ASX/Media Release

# Immutep Reports Improving Results from INSIGHT-004 Trial

- 41.7% of patients showed a Partial Response to the combination therapy of eftilagimod alpha and avelumab (previously 33%)
- Encouraging early anti-tumour activity signals in a variety of cancer indications not typically sensitive to immune checkpoint inhibitor (ICI) therapy
- Combination of eftilagimod alpha and avelumab continues to be safe and well tolerated

**SYDNEY, AUSTRALIA – 18 September 2020 – Immutep Limited** (ASX: IMM; NASDAQ: IMMP) is pleased to report further interim data from its ongoing INSIGHT-004 Phase I clinical trial. The data were presented at the ESMO Virtual Congress 2020 on 17 September 2020, CEST (poster ID number 1032P) by trial investigator at Institute of Clinical Cancer Research, Krankenhaus Nordwest (IKF), PD Dr. Thorsten Götze.

INSIGHT-004 is evaluating the combination of Immutep's lead product candidate, eftilagimod alpha ("IMP321" or "efti") with avelumab (Bavenico), a human anti-PD-L1 antibody, in 12 patients with different solid tumours, primarily gastrointestinal. It is being conducted under Immutep's collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer Inc., which are co-developing and co-commercialising avelumab. INSIGHT-004 is the fourth arm (Stratum D) of the investigator-initiated INSIGHT trial which is conducted by IKF in Frankfurt, Germany.

**Prof Salah-Eddin Al-Batran, INSIGHT-004 trial investigator and Director of IKF said:** "It is encouraging to see the range of patients with different solid cancers that are responding to the combination of efti and avelumab, including PD-L1-negative cervical cancer, squamous anal cell carcinoma and mesothelioma. These tumours are not typically responsive to immune checkpoint therapy and warrant further investigation."

**Results Summary (data cut off 12 June 2020)**

- 41.7% of patients (5 / 12) showed a partial response (PR) to the combination therapy according to RECIST 1.1. Previously 33% showed a PR (June 2020).
- Encouraging durable deep responses in PD-L1 negative cancer.

| **Tumor response – according to RECIST 1.1** | **Total** N (%) Total (N=12) |
|---|---|
| Complete Response (CR) | 0 (0) |
| Partial Response (PR) | 5 (41.7%) |
| Stable Disease (SD) | 1 (8.3%) |
| Progressive Disease (PD)* | 5 (41.7%) |
| Not Evaluable (NE)** | 1 (8.3%) |
| **Objective Response Rate (ORR)** | **5 (41.7%)** |
| **Disease Control Rate (DCR)** | **6 (50%)** |

*Includes 2 patients with clinical progression
**Response assessment not yet performed

**Safety**
Interim results from INSIGHT-004 show that the combination of efti and avelumab is well tolerated with no dose limiting toxicities, building on efti's strong safety profile to date.

**IKF INSIGHT Trial Poster**
IKF also presented data from the broader INSIGHT trial at ESMO showing that intratumoral and intraperitoneal administration of efti up to 30 mg displayed signals of clinical and cytokine responses. Both IKF posters are appended below and are available on the Company's website at https://www.immutep.com/investors-media/presentations.html.

**About INSIGHT-004**
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. It is the first combination trial of an approved and marketed anti-PD-L1 drug and efti.

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.

**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 MSD, Kenilworth, NJ, USA (known as "Merck & Co., Inc." in 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.

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

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