ASX/Media Release

Immutep Announces Improving Data from the Phase II TACTI-002 Study

- First complete response reported in 2nd line head and neck squamous cell carcinoma (HNSCC)
- Improving Overall Response Rate (iORR) in HNSCC, increasing to 38.9% (previously 33% iORR)
- Progression free survival (PFS) continues to improve in 1st line non-small cell lung cancer (NSCLC) patients, estimated at more than 9 months

SYDNEY, AUSTRALIA – 1 June 2020 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) announces new interim data from its ongoing Phase II TACTI-002 study. This data relates to the cut-off date of 4 May 2020 and shows improving efficacy results. The results were presented as a poster short talk by trial investigator, Dr Enriqueta Felip, of Vall d'Hebron University Hospital in Barcelona, Spain, at the 2020 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting. The poster presentation from Dr. Felip is available on the company's website (click here).

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 the Company'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 Non-Small Cell Lung Cancer (NSCLC) in first and second line.

Immutep CSO and CMO, Dr Frederic Triebel said: "TACTI-002 is generating increasingly promising data from both the NSCLC and HNSCC arms of study, as patients continue to receive efti in combination with KEYTRUDA. Remarkably, one HNSCC patient has even achieved a complete response, bringing the total response rate to an improved 39% in this arm. This is an early indication that the efti in combination with pembrolizumab may more than double the proportion of HNSCC patients that respond to pembrolizumab monotherapy, which is usually 18% or less[1]."

Trial investigator, Dr. Felip said: "It is encouraging to see that patients continue to receive benefit from the combination treatment. We now expect progression free survival to be more than 9 months for patients with 1st line NSCLC, significantly longer than the 5-6 months delivered by pembrolizumab monotherapy. We are alo seeing deeper responses in both arms with patients responding after a number of months of treatment. The improving data in both HNSCC and NSCLC patients supports the use of efti in combination with pembrolizumab as a promising new therapeutic option for patients."

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

- iORR of 53%, with 9 out of 17 patients reporting a Partial Response (iPR) according to iRECIST.
- 71% (12/17) of patients with target lesion decrease (tumour shrinkage responses in all PD-L1 subgroups. 4 out of 9 patients with PRs had a Tumour Proportion Score less than 50% (typically less responsive to anti-PD-1 monotherapy such as pembrolizumab)
- 41% (7/17) of patients were still under treatment at data cut-off, indicating an estimated median PFS more than 9 months
- All three PD-L1 subgroups present, indicating the trial is a PD-L1 all comer study

[1] KEYNOTE-040

Tumor response – iBOR as per iRECIST	N (%) Total (N=17)
Complete Response (iCR)	0 (0.0)
Partial Response (iPR)	9 (52.9)
Stable Disease (iSD)	5 (29.4)
Progressive Disease (iPD)	3 (17.7)
Objective Response Rate (iORR)	**9 (52.9)**
Disease Control Rate (iDCR)	**14 (82.4)**

Stage 1 Part C (2nd line HNSCC):

- iORR has increased to 38.9% (7 out of 18 patients), previously 33% from earlier data cut-off of 20 March
- 1 patient has reported a Complete Response (iCR) and 6 patients reported iPRs, including, 1 iPR after pseudoprogression
- 44% (8) of patients still under therapy
- All three PD-L1 subgroups present -> PD-L1 all comer study

Tumor response – iBOR as per iRECIST	N (%) Total (N=18)
Complete Response (iCR)	1 (5.6)
Partial Response (iPR)	6 (33.3)
Stable Disease (iSD)	2 (11.1)
Progressive Disease (iPD)	7 (38.9)
Not evaluable	2 (11.1)
Objective Response Rate (iORR)	7 (38.9)
Disease Control Rate (iDCR)	**9 (50.0)**

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 77 patients out of up to 109 already enrolled at 12 clinical sites across Australia, Europe, the UK and US. Recruitment details for each Part are below and are current as at 29 May 2020.

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

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 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.