ASX/Media Release

Immutep Announces Improving Results from Stage I of Phase II TACTI-002 Study

- Three complete responses (complete disappearance of all lesions) reported: two in 2nd line head and neck squamous cell carcinoma (HNSCC) and one in 1st line non-small cell lung cancer (NSCLC)
- Five responses in patients (both indications) with negative (< 1%) or moderate PD-L1 expression where pembrolizumab monotherapy does not work well
- Median Progression Free Survival (PFS) of 4.3 months in HNSCC patients and 47% progression free at 6 months in this very aggressive late stage disease
- PFS continues to improve in 1st line NSCLC patients with median PFS of 11.8 months and patients with responses have durable ones

SYDNEY, AUSTRALIA – 18 September 2020 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) announces new interim data from its ongoing Phase II TACTI-002 study. The data was presented in two poster presentations at the ESMO Virtual Congress 2020 on 17 September 2020 and relates to the cut-off date of 21 August 2020.

The posters are available on Immutep's website at https://www.immutep.com/investors-media/presentations.html

TACTI-002 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® (pembrolizumab) in up to 109 patients with 2nd line head and neck squamous cell carcinoma (HNSCC, Part C) or non-small cell lung cancer (NSCLC) in 1st and 2nd line (Parts A and B, respectively).

Principal investigator, Dr Martin Forster, University College London Hospital, said: "We are very encouraged by the results in this patient group with resistant late stage Head & Neck Cancers where the likelihood of response to other treatments is small. The durability of responses and the two patients with a complete response are extremely promising signals and this combination should be further investigated."

Immutep CSO and CMO, Dr Frederic Triebel said: "The combination of efti and pembrolizumab is reporting encouraging progression free survival in patients with HNSCC and NSCLC, improving on the results from separate historical trials. For example, in comparable studies, HNSCC patients receiving pembrolizumab monotherapy had a PFS of 2.1 months, or 2.3 months if given chemotherapy[1,2]. This compares to a PFS of 4.3 months in HNSCC patients from the TACTI-002 trial, thus far. To have these very good and durable responses in both groups and without the use of chemotherapy is highly encouraging for efti."

Stage 1 of Part C (2nd line HNSCC, N=18):

- Median PFS of 4.3 months, with 47.1% of patients progression free at 6 months of treatment
- iORR maintained at 38.9% (7 / 18 patients and iORR of 43.75% in evaluable patients), including:
    - 2 patients recorded a Complete Response (iCR) according to iRECIST

[1] Keynote-040 results: available from https://www.esmo.org/newsroom/press-office/KEYNOTE-040-Evaluates-Pembrolizumab-in-Head-and-Neck-Cancer

[2] RL Ferris et al.: Nivolumab for Recurrent Squamous-Cell Carcinoma of the Head and Neck. N Engl J Med 2016;375:1856-67.

- 5 patients recorded a Partial Response (iPR) including 1 iPR after pseudo progression
- 6 / 7 responders still receiving treatment for 8+ to 17+ months, indicating durable responses
- 67% of patients alive at 9 months with a minimum follow-up of 8+ months

- All three PD-L1 subgroups enrolled in Stage 1, indicating PD-L1 all comer study

Tumour response – iBOR as per iRECIST	N (%) Total (N=18)
Complete Response (iCR)	2 (11.1)
Partial Response (iPR)	5 (27.8)
Stable Disease (iSD)	2 (11.1)
Progressive Disease (iPD)	7 (38.9)
Not evaluable	2 (11.1)
iORR in evaluable pts (iORR)	7 (43.75)
Objective Response Rate (iORR)	7 (38.9)

Stage 1 of Part A (1st line NSCLC, N=17):

- Continued improvement in PFS, with median PFS of 11.8 months and 45% of patients progression free at 12 months
- All three PD-L1 subgroups present, indicating the trial is a PD-L1 all comer study. Includes 4 responses in patients with PD-L1 expression of < 50%; 1 response in PD-L1 negative patients
- iORR maintained at 52.9%, including:
  - 1 patient with an iCR and 8 patients with iPRs; 8 of them confirmed
  - 2 late responders after 8 and 11 months
- 35% (6/17) of patients were still under treatment at data cut-off, all have received 12+ months of therapy

Tumour response – iBOR as per iRECIST	N (%) Total (N=17)
Complete Response (iCR)	1 (5.9)
Partial Response (iPR)	8 (47.1)
Stable Disease (iSD)	4 (23.5)
Progressive Disease (iPD)	4 (23.5)
Objective Response Rate (iORR)	**9 (52.9)**

Safety

The combination treatment continues to be safe and well tolerated with no new safety signals reported thus far.

TACTI-002 Recruitment Update

Trial recruitment continues to progress well, with 89 patients out of up to 109 already enrolled at 12 clinical sites across Australia, Europe, the UK and US.

Recruitment details for each Part of the trial are shown below and are current as at 17 September 2020.

At present, recruitment is ongoing for Stage 2 of Part C. Pending the Data Monitoring Committee's recommendation, Immutep will consider opening Stage 2 of Part B for recruitment.

	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)	23/23	-/13	TBA
Part C (2nd line HNSCC)	18/18	12/19	ONGOING

Next Results
Immutep expects to report first data from Stage 2 and more mature data from Stage 1 at a conference later this calendar year.

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 Australia, Europe, the UK and US.

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 and HNSCC. PD-L1 expression is typically reported in three groups for NSCLC: < 1%, 1-49% and ≥ 50% (Tumour Proportion Score or TPS) and in HNSCC: < 1%, 1-19% and ≥ 20% (Combined Positive Score or CPS). Patients with a high PD-L1 status are typically more responsive to anti-PD-1 therapy 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. Pembrolizumab monotherapy is registered in the US (regardless of PD-L1 expression) and EU (≥ 50% TPS score) for second line HNSCC patients.

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 related 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-3 protein (LAG-3Ig) 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 (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 (clinicaltrials.gov identifier NCT03252938); and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT02676869).

Additional LAG-3 products, including antibodies, for immune response modulation in autoimmunity and cancer are being developed by Immutep's large pharmaceutical partners. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

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.