

ASX Announcement

IMMUTEP EXPANDS PART C OF TACTI-002 DUE TO POSITIVE DATA

- Recruitment completed for stage 1 of Part C of TACTI-002 trial, for patients with second line Head and Neck Squamous Cell Carcinoma (HNSCC)
- Part C has been expanded to include an additional 19 HNSCC patients, creating stage 2 of Part C
- Follows Data Monitoring Committee (DMC) decision after the predefined number of partial responses were observed in patients participating in stage 1 of Part C
- AIPAC remains on track to report first progression-free survival data and overall response rate data in Q1 CY20

SYDNEY, AUSTRALIA – January 9, 2020 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, provides an update on its TACTI-002 and AIPAC studies for its lead product candidate, eftilagimod alpha (“efti” or “IMP321”).

TACTI-002 – Phase II study

The requisite number of predefined patient responses was observed in stage 1 of Part C. The decision by the DMC to recommend opening stage 2 recruitment follows its review of preliminary safety and efficacy data and is based on a predefined efficacy threshold.

This allows the Company to now proceed with the recruitment of an additional 19 patients, forming stage 2 of Part C of the study, having now also completed recruitment of the 18 HNSCC patients for stage 1. The staged approach to patient enrolment is based on the study’s Simon’s two-stage clinical trial design.

Stage 1 of Part A (first line Non-Small Cell Lung Cancer, NSCLC) was expanded in September 2019. Recruitment is ongoing for Part B (second line NSCLC) with 10 out of 23 patients now participating, and for stage 2 of Part A (first line NSCLC), where 4 out of 19 patients are now participating. The Company expects to report more mature data from TACTI-002 in Q1 CY20.

TACTI-002 is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada).

Immutep CSO and CMO, Dr Frederic Triebel said: “The study is progressing well as the expansion of Part C to include 19 additional patients with second line HNSCC marks the second out of three parts of our TACTI-002 study to be expanded, having already observed the pre-determined number of partial responses in Parts A and C patients.”

AIPAC – Phase IIb study in metastatic breast cancer

The Company continues to progress its AIPAC trial which evaluates efti in combination with chemotherapy in 227 metastatic breast cancer patients in a randomized, double blinded, placebo-controlled phase IIb clinical

trial. The first progression-free survival read-out remains on track for Q1 CY20 and is expected to be reported in March 2020.

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 efti with MSD’s KEYTRUDA[®] (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. 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[®] (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 (clinical trials.gov identifier NCT03252938); and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT02676869).

This announcement was authorised for release by the board of Immutep Limited.

Further information can be found on the Company’s website www.immutep.com or by contacting:

Australian Investors/Media:

Catherine Strong, Citadel-MAGNUS
+61 (0)406 759 268; cstrong@citadelmagnus.com

U.S. Media:

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