

ASX/Media Release

## Immutep to present Phase II TACTI-002 data at SITC 2021

**SYDNEY, AUSTRALIA – 4 October 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, is pleased to announce data from Part C of its ongoing Phase II TACTI-002 trial and the study design for its Phase IIb TACTI-003 trial will be presented in posters at the Society for Immunotherapy of Cancer (SITC) Annual Meeting 2021 which is taking place in Washington, US and virtually from 10-14 November 2021.

As previously announced, final Overall Survival data from Immutep’s Phase IIb AIPAC trial will also be presented at SITC 2021 as a *late breaker* poster presentation.

The poster abstracts are planned to be published on the SITC 2021 website on Tuesday 9 November 2021 at 8 am US Eastern Standard Time (EST).

Posters with any new data that are not part of the abstracts will be available on the SITC 2021 website from 7 am on Friday 12 November US EST and will be made available on Immutep’s website at [www.immutep.com](http://www.immutep.com).

### **TACTI-002**

**Title:** Results from a Phase II study of efitilagimod alpha (soluble LAG-3 protein) and pembrolizumab in patients with PD-L1 unselected metastatic 2nd line head and neck squamous cell carcinoma (HNSCC).

**Authors:** López Pousa, E Felip, M Forster, B Doger, P Roxburgh, P Bajaj, J A Peguero, E Carcereny, M Krebs, C Mueller, F Triebel

**Poster number:** #359

**Presentation date:** Nov 12, 2021 – Nov 13, 2021, 7:00 am - 8:30 pm

### **TACTI-003**

**Title:** A Phase II study of efitilagimod alpha (soluble LAG-3 protein) and pembrolizumab in patients unselected for PD-L1 expression in first line metastatic head and neck squamous cell carcinoma (HNSCC).

**Authors:** J A Peguero, F Triebel

**Poster number:** #440

**Presentation date:** Nov 12, 2021 – Nov 13, 2021, 7:00 am - 8:30 pm

### **About the Society for Immunotherapy of Cancer (SITC)**

SITC is the world’s leading member-driven organisation specifically dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy. The SITC Annual Meeting is the largest conference solely focused on cancer immunotherapy and brings together stakeholders across the

cancer immunotherapy field to advance the science, discover breakthroughs and educate the world on cancer immunotherapy.

### **About TACTI-002**

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<sup>®</sup> (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  $\geq 50\%$  (Tumour Proportion Score or TPS) and in HNSCC: < 1, 1-19 and  $\geq 20$  (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 TACTI-003**

TACTI-003 is a Phase IIb clinical trial in first line head and neck squamous cell carcinoma (HNSCC) in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA, known as “MSD” outside the United States and Canada. It will evaluate efti in combination with MSD’s KEYTRUDA<sup>®</sup> (pembrolizumab) as a first line therapy in unresectable recurrent or metastatic HNSCC patients with PD-L1 negative and PD-L1 positive (CPS  $\geq 1$ ) tumors. It will be a randomised, controlled clinical study in approximately 154 first line HNSCC patients and will take place across Australia, Europe and the US in up to 35 clinical sites.

The study will evaluate the safety and efficacy of efti in combination with pembrolizumab, compared to pembrolizumab alone in first line metastatic or recurrent HNSCC patients with PD-L1 positive (CPS  $\geq 1$ ) tumors (cohort A), and determine the efficacy and safety of efti plus pembrolizumab in patients with PD-L1 negative tumors (CPS < 1) (cohort B). According to the current plans, about 130 patients in cohort A will be randomised 1:1 to receive either efti plus pembrolizumab or pembrolizumab alone. Subjects in cohort B (up to 24 patients) will receive a combination of efti and pembrolizumab.

The primary endpoint of the study is the Overall Response Rate (ORR) according to RECIST 1.1. and iRECIST will be used for treatment decisions. Secondary endpoints include OS and Progression Free Survival (PFS).

### **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, infectious disease 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 efitlagimod alpha ("efti" or "IMP321"), a soluble LAG-3 protein, 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](http://www.immutep.com) or by contacting:

#### **Australian Investors/Media:**

Catherine Strong, Citadel-MAGNUS  
+61 (0)406 759 268; [cstrong@citadelmagnus.com](mailto:cstrong@citadelmagnus.com)

#### **U.S. Media:**

Tim McCarthy, LifeSci Advisors  
+1 (212) 915.2564; [tim@lifesciadvisors.com](mailto:tim@lifesciadvisors.com)

This announcement was authorised for release by the CEO of Immutep Limited, Marc Voigt.