

## ASX/Media Release

### Immutep Announces Expansion of Part A of TACTI-002 Phase II Clinical Trial due to Positive Interim Data

- Requisite clinical responses achieved in cohort 1 of Part A (1<sup>st</sup> line NSCLC) of TACTI-002 Phase II clinical trial to allow for recruitment of cohort 2
- Recruitment of cohort 2 of Part A of TACTI-002, additional 19 patients, will begin shortly
- Recruitment of the first cohorts of parts B and C continues
- Data from the ongoing TACTI-002 Phase II clinical trial will be presented at the 34<sup>th</sup> Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November 2019

**SYDNEY, AUSTRALIA – September 26, 2019** – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMMP) (“Immutep” or the “Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, announces that the requisite number of predefined patient responses has been exceeded in cohort 1 of Part A (first line non-small cell lung cancer (NSCLC)) of the TACTI-002 Phase II clinical trial based on an interim analysis. This allows the Company to proceed with the recruitment of an additional 19 patients for cohort 2 of Part A of the study. TACTI-002 is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada).

The decision by the Data Monitoring Committee (DMC) to open cohort 2 follows the review of preliminary safety and efficacy data and their recommendation is based on predefined safety and efficacy thresholds. For seven out of 17 (41.2 %) a partial response (PR) according to RECIST 1.1 was observed as the best overall response (BOR) as of the data cut-off (September 6, 2019) in this interim analysis. An additional six patients had a stabilization of disease (SD) as best overall response at this point leading to a disease control rate of 76.5 % in this highly aggressive tumour entity. Twelve patients are currently continuing treatment. Patients were allowed to participate regardless of their PD-L1 status which is a well-known predictive marker for response to pembrolizumab in NSCLC. While the response rate of pembrolizumab in NSCLC patients with  $\geq 50$  % PD-L1 expression is approximately 40%, it is between 15-20 % in patients with 1-49 % PD-L1 expression on the tumour. Patients with no PD-L1 expression are expected to benefit significantly less than that. The final BOR numbers will not be available until the final patient that was enrolled in cohort 1 of Part A (in June 2019) has been on study for six months and is assessed radiologically.

This staged approach of patient enrolment is based on, and is consistent with, the Simon’s two-stage clinical trial design. Accordingly, an additional 19 patients will be recruited to participate in Part A, bringing the total number of patients in Part A to 36. Recruitment of cohort 2 of Part A of the study will begin shortly.

Recruitment is ongoing for Parts B (second line non-small cell lung cancer) and C (second line head and neck squamous cell carcinoma (HNSCC) of the trial.

Data from the TACTI-002 Phase II clinical trial will be presented at the 34<sup>th</sup> Annual Meeting of the Society for Immunotherapy of Cancer (SITC), which is taking place on November 6-10, 2019 at the Gaylord National Hotel & Convention Centre in National Harbor, MD.

All patients are receiving the therapeutic combination of Immutep's lead product candidate eftilagimod alpha ("efti" or "IMP321") with KEYTRUDA<sup>®</sup> (or pembrolizumab, an anti-PD-1 therapy) at clinical trial sites across the U.S., Europe and Australia.

**Immutep CSO and CMO, Dr Frederic Triebel said:** "We are pleased with the recruitment of patients in the TACTI-002 clinical trial to date. After dosing the first patient in March this year, we already have 32 patients on study. In addition, we are encouraged by the early signals of efficacy seen in the more advanced part A of the study that appear to be consistent with the synergistic efficacy seen in combining efti with pembrolizumab in the TACTI-mel clinical trial. We very much look forward to presenting more detailed and more mature data at the 34<sup>th</sup> Annual Meeting of SITC in November."

### **About TACTI-002**

TACTI-002 (Two ACTIVE Immunotherapies) is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada). The study is evaluating the combination of Immutep's lead product candidate eftilagimod alpha ("efti" or "IMP321") with MSD's KEYTRUDA<sup>®</sup> (or pembrolizumab, an anti-PD-1 therapy) in up to 109 patients with second line head and neck squamous cell carcinoma or non-small cell lung cancer in first and second line. The trial is a Phase II, Simon's two-stage, non-comparative, open-label, single-arm, multicentre clinical study that is taking place in up to 13 study centres across the U.S., Europe and Australia.

### **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, is a best-and-first-in-class MHC II agonist. 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 being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada) referred to as TACTI-002 (Two ACTIVE Immunotherapies) to evaluate a combination of efti with KEYTRUDA<sup>®</sup> (or pembrolizumab, an anti-PD-1 therapy) in several different solid tumours (clinicaltrials.gov identifier NCT03625323); a Phase I clinical trial being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. 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). Immutep is also developing a best-and-first-in-class LAG-3 agonist monoclonal antibody for autoimmune diseases (IMP761) that is currently in preclinical development.

Further information can be found on the Company's website [www.immutep.com](http://www.immutep.com) or by contacting:

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