

## ASX/Media Release

### Operational Update

#### Highlights

- Recruitment for the AIPAC study expected to be completed in Q2 2019
- 15 patients enrolled in TACTI-002 Phase II collaboration study with MSD
- Trial protocol approved for the INSIGHT-004 Phase I collaboration study with Merck KGaA and Pfizer
- Ongoing progress with partnered programs

**SYDNEY, AUSTRALIA – April 30, 2019 – [Immutep Limited](#)** (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, provides an update for the ongoing development of its product candidates.

#### Efti Clinical Update

##### **AIPAC – Phase IIb Clinical Trial**

To date, there have been 211 patients enrolled in the Company’s Phase IIb AIPAC clinical trial, which is evaluating eftilagimod alpha (“efti” or “IMP321”) in combination with paclitaxel, a chemotherapy, in metastatic breast cancer. Full recruitment of the trial, 226 patients, is expected to occur in the second quarter of this year. The trial is being conducted at 33 clinical trial sites across Germany, the UK, France, Hungary, Belgium, Poland and the Netherlands.

The first read out of Progression Free Survival (PFS) data is expected within the next 11 months, but not before Q4 2019, depending on the number of predefined progression events. Other endpoints include Overall Response Rate (ORR) and Overall Survival (OS).

##### **TACTI-002 – Phase II Clinical Trial**

15 patients have been enrolled in Immutep’s Phase II TACTI-002 clinical trial across seven clinical sites in the U.S., Europe and Australia. This figure includes 11 patients in the first line non-small cell lung cancer (NSCLC) cohort, which requires 17 patients to complete recruitment of this initial cohort.

The TACTI-002 study is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada) and is evaluating the combination of efti with MSD’s KEYTRUDA® (or pembrolizumab, an anti-PD-1 therapy) in up to 109 patients with second line head and neck squamous cell carcinoma or NSCLC in first and second line.

Patient recruitment is ongoing and Immutep expects to report first data from the study in mid-2019.

### TACTI-mel – Phase I Clinical Trial

Immutep reported positive, more mature data from its ongoing and fully recruited TACTI-mel Phase I clinical study in melanoma in March. The trial is evaluating the combination of efti with anti-PD-1 therapy KEYTRUDA<sup>®</sup> (pembrolizumab) in 24 patients with unresectable or metastatic melanoma.

Key findings from the ongoing trial were as follows:

	Part A (starting cycle 5 of pembrolizumab therapy) N=18	Part B (starting day 1 cycle 1 of pembrolizumab 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).

In addition, efti continues to have a very favorable safety profile in doses up to 30 mg administered s.c. every 2 weeks. The data was presented at the World Immunotherapy Congress 2019.

### INSIGHT & INSIGHT-004 – Phase I Clinical Trials

INSIGHT-004 is a Phase I clinical trial in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. and the Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH (IKF) which is evaluating the combination of efti with avelumab, a human anti-PD-L1 antibody, in patients with advanced solid malignancies. The trial protocol has now been approved by the competent authority and ethics committee and Immutep expects the first patient to be recruited in Q2 2019.

This study is taking place as an extension to the INSIGHT trial, an investigator sponsored explorative trial which is already underway and being run by our partner, IKF.

13 patients are now enrolled in the INSIGHT clinical trial, which is evaluating the potential of efti in different settings in terms of route of administration and indications.

### IMP761 Update

#### IMP761 - Preclinical Results

Immutep reported positive results from its preclinical study of IMP761, a novel LAG-3 agonist antibody being developed for the treatment of autoimmune diseases, in March. The preclinical results showed that IMP761 decreases inflammation at the tissue site, demonstrating its potential as a new therapy that could treat the cause of autoimmune disease, rather than just the symptoms.

Specifically, *in vitro* results showed that IMP761 caused the down-regulation of human T cell proliferation and activation. In addition, the *in vivo* studies showed that IMP761 causes down-modulation of T cell infiltration in a non-human-primate animal model. These results were presented at the 14th Congress of European Crohn's and Colitis Organisation (ECCO) Conference.

The Company is continuing cell line development and GMP manufacturing preparations for IMP761 to progress the antibody towards clinical development.

#### **Update on programs fully funded by Immutep's licensing partners**

##### **GlaxoSmithKline - GSK2831781 / IMP731**

GlaxoSmithKline (GSK) has announced that it will be pursuing a proof-of-concept study in ulcerative colitis for GSK2831781, which is derived from Immutep's IMP731 antibody. This Phase II clinical study is expected to commence shortly.

##### **Novartis - LAG525 / IMP701**

Novartis is continuing its clinical development program for LAG525, or IMP701, in oncology. Currently, there are five ongoing Phase I/II clinical trials evaluating this product candidate.

##### **CYTLIMIC - efti**

Immutep is working with CYTLIMIC to prepare for CYTLIMIC's clinical trials to evaluate efti as part of a therapeutic cancer vaccine, called CYT001. The vaccine contains cancer antigens to boost a patient's own immune cells to recognise and kill cancer cells related to the antigens.

##### **Eddingpharm (EOC Pharma) - efti**

Immutep's partner and Chinese licensee, EOC Pharma, is continuing the recruitment of patients for its Phase I clinical study of efti for the treatment of metastatic breast cancer. Immutep expects further progress from EOC Pharma later in 2019.

#### **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](http://www.immutep.com) or by contacting:

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