

## ASX/Media Release

### INSIGHT: First Patient Dosed in the 4<sup>th</sup> arm called “INSIGHT-004”

#### Highlights

- First patient received first dose in INSIGHT-004, a phase I clinical trial
- Evaluates the combination of efitlagimod alpha with avelumab (BAVENCIO®) in different cancer indications
- Patient recruitment for the trial is ongoing in Germany, with first data expected in 2019

**SYDNEY, AUSTRALIA – June 6, 2019** – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, announces that the first patient in (FPI) the INSIGHT-004 Phase I clinical trial has been enrolled in Germany and has received the first dose of treatment.

INSIGHT-004 (4<sup>th</sup> arm of the INSIGHT trial) is being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. (announced 24 September 2018). The study evaluates the safety, tolerability and recommended Phase II dose of Immutep’s lead immunotherapy product candidate efitlagimod alpha (“efti” or “IMP321”) when administered in combination with avelumab (BAVENCIO®) in 12 patients with advanced solid malignancies. Overall response rate according to RECIST 1.1 is the primary efficacy endpoint.

Under the trial protocol, patients will receive 800mg avelumab intravenously and either 6mg or 30mg of IMP321 by subcutaneous injections, once every two weeks for up to 12 cycles. Thereafter, patients may move into the maintenance phase to continue to receive avelumab monotherapy once every two weeks for a further 12 cycles.

Avelumab is an anti-PD-L1 therapy that is being co-developed and co-commercialised by Merck KGaA, Darmstadt, Germany and Pfizer under a strategic alliance. The Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany (“IKF”) is the sponsor of the clinical trial which is being conducted under the protocol of the ongoing INSIGHT clinical study, with lead investigator Prof. Dr. Salah-Eddin Al-Batran.

**Prof. Dr. Salah-Eddin Al-Batran, lead investigator of INSIGHT-004 commented:** “INSIGHT-004 aims to address two separate parts of the cancer immunity cycle. As an anti-PD-L1 therapy, avelumab works in part by releasing the brakes of the body’s immune system, while efti is a first-in-class antigen presenting cell activator that pushes the accelerator of the patient’s immune system. Our hope is the combination treatment is safe and patients with advanced solid cancers benefit.”

**Immutep CSO and CMO, Dr Frederic Triebel, said:** “The commencement of our INSIGHT-004 trial in Germany is exciting as this is a new study with our collaboration partners Merck KGaA, Darmstadt, Germany, and Pfizer. Patient recruitment will continue in Germany and we look forward to the first data in 2019.”

### **About INSIGHT-004**

INSIGHT-004 is being conducted under ImmuteP's collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. It is evaluating the safety, tolerability and recommended Phase II dose of ImmuteP's lead immunotherapy product candidate eftilagimod alpha ("efti" or "IMP321") when given in combination with avelumab in 12 patients with advanced solid malignancies.

INSIGHT-004 is being conducted as an amendment to the ongoing INSIGHT Phase I clinical trial. The Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany ("IKF") is the sponsor of the clinical trial which is being conducted under the existing protocol of the ongoing INSIGHT clinical study. Prof. Dr. Salah-Eddin Al-Batran, the lead investigator of INSIGHT and member of ImmuteP's clinical advisory board, is the lead investigator of INSIGHT-004.

ImmuteP expects IKF to report first data from INSIGHT-004 in 2019.

For more information regarding the INSIGHT-004 which forms part of the INSIGHT trial, visit [clinicaltrials.gov](http://clinicaltrials.gov) (INSIGHT identifier NCT03252938). INSIGHT-004 refers to the fourth arm of the INSIGHT trial where IMP321 is given in combination with avelumab.

### **Avelumab Approved Indications**

Avelumab (BAVENCIO<sup>®</sup>) in combination with axitinib is indicated in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

The US Food and Drug Administration (FDA) also granted accelerated approval for avelumab (BAVENCIO<sup>®</sup>) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab is currently approved for patients with MCC in more than 45 countries globally, with the majority of these approvals in a broad indication that is not limited to a specific line of treatment.

### **Avelumab Important Safety Information from the US FDA-Approved Label**

The warnings and precautions for avelumab (BAVENCIO<sup>®</sup>) include immune-mediated adverse reactions (such as pneumonitis and hepatitis [including fatal cases], colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions [which can be severe and have included fatal cases]), infusion-related reactions, major adverse cardiovascular events (MACE), and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO<sup>®</sup> include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash. Additional common adverse reactions reported in patients receiving BAVENCIO<sup>®</sup> in combination with axitinib include hypertension, mucositis,

palmar-plantar erythrodysesthesia, dysphonia, hypothyroidism, hepatotoxicity, cough, dyspnea, abdominal pain, and headache. Clinical chemistry and hematology laboratory value abnormalities have been reported including but not limited to grade 3-4 lymphopenia, anemia, elevated cholesterol and liver enzymes.

For full Prescribing Information and Medication Guide for BAVENCIO<sup>®</sup>, please see [www.BAVENCIO.com](http://www.BAVENCIO.com).

### **About Immunetep**

Immunetep is a globally active biotechnology company that is a leader in the development of immunotherapeutic products for the treatment of cancer and autoimmune disease. Immunetep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximize value to shareholders. Immunetep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Immunetep'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; a Phase II clinical trial referred to as TACTI-002 (Two ACTIVE Immunotherapies) to evaluate a combination of efti with KEYTRUDA<sup>®</sup> (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.immunetep.com](http://www.immunetep.com) or by contacting:

#### **U.S. Investors:**

Jay Campbell, Chief Business Officer, Immunetep Limited  
+1 (917) 860-9404; [jay.campbell@immunetep.com](mailto:jay.campbell@immunetep.com)

#### **Australian Investors/Media:**

Matthew Gregorowski, Citadel-MAGNUS  
+61 2 8234 0105; [mgregorowski@citadelmagnus.com](mailto:mgregorowski@citadelmagnus.com)

#### **U.S. Media:**

Garth Russell, LifeSci Advisors  
+1 (646) 876-3613; [garth@lifesciadvisors.com](mailto:garth@lifesciadvisors.com)