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Immutep Announces Data from Ongoing TACTI-mel Phase I Clinical Trial in Unresectable or Metastatic Melanoma

Presented at the World Immunotherapy Congress USA 2019

SYDNEY, AUSTRALIA – 6 March 2019 - Immutep Limited (ASX: IMM; NASDAQ: IMMP) (Immutep or the Company), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, today announced positive, more mature data from its ongoing TACTI-mel phase I clinical study of the Company’s lead product candidate, eftilagimod alpha (“efti” or “IMP321”). The data will be presented at the World Immunotherapy Congress 2019 in San Diego USA, by Dr. Frédéric Triebel, Immutep’s Chief Scientific Officer and Chief Medical Officer at 3:00 PM Pacific Standard Time on 5th March 2019.

The TACTI-mel study is evaluating the combination of efti with anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in 24 patients with unresectable or metastatic melanoma. It is a multi-center, open-label clinical trial that involves four cohorts of six patients, each cohort testing different dosages of efti, including 1 milligram (mg), 6 mg and 30 mg, in combination with pembrolizumab.

Part A of the study is starting the combination therapy at cycle 5 of the pembrolizumab treatment in three cohorts with a treatment duration of 6 months. Part B of the study includes a 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.

Key findings from the ongoing trial were as follows:

	Part A (starting cycle 5 of pembro therapy) N=18	Part B (starting day 1 cycle 1 of pembro therapy) N=6
Overall Response Rate (ORR)	33% (61%*)	50%
Disease Control Rate (DCR)	66%	66%

*Exploratory ORR when tumour size is measured according to irRC from day 1 of cycle 1 of pembrolizumab and following combination therapy (which starts at cycle 5 of pembrolizumab treatment).

Safety results (total n=24):

- Efti has very favorable safety profile in doses up to 30 mg administered s.c. every 2 weeks;
- Combination with PD-1 antagonists is feasible without dose limiting toxicity (DLTs) or reaching MTD; and
- No DLT or new safety signal have been observed in either part of the study.

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Notes to the results

Part B

- All patients high risk with 100% M1c status, 83% elevated LDH and 50% ECOG 1;
- Very deep responses with 1 patient having complete disappearance of target lesions at 3 months already; and
- Treatment is ongoing (6+ months) in 4 patients.

Part A

- Late stage (78 % M1C stage, 38 % elevated LDH) patients sub-optimally responding to pembrolizumab monotherapy;
- Long lasting and durable responses (up to 30 months) continue to be observed in a subset of patients, 4 patients still in PFS follow-up; and
- Tumor shrinkage in 56% of patients incl. 2 patients with complete disappearance of all target lesions.

The full presentation slides from this event can be accessed via Immutep's website.

Immutep CSO and CMO, Frédéric Triebel, CEO, Marc Voigt and Director of Clinical Development, Christian Mueller will discuss the data, along with the clinical development program for IMP321, including other trials, on a global webcast in the coming weeks. Details of the webcast will be announced separately.

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 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).

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 (clinicaltrials.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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