

ASX Announcement

IMMUTEP COMPLETES RECRUITMENT FOR PART A OF PHASE II TACTI-002 STUDY

- Completes recruitment of patients with first line Non-Small Cell Lung Cancer (NSCLC)
- 81 patients out of up to 109 now participating across the trial, with recruitment continuing for Part B and stage 2 of Part C
- Further interim data from TACTI-002 expected throughout CY20

SYDNEY, AUSTRALIA – June 29, 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 2 of Part A (1st line NSCLC) of its TACTI-002 Phase II study, completing recruitment for Part A.

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).

ImmuteP recently reported new data from TACTI-002 at the American Society of Clinical Oncology's Annual Meeting 2020, including results from stage 1 of Part A which showed an improving Progression Free Survival ("PFS") estimate of more than 9 months in patients with 1st line NSCLC.

The Company expects to report more mature data from TACTI-002 in H2 CY20.

TACTI-002 Recruitment Update

In total 81 patients out of up to 109 (74%) are already enrolled in the trial at 12 clinical sites across Australia, Europe, the UK and US. Recruitment is ongoing for Part B (second line NSCLC) and for stage 2 of Part C (2nd line HNSCC). Current recruitment numbers for each Part are below.

	Stage 1 (N) Actual/target	Stage 2 (N) Actual / target	
Part A (1st line NSCLC)	17/17	19/19	COMPLETE
Part B (2nd line NSCLC)	21/23	-/13	ONGOING
Part C (2nd line HNSCC)	18/18	6/19	ONGOING

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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, UK and Australia.

Patients participating in three parts:

- Part A - First line Non-Small Cell Lung Cancer (NSCLC), PD-X naive
- Part B - Second line NSCLC, PD-X refractory
- Part C - Second line Head and Neck Squamous Cell Carcinoma (HNSCC), PD-X naive

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 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);

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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 Immunetep Limited.

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

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