

ASX/Media Release

**IMMUTEP PRESENTS POSITIVE INTERIM DATA
FROM PHASE II TACTI-002 TRIAL AT SITC**

- Part A comprises NSCLC patients with all levels of PD-L1 expression, being an all comer trial
- Preliminary Overall Response Rate (ORR) of 41% from stage 1¹ of Part A
- ORR compares favourably to standard of care treatments for all comer PD-L1 NSCLC patients
- Twelve patients (71%) continuing treatment in stage 1 of Part A with a median follow-up of 5.6 months and no patient with a partial response progressing thus far
- Recruitment started for stage 2 of Part A and is ongoing for stage 1 in Parts B and C
- More mature data from TACTI-002 to be reported in Q1 of 2020

SYDNEY, AUSTRALIA – November 8, 2019 – [ImmuteP Limited](#) (ASX: IMM; NASDAQ: IMMP) ("ImmuteP" or "the Company"), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, reports positive interim data from its open label TACTI-002 Phase II clinical trial, building on the first top line data reported on 26 September 2019. The data is being presented today at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) by principal investigator, Dr. Julio Antonio Peguero, MD of Oncology Consultants in Texas.

TACTI-002 is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada). It is evaluating the combination of ImmuteP's lead product candidate eftilagimod alpha ("efti" or "IMP321") with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in up to 109 patients with non-small cell lung cancer (NSCLC) in first and second line or second line head and neck squamous cell carcinoma (HNSCC).

TACTI-002 is an all comer study in terms of PD-L1 status determined by their Tumor Proportion Score (TPS), meaning patients were eligible to participate regardless of their PD-L1 status TPS which ranges from < 1%; 1-49% and ≥50%. PD-L1 status TPS is a well-known predictive marker for response to pembrolizumab in first line NSCLC.

As of the data cutoff date of 16 October 2019, the results are:

	Part A (stage 1) n=17
Overall Response Rate (ORR) (According to iRECIST)	7/17 (41%)
Disease Control Rate (DCR) (According to iRECIST and RECIST 1.1)	13/17 (76.5%)
Patients continuing therapy	12/17 (71%)

¹ Previously referred to as "cohort 1"

As of the data cutoff date, the ORR for patients in of Part A stage 1 was 41%. In total 13 patients (76.5%) had a reduction in target lesions. As announced in September, in 13 out of 17 patients tumours stopped growing (according to iRECIST), including seven patients with a partial response (41%), and six with stabilisation of disease (35%). This indicates a disease control rate (DCR) of 76.5%.

Patients have been participating in the study between 0.7 and 7.4 months with a median follow-up of 5.6 months for now. None of the responding patients (7/17) have shown disease progression so far and 12 patients are continuing treatment with median PFS not yet reached.

ImmuteP CSO and CMO, Dr Frederic Triebel said: “It’s exciting to see that median PFS has not yet been reached in stage 1 of Part A, with nine patients already on trial for more than 24 weeks. Also, the 41% response rate compares favorably to other standard of care treatments available for NSCLC first-line patients, specifically single agent pembrolizumab or doublet chemotherapy. As treatment continues, we are hopeful that patients with this highly aggressive tumour will continue to benefit from the combination therapy, irrespective of their PD-L1 status even though some patients are just at an earlier stage of treatment.”

Comparison to other therapies

The TACTI-002 ORR of 41% is higher than would be expected from a PD-L1 all comer (where patients have a range low to high PD-L1 TPS expression) trial of pembrolizumab given that PD-L1 expression TPS is predictive for response to pembrolizumab (the higher the better). Typical ORR of pembrolizumab alone for patients with high (TPS \geq 50%) PD-L1 expression in the tumour, is 39%. For patients with TPS \geq 1% PD-L1 expression in the tumour the reported ORR is 27.2%. For pembrolizumab alone in patients with 1-49% PD-L1 the reported ORR is 16.7%.²

The TACTI-002 ORR is also higher than would be expected with a doublet chemotherapy regimen where typically response rates of around 26% are reported.³

Safety Results and Next Steps

Safety results across all Parts (A, B and C) is excellent, with no new safety signals being observed, confirming previous results in the TACTI-mel trial.

ImmuteP has now commenced the recruitment of an additional 19 patients with first line NSCLC, known as stage 2 of Part A. This follows the Data Monitoring Committee’s decision based on its review of preliminary safety and efficacy data. Recruitment is ongoing for Part B (second line NSCLC) with 8 out of 23 patients recruited and Part C (second line HNSCC) with 14 out of 18 patients recruited and showing encouraging early signs of efficacy. The staged approach to patient enrolment is based on the Simon’s two-stage clinical trial design.

The Company expects to report more mature data from TACTI-002 in Q1 of 2020.

² KN042

³ KN189; CM227 trials

The SITC poster presentation of the TACTI-002 interim data summarised above is available on our website at <http://www.immutep.com/investors-media/presentations.html>

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[®] (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 (clinicaltrials.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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