

## ASX/Media Release

### IMMUTEP OPERATIONAL UPDATE

- AIPAC reaches ~72% of events and TACTI-002 recruitment is progressing well
- New data from TACTI-002 and INSIGHT-004 to be reported at ASCO in June 2021
- TACTI-003 clinical trial design enables evaluation of efti in 1<sup>st</sup> line recurrent or metastatic HNSCC patients to better understand its effect in combination with pembrolizumab
- Robust financial position with cash runway into calendar year 2023, beyond several significant data read-outs

**SYDNEY, AUSTRALIA – 7 May 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, provides an update on its clinical and preclinical programs.

#### **Eftilagimod alpha ("efti") Update**

##### **AIPAC - Phase IIb clinical trial**

The Company is on track to report final overall survival (OS) data from this metastatic breast cancer trial in H2 of calendar year 2021. Currently the trial has reached approximately 72% of events, indicating 72% of total patients with this late-stage cancer had been followed through until death. Immutep previously reported an improving OS trend from initial data from approximately 60% of events at the San Antonio Breast Cancer Conference in December 2020.

##### **TACTI-002 (also designated KEYNOTE-798) - Phase II clinical trial**

The study is continuing to enrol 1<sup>st</sup> line non-small cell lung cancer (NSCLC) patients (Part A), with 54 patients out of up to 110 patients now enrolled and having received at least the first treatment. Immutep and its collaboration partner, Merck & Co. Inc, Kenilworth, NJ, USA ("MSD") expanded Part A of the TACTI-002 study to up to 110 patients following the encouraging results presented at the Society for Immunotherapy of Cancer's (SITC) Congress in November 2020.

Recruitment is also ongoing for patients with 2<sup>nd</sup> line NSCLC (Part B) which was expanded under the study's Simon's two-stage clinical trial design. Currently, 27 patients of a total of 36 patients have received the first treatment. In 2<sup>nd</sup> line head and neck squamous cell carcinoma (HNSCC, Part C) the recruitment of patients is complete.

Currently the recruitment of TACTI-002 is tracking well and new clinical data from TACTI-002 is planned to be presented at the American Society of Clinical Oncology Annual Meeting (ASCO) 2021 (4-8 June).

##### **TACTI-003 – a Phase IIb Clinical Trial in 1<sup>st</sup> line Head and Neck Cancer**

Subject to approval by relevant competent authorities, ethics committees and institutional review boards (IRBs), TACTI-003 will evaluate efti in combination with MSD's KEYTRUDA® (pembrolizumab) as a first line

therapy in unresectable recurrent or metastatic HNSCC patients with PD-L1 negative and PD-L1 positive (CPS  $\geq 1$ ) tumours. It will be a randomised, controlled clinical study in approximately 154 first line HNSCC patients and will take place across Australia, Europe and the United States of America 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 1<sup>st</sup> line metastatic or recurrent HNSCC patients with PD-L1 positive (CPS  $\geq 1$ ) tumours (cohort A), and determine the efficacy and safety of efti plus pembrolizumab in patients with PD-L1 negative tumours (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). Following the grant of Fast Track designation for efti to treat 1<sup>st</sup> line HNSCC patients by the US FDA in early April 2021 and the appointment of a Contract Research Organisation (CRO), Immutep is on track to start the study in mid-2021.

#### **INSIGHT-004 - Phase I clinical trial**

The INSIGHT-004 study is expected to deliver final data at ASCO 2021 in a poster discussion. INSIGHT-004 is the fourth arm of the INSIGHT trial (INSIGHT-004 is also known as Stratum D of INSIGHT) which is being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc.

#### **IMP761 Update**

The Company has completed the selection of a high-producing CHO cell line for its IMP761 IgG4 mAb and is in the process of selecting a contract manufacturing organisation (CMO) for GMP manufacturing of its preclinical candidate IMP761.

#### **Financial Update**

Immutep continues to be in a robust financial position with a cash runway into calendar year 2023, beyond the expected timing for several significant data read-outs from its trials.

#### **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](http://www.immutep.com) or by contacting:

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