ASX/Media Release

Immutep Reports First Results from INSIGHT-004 Study

- First data from this collaboration study with Merck KGaA, Darmstadt, Germany, and Pfizer Inc and sponsor, IKF, presented at ASCO
- Encouraging early activity signals in a variety of cancer indications
- Overall, 33% of patients showed a Partial Response to the combination therapy of eftilagimod alpha and avelumab, with three patients not yet evaluable
- Eftilagimod alpha continues to be well tolerated, including in combination with avelumab
- Further data expected to be reported throughout 2020

SYDNEY, AUSTRALIA – 1 June 2020 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) is pleased to report first interim data from its ongoing INSIGHT-004 Phase I clinical trial. The study is a phase I trial evaluating the combination of Immutep's lead product candidate, eftilagimod alpha ("IMP321" or "efti") with avelumab, a human anti-PD-L1 antibody, in 12 patients with solid cancers. Avelumab is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc. The data was reported in a short talk poster presentation by Dr Thorsten O. Goetze, trial investigator, at the virtual event for the 2020 American Society of Clinical Oncology's (ASCO) Annual Meeting. The poster presentation from Dr Goetze is available on the company's website (click here).

INSIGHT-004 is the fourth arm of the investigator-initiated INSIGHT trial which is being conducted by the Institute of Clinical Cancer Research IKF at Krankenhaus Nordwest in Frankfurt. It is being conducted under Immutep's collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer Inc., and is evaluating the safety, tolerability and recommended Phase II dose of efti when given in combination with avelumab. Patients in cohort 1 receive 6mg doses of efti every two weeks with the standard dose of avelumab (800mg every two weeks), while patients in cohort 2 receive a higher dose of efti, 30mg, with avelumab.

INSIGHT-004 reached full recruitment in April 2020 and has recruited patients in different solid tumors, primarily with gastrointestinal indications. It is the first combination trial of an approved and marketed anti-PD-L1 drug and efti.

Prof Salah-Eddin Al-Batran, INSIGHT-004 trial investigator and Director of Oncology at IKF said: "It is good to see a number of patients are responding to the combination therapy of efti and avelumab, particularly as three patients in cohort 2 are still very early on in their treatment and haven't yet been assessed. INSIGHT-004 is progressing well and we are pleased that efti continues to be safe and well tolerated by patients. These patients typically are heavily pretreated and do not have any good therapy options."

Interim Activity

Tumor response – according to RECIST 1.1	**Total** N (%) Total (N=12)
Complete Response (CR)	0 (0)
Partial Response (PR)	4 (33%)
Stable Disease (SD)	1 (8%)

Progressive Disease (PD)	4 (33%)
Not yet assessed	3
Objective Response Rate (ORR)	**4 (33%)**
Disease Control Rate (DCR)	**5 (42%)**

Summary

- 33% of patients (4 out of 12) showed a partial response (PR) to the combination therapy according to RECIST 1.1.
- In cohort 2, 3 patients out of 6 have not yet had their response assessed but are still under therapy without clinical signs of tumour progression
- Encouraging single PR cases, one in esophagogastric junction carcinoma, one in colon adenocarcinoma, one in squamous cell anal carcinoma and one in pleural mesothelioma

Safety

Interim results from the first cohort in the trial show that the combination treatment is well tolerated with no dose limiting toxicities, building on efti's strong safety profile to date. Safety data from cohort 2 will be reported at a later date.

About Immutep

Immutep is a globally active biotechnology company that is a leader in the development of LAG-3 related 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-3 protein (LAG-3Ig) 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 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 (clinicaltrials.gov identifier NCT03252938); and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT02676869).

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.

This announcement was authorised for release by the Board of Immutep Limited.

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