

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

31 July 2018

**IMMUTEP'S LAG-3 IMMUNOSTIMULANT PRODUCT CANDIDATE, EFTI, RECEIVES IND APPROVAL FROM U.S. FDA**

On schedule to initiate the TACTI-002 Phase II clinical study in 2H 2018

SYDNEY, AUSTRALIA - Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company") is pleased to announce the approval of its Investigational New Drug ("IND") application by the U.S. Food and Drug Administration ("FDA") for efitlagimod alpha ("efti" or "IMP321"), a LAG-3Ig fusion protein.

The FDA approval of the IND allows the Company, subject to the completion of other preparatory steps, to initiate the TACTI-002 Phase II clinical study in the U.S. that will evaluate the combination of efti and anti-PD-1 therapy KEYTRUDA<sup>®</sup> (pembrolizumab) in patients with non-small cell lung carcinoma ("NSCLC") or head and neck carcinoma. Immutep expects to commence the TACTI-002 trial in the second half of 2018 and to report the first data from the trial in 2019.

"We are very excited to be able to initiate the Phase II study soon, now that we have received the approval from the FDA of the IND for efti, especially as it enables us to start clinical development of efti in the U.S." said Marc Voigt, CEO of Immutep. "This is one more important milestone for the Company's pipeline of LAG-3 immunotherapeutic products that aim to transform the treatment of cancer and autoimmune diseases. Through our clinical programs, and the efforts of our partners, we believe Immutep is securely positioned to play an important role in the development of combination therapies utilizing LAG-3."

The IND application allows Immutep to ship efti across U.S. state borders to U.S. clinical investigators participating in the Company's planned TACTI-002 Phase II clinical study.

**About the TACTI-002 clinical trial**

Up to 120 patients will be recruited for the TACTI-002 (Two ACTive Immunotherapies) Phase II study which will take place across approximately 15 study centres in the U.S., Europe and Australia. The trial is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada). It will evaluate the safety and efficacy of the combination of efti with MSD's KEYTRUDA<sup>®</sup> (pembrolizumab) in patients with non-small cell lung carcinoma or head and neck carcinoma. It will be a Simon two-stage, non-comparative, open-label, single-arm, multicentre clinical study. Patients participating in the trial will be given the combination treatment from day 1 of cycle 1 of KEYTRUDA treatment.

**About Efitlagimod Alpha**

Efitlagimod alpha is a MHC II agonist that is a soluble recombinant fusion protein consisting of the Fc portion of a human antibody and the four extracellular domains of LAG-3. Efti has been engineered to be

soluble rather than expressed on the surface of cells, is very stable, and has a high affinity for dendritic cells. It is a first-in-class antigen presenting cell (“APC”) activator, which has been proven to induce sustained immune responses in cancer patients when used at low dose, as a cancer vaccine adjuvant or used at higher doses to get a systemic effect (i.e. general APC activation). Efti binds to MHC II on immature dendritic cells, with high affinity, which results in boosting and sustaining CD8<sup>+</sup> T cell responses.

Efti has been shown to be safe and well tolerated, thus making it an ideal combination partner for other drugs or drug candidates, which is the most promising way to fight cancer.

### **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 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 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-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 [www.immutep.com](http://www.immutep.com) or contact:

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

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

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

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

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