

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

# TACTI-mel Patient Recruitment Complete and Operational Update

- Patient recruitment completed for Part B of ongoing TACTI-mel Phase I clinical trial
- Progress on Immutep's TACTI-002 and AIPAC
- GSK nominates ulcerative colitis as its lead indication for IMP731 (GSK2831781)
- Novartis commences new Phase II trial for IMP701 (LAG525) in triple-negative breast cancer
- EOC Pharma plans to commence its Phase I clinical trial of efti in China in metastatic breast cancer in September 2018

**SYDNEY, AUSTRALIA – August 7, 2018 – Immutep Limited** (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, provides an operational update on the Company's ongoing clinical development of eftilagimod alpha ("efti" or "IMP321") as well as the Company's partnered clinical programs.

#### **TACTI-mel Part B Patient Recruitment Completed**

Immutep reports that the final patient in Part B of the ongoing TACTI-mel Phase I clinical trial in Australia has now been recruited and is receiving treatment.

The TACTI-mel (<u>Two ACTive Immunotherapeutics in mel</u>anoma) trial is evaluating the combination of efti and KEYTRUDA<sup>®</sup> (pembrolizumab) in unresectable or metastatic melanoma patients. Following the study's expansion earlier this year, an additional cohort of six patients was recruited to the study, bringing the total number of patients participating in the trial to 24.

The completion of patient recruitment occurred as the final patient in the new cohort received their first dose of the two drugs. The actual cohort of patients will receive 30 mg of efti in combination with pembrolizumab starting at cycle one day one of pembrolizumab. Patients will be treated for up to 12 months.

Safety assessment is the main objective of this study. Interim data reported to date from the first three cohorts indicates that the combination treatment is delivering long lasting and durable responses in a subset of patients.

### TACTI-002 IND Approved by U.S. FDA

Immutep announced the approval of its IND by the U.S. FDA on 31 July 2018. Immutep continues to progress the relevant regulatory and ethics approvals needed to commence its planned TACTI-002 Phase II clinical study, as well as continuing the site selection process. The trial is set to commence in the second half of calendar year 2018 and the Company expects to report the first data from the trial in calendar year 2019.



## **AIPAC Patient Recruitment Progressing**

Having passed the midway point of recruitment for Immutep's AIPAC Phase IIb clinical trial in Europe in June 2018, the Company is pleased to report that patient recruitment continues on track, with 126 patients (out of a planned 226 patients) now participating in the study. The recruitment is ongoing across Belgium, the Netherlands, Poland, Hungary, United Kingdom, France and Germany. First Progression-Free Survival data is expected in calendar year 2019.

# **Partnering Clinical Update**

#### GSK nominates ulcerative colitis as lead indication for GSK2831781

Immutep's alliance partner, GlaxoSmithKline ("GSK"), is continuing to progress the development of GSK2831781 ("GSK'781"), a fully humanised monoclonal antibody derived from Immutep's IMP731 antibody. GSK recently announced that the lead indication for GSK'781 will be ulcerative colitis and anticipates that Proof of Concept data will be available in 2020. A new clinical study will build on GSK's Phase I clinical trial of the product candidate in psoriasis, which was completed in March 2018. GSK holds the exclusive worldwide development and commercialisation rights to GSK'781 (IMP731) from Immutep.

#### **Novartis Commences One Phase II Clinical Trial for LAG525**

Immutep's partner, Novartis, has commenced one of the two new Phase II clinical trials for LAG525, a fully humanised antibody derived from Immutep's IMP701 antibody. The recruitment of 96 patients for a new clinical trial evaluating LAG525 in triple-negative breast cancer started in July and recruitment of 135 patients in metastatic melanoma is planned to begin this month (August). This follows Novartis' decision in April 2018 to expand its clinical development program for LAG525. Novartis holds the exclusive worldwide development and commercialisation rights to LAG525 (IMP701) from Immutep.

### EOC Pharma to commence its Phase I clinical trial for efti in China

Immutep's Chinese partner for efti in China, EOC Pharma, is expected to commence its Phase I trial of efti in combination with chemo-therapy treatment, paclitaxel, in metastatic breast cancer in September 2018, encouraged by Immutep's progress with its AIPAC study in Europe. EOC Pharma is an oncology focused affiliate of Eddingpharm and plans to recruit 18 patients for the trial. EOC Pharma holds the exclusive development and commercialisation rights for efti in China, including Hong Kong, Macau, and Taiwan. EOC Pharma refers to efti as "EOC202".

# **IKF progresses INSIGHT trial**

Immutep's partner IKF in Frankfurt, Germany, has advised that the investigator-initiated Phase I clinical trial of efti in solid tumours is on track to report interim data later in calendar year 2018.

For updates on the clinical trials being conducted by Immutep's partners, please visit clinicaltrials.gov.

# About Immutep's TACTI-002 and AIPAC clinical trials for efti

TACTI-002 (<u>Two ACTive Immunotherapies</u>) is a Phase II clinical study which will be conducted in conjunction with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada). It will evaluate the combination of efti with MSD's KEYTRUDA<sup>®</sup> (pembrolizumab) in up to 120 patients with head



and neck squamous cell carcinoma or non-small cell lung cancer, in up to 15 study centres across the U.S., Europe and Australia.

AIPAC (Active Immunotherapy PAClitaxel) is Immutep's Phase IIb clinical trial evaluating efti in combination with paclitaxel in hormone receptor positive metastatic breast cancer. The study is conducted at up to 35 sites in Europe (Belgium, Germany, Netherlands, Hungary, Poland, France and United Kingdom). Following positive safety data, Immutep is progressing the randomised phase of trial where it plans to recruit 226 patients.

## **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'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 is currently in a Phase IIb clinical trial as a chemoimmunotherapy for metastatic breast cancer termed AIPAC (clinicaltrials.gov identifier NCT 02614833) and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT 02676869). Additional LAG-three 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 United States.

Further information can be found on the Company's website <a href="www.immutep.com">www.immutep.com</a> or by contacting:

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

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

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

# Australian Investors/Media:

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