

ASX/Media Release

IMMUTEP EXPANDS PART B OF TACTI-002 STUDY

Follows positive efficacy and safety review

SYDNEY, AUSTRALIA – 5 March 2021 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, is pleased to report it has decided to expand Part B of its TACTI-002 Phase II trial, under the study’s Simon’s two-stage clinical trial design. Immutep has commenced recruitment of an additional 13 second line Non-Small Cell Lung Cancer (NSCLC) patients, forming Stage 2 of Part B.

The decision follows a preliminary safety and efficacy review by the Data Monitoring Committee and its recommendation, based on the patients recruited in Stage 1 of Part B.

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 efiti 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 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 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.