment; and
- Treatment is ongoing in 4 patients.

Key findings from part A (n=18) were as follows:

- Long lasting and durable responses (up to 27 months) continue to be observed in a subset of patients;
- 13 patients (72%) were progression free at 6 months, if calculated from cycle 1, day 1 of pembrolizumab treatment;
- ORR of 33% (6/18) was reported according to the protocol when measured from start of combination treatment (cycle 5 of pembrolizumab treatment) in patients with suboptimal response to pembrolizumab monotherapy;



- Exploratory overall response rate ("ORR") of 61% (11/18 patients) when tumor size is measured starting from cycle 1, day 1 of pembrolizumab monotherapy and following combination therapy (which starts at cycle 5 of pembrolizumab treatment) according to irRC; and
- No new safety signals have been observed.

"We are very pleased by this initial data which further supports our hypothesis that the combination of efti and pembrolizumab may be a hopeful solution for cancer patients," said Frederic Triebel, CSO and CMO of Immutep. "Based on these encouraging results we are looking forward to the start of our TACTI-002 trial where exactly this combination will be tested in three different cancer indications."

The presentation slides are available on the Company's website at <a href="https://www.immutep.com/investors-media/presentations.html">https://www.immutep.com/investors-media/presentations.html</a>

#### About the TACTI-mel clinical trial

The ongoing TACTI-mel (<u>Two ACT</u>ive <u>Immunotherapies in melanoma</u>) Phase I clinical trial is a multi-center, open-label study evaluating the combination of eftilagimod alpha ("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).

Part A of the study is dosing escalating (1, 6 or 30 mg of efti), starting the combination treatment at cycle 5 in three cohorts of six patients with a treatment duration of 6 months. Part B of the study includes an additional cohort of 6 patients at 30 mg of efti in combination with pembrolizumab, starting at cycle 1, day 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 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 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 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 <a href="www.immutep.com">www.immutep.com</a> or by contacting:

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