

ASX/Media Release (Code: ASX: IMM; NASDAQ: IMMP)

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# **Operational Update**

- First two patients of the additional cohort of the Phase I, TACTI-mel trial have commenced treatment; data to be reported mid-2018
- AIPAC trial: 33 out of a planned 34 clinical sites now active with full recruitment expected in mid-2018 (O3)
- Six patients recruited for investigator-initiated Phase I trial, INSIGHT
- Preparations for new Phase II clinical trial program, TACTI-002 underway, with trial expected to commence in the second half of calendar 2018

SYDNEY, AUSTRALIA - Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or the "Company"), provides an operational update on the Company's ongoing development activities for its lead product candidates, eftilagimod alpha ("efti" or "IMP321"), and IMP761, along with partner updates.

### **Efti Clinical Update**

The first two out of six patients of the additional cohort of the Company's TACTI-mel (<u>Two ACT</u>ive <u>Immunotherapeutics in mel</u>anoma) Phase I clinical trial in Australia have commenced their treatment. This follows the recruitment of all 18 patients in the initial three cohorts of TACTI-mel and the subsequent expansion of the trial to include an additional cohort of six patients in February 2018. The TACTI-mel trial evaluates the combination of efti and anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in unresectable or metastatic melanoma patients, with the additional cohort receiving 30mg of efti in combination with pembrolizumab starting at cycle one of pembrolizumab. The Company plans to present data from the TACTI-mel trial in the middle of this calendar year.

In the AIPAC (Active Immunotherapy PAClitaxel) clinical trial, 33 out of a planned 34 clinical sites across Belgium, the Netherlands, Poland, Hungary, United Kingdom, France and Germany are now actively recruiting and treating patients. The trial evaluates efti in combination with paclitaxel in metastatic breast cancer. The study remains on track to be to be fully recruited with 226 patients in Q3 of calendar year 2018; first Progression Free Survival data are expected in calendar year 2019.

Six patients have now been recruited for the investigator-initiated Phase I clinical trial INSIGHT, which is being conducted in Frankfurt, Germany. These patients are receiving escalating doses of efti either via local (intratumoral) or loco-regional (intraperitoneal) injection. The objective of the study is to determine the recommended dose for each administration route for an intended Phase II clinical trial.

Following the Company's announcement on 12 March 2018 of its clinical trial collaboration and supply agreement with Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the United States and Canada), through a subsidiary, to evaluate the combination of Immutep's lead immunotherapy product candidate, efti with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab), Immutep is preparing to start its new clinical trial program TACTI-002 (Two ACTive Immunotherapies) in the second half of calendar 2018. This new trial will evaluate the combination of efti with KEYTRUDA® in patients with advanced non-small cell lung cancer, head and neck cancer, or ovarian cancer. The Company plans to file the respective



Investigational New Drug application (IND) with the U.S. Food and Drug Administration (FDA) in the first half of calendar 2018.

### MP761 Update

Immutep's IMP761 (a LAG-3-specific antibody with unique agonistic properties) is currently being tested in vivo in animal models. IMP761 is the first known therapeutic agonist LAG-3 antibody. To our knowledge, no other company has developed a therapeutic agonist antibody to one of the three main immune checkpoint molecules, namely CTLA-4, PD-1 and LAG-3, as an immuno-suppressive drug for auto-immune diseases.

### **Efti Partnering Update**

#### **EOC Pharma**

Immutep's Chinese partner for efti, EOC Pharma, an oncology focused affiliate of Eddingpharm, received approval for the IND status in China and is expected to start clinical development in China with efti in H1 2018.

### **CYTLIMIC**

Immutep is also pleased to report that its partner CYTLIMIC has started a Phase I clinical trial for adjuvant immunotherapy at the Yamaguchi University Graduate School of Medicine in Japan. The study is the second that will test CYTLIMIC's cancer peptide vaccine in combination with efti.

### **About Immutep**

Immutep is a globally active biotechnology company that is a leader in the development of immunotherapeutic products for the treatment of cancer. Immutep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximise value to shareholders.

Immutep's current lead product 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 has completed early Phase II trials as an APC activator boosting T cell responses for cancer chemo-immunotherapy. 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.

Immutep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the U.S. For further information please visit <a href="https://www.immutep.com">www.immutep.com</a> or contact:

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

Jay Campbell, Vice President of Business Development and Investor Relations, Immutep Limited +1 (917) 860-9404; jay.campbell@immutep.com

## Australian Investors/Media:

Matthew Gregorowski, Citadel-MAGNUS +61 2 8234 0105; mgregorowski@citadelmagnus.com