ASX/Media Release

Immutep Completes Recruitment of 2nd line PD-1/PD-L1 refractory NSCLC Patients in TACTI-002

- Last 2nd line PD-1/PD-L1 refractory non-small cell lung cancer (NSCLC) patient has been enrolled and safely dosed, completing recruitment of Stage 2 of Part B
- Total of 154 patients out of up to 183 patients (84%) now participating in the expanded trial, with recruitment continuing for the expansion stage of Part A
- Further data expected to be reported in calendar year 2021 or early calendar year 2022

SYDNEY, AUSTRALIA – 1 September 2021 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel LAG-3 related immunotherapy treatments for cancer and autoimmune disease, announces that the last patient has been enrolled and safely dosed in Stage 2 of Part B of its Phase II TACTI-002 study (also designated KEYNOTE-798). This completes the recruitment of 2nd line PD-1/PD-L1 refractory non-small cell lung cancer (NSCLC) patients into the trial.

Immutep expects to report further data from TACTI-002 at a scientific conference in calendar year 2021 or early calendar year 2022.

Patient recruitment is now complete for Parts B and C of TACTI-002 and continues to progress well for the expansion stage of Part A (see *Table 1*). A total of 154 patients out of up to 183 are now participating in TACTI-002 at currently 19 clinical sites across Australia, Europe, the UK and US.

Table 1 – TACTI-002 Recruitment (as at 24th August 2021)

	Stage 1 (N) Actual / Target	Stage 2 (N) Actual / Target	Recruitment Status	Expansion Stage 3 Actual / Target
Part A (1st line NSCLC)	17/17	19/19	EXPANDED	43/74
Part B (2nd line NSCLC)	23/23	13/13	COMPLETE	
Part C (2nd line HNSCC)	18/18	21/19[1]	COMPLETE	

The data presented for 2nd line PD-1/PD-L1 resistant NSCLC at the Society for Immunotherapy of Cancer (SITC) 35th Anniversary 2020 Annual Meeting as part of a late breaker poster looked encouraging, especially when compared to alternative treatment options. Based on the data, the DMC confirmed a positive risk-benefit-ratio in this very difficult to treat patient population with confirmed progression (i.e. two consecutive scans) and often low PD-L1 expression levels and recommended the opening of Stage 2 of this part in March 2021.

1 Two extra patients were treated as allowed under the trial protocol since 2 patients had dropped out due to Covid-19 prior to first post-baseline staging.

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 183 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 study centres across Australia, Europe, the UK and US.

Patients participate in one of the following:

- 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.

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 fusion protein (LAG-3Ig), which is a first-in-class antigen presenting cell (APC) activator being explored in cancer and infectious disease. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease. Additional LAG-3 products, including antibodies for immune response modulation, are being developed by Immutep's large pharmaceutical partners.

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

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