

ASX Announcement

IMMUTEP COMPLETES RECRUITMENT FOR STAGE 1 OF PART B IN TACTI-002 STUDY

- 23 patients with second line Non-Small Cell Lung Cancer (NSCLC) participating in Stage 1, Part B
- Total of 87 patients out of up to 109 patients (80%) are enrolled and participating in the trial, with recruitment continuing for stage 2 of Part C at present
- Further data from TACTI-002 expected throughout calendar year 2020

SYDNEY, AUSTRALIA – 18 August, 2020 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, is pleased to report it has enrolled and safely dosed the last patient for stage 1 of Part B of its TACTI-002 Phase II study, completing recruitment of stage 1 of Part B.

Based on the study’s Simon’s two-stage clinical trial design, safety and efficacy data will be provided to the Data Monitoring Committee (DMC) for its review and recommendation regarding opening recruitment into stage 2 of Part B once all patients have undergone at least one tumour imaging after treatment.

TACTI-002 is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada) and is evaluating the combination of Immutep’s lead product candidate, eftilagimod alpha (“efti” or “IMP321”) with MSD’s KEYTRUDA® (pembrolizumab) in up to 109 patients with second line Head and Neck Squamous Cell Carcinoma (HNSCC) or NSCLC in first and second line.

TACTI-002 Recruitment

Recruitment details for each Part of TACTI-002 are below. At present, recruitment is ongoing for Stage 2 of Part C. Pending the DMC’s recommendation, Immutep will consider opening stage 2 of Part B for recruitment.

	Stage 1 (N) Actual/target	Stage 2 (N) Actual / target	Recruitment status
Part A (1st line NSCLC)	17/17	19/19	COMPLETE
Part B (2nd line NSCLC)	23/23	-/13	TBA
Part C (2nd line HNSCC)	18/18	10/19	ONGOING

About the TACT-002 Trial

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® (pembrolizumab) 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 12 study centres across the U.S., Europe and Australia.

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TACTI-002 is an all comer study in terms of PD-L1 status, a well-known predictive marker for response to pembrolizumab monotherapy especially in NSCLC. PD-L1 expression is typically reported in three groups for NSCLC: < 1%, 1-49% and ≥50% (Tumour Proportion Score or TPS). Patients with a high PD-L1 status are typically more responsive to anti-PD-1 monotherapy such as pembrolizumab, whereas those with low PD-L1 status are overall significantly less responsive. Pembrolizumab monotherapy is registered in the US and the EU for first-line NSCLC patients with a TPS score ≥1% (US) and ≥50% (EU), reflecting 65% and 30% of all first line NSCLC patients, respectively.

More information about the trial can be found on Immutep's website or on ClinicalTrials.gov (Identifier: NCT03625323).

About Immutep

Immutep is a globally active biotechnology company that is a leader in the development of LAG-3 immunotherapies 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 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 which is a first-in-class antigen presenting cell (APC) activator. Efti is currently in a Phase IIb clinical trial known as AIPAC which is evaluating efti in combination with chemotherapy for the treatment of metastatic breast cancer (clinicaltrials.gov identifier NCT02614833); 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 to evaluate a combination of efti with KEYTRUDA® (pembrolizumab) 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).

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

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