ASX/Media Release

Immutep Successfully Completes Recruitment for Phase II TACTI-002 Study of LAG-3 Therapy, Eftilagimod Alpha

- Enrolled and dosed last patient in the expansion stage of Part A (1st line non-small cell lung cancer (NSCLC)) needed to complete recruitment into all cohorts of the TACTI-002 study
- Interim data from Part C (2nd line head & neck squamous cell carcinoma (HNSCC) patients) presented at SITC 2021
- Additional data from TACTI-002 expected to be reported in H1 calendar year 2022

SYDNEY, AUSTRALIA – 19 November 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 the last patient has been enrolled in the expansion stage of Part A of its Phase II TACTI-002 study (also designated KEYNOTE-798). The Company announced that the TACTI-002 study has completed recruitment of patients across all cohorts.

A total of 185 patients are now participating in TACTI-002 across Parts A, B, and C (see Table 1) at 20 clinical sites in Australia, Europe, and the US.[1] Notably, recruitment into the expansion stage of Part A was completed faster than anticipated, with all patients in this stage being recruited in under 12 months.

As announced previously, further interim data from Part C (2nd line HNSCC) was presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting 2021, which took place from 10-14 November 2021. Further data from TACTI-002 (including from Part A) will be reported in the first half of calendar year 2022.

Immutep CEO, Marc Voigt commented: "The completion of recruitment for our Phase II TACTI-002 trial marks the achievement of a major milestone for Immutep. Our clinical team and partners have worked hard to continue the pace of patient enrolment and finished recruitment much earlier than originally anticipated, despite some challenging conditions brought on by the COVID-19 pandemic. We are excited to be reporting further results from this trial in the coming months. We sincerely thank the patients and their families, and our various partners, for their ongoing support of this important trial."

Table 1 – TACTI-002 Recruitment (as at 18 November 2021)

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

[1] Up to 5 additional patients may be recruited into the expansion stage of Part A meaning the total number of patients may be more than originally planned as there are still patients currently in screening.
[2] 2 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 TACTI-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 eftilagimod alpha (efti) with MSD's KEYTRUDA® (pembrolizumab) in 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, and the US.

Patients participate in one of the following:

- Part A - First line Non-Small Cell Lung Cancer (NSCLC), PD-X naïve - given the promising results of the first two stages of Part A, an expansion stage with 74 additional patients was commenced in November 2020 to assist with trial design in subsequent late-stage settings
- Part B - Second line NSCLC, PD-X refractory
- Part C - Second line Head and Neck Squamous Cell Carcinoma (HNSCC), PD-X naïve

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.

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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This announcement was authorised for release by the Board of Immutep Limited.