

## ASX/Media Release

### **Immutep's efti in combination with MSD's pembrolizumab shows encouraging antitumor activity in difficult to treat 2<sup>nd</sup> line metastatic lung cancer patients**

- All enrolled patients were 2<sup>nd</sup> line metastatic non-small cell lung carcinoma (NSCLC) patients that had confirmed progressive disease after prior PD-1 or PD-L1 therapy (PD-X refractory)
- Encouraging interim Disease Control Rate (DCR) of 36.1% (13/36) and 26% progression free at 6 months
- 73.7% of evaluable patients (14/19) had tumour shrinkage or tumour growth deceleration compared to pre-study situation
- Encouraging preliminary Overall Survival (OS) at the 6-month landmark, with a 73% survival rate
- 5.6% of patients (2/36) had confirmed and durable partial responses, with both patients continuing in the trial for over 9 months and 23 months, well beyond expectations
- Efti continues to be safe and well tolerated

**SYDNEY, AUSTRALIA – 30 March 2022** – [Immutep Limited](https://www.immutep.com) (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel LAG-3-related immunotherapy treatments for cancer and autoimmune disease, announces new interim data in 2<sup>nd</sup> line metastatic NSCLC from its Phase II TACTI-002 trial. The data was published in a poster presentation today at ESMO's European Lung Cancer Congress (ELCC) 2022 in Prague, Czech Republic and is also available on the Company's website:

<https://www.immutep.com/investors-media/presentations.html>

This part of TACTI-002, known as Part B, evaluates Immutep's lead product candidate, eftilagimod alpha ("efti" or "IMP321") in combination with MSD's KEYTRUDA<sup>®</sup> (pembrolizumab) in a total of 36 patients with PD-L1 unselected 2<sup>nd</sup> line PD-X refractory metastatic NSCLC. The new data reflects the first interim results combining Stages 1 (23 patients) and 2 (13 patients) in 2<sup>nd</sup> line NSCLC.

**Immutep CSO and CMO, Dr Frederic Triebel, noted:** "It is very encouraging to see efti, in combination with pembrolizumab, showing an encouraging early overall survival rate of 73% at the six-month landmark, and promising interim disease control and tumour growth kinetics. The early signs are supportive that efti may boost the patient's immune system to enable pembrolizumab to work more effectively in these patients with advanced lung cancer, while being safe and well tolerated."

**TACTI-002 Principal Investigator, Dr Matthew G. Krebs of The University of Manchester and The Christie NHS Foundation Trust, said:** "These interim results show an encouraging disease control rate of 36.1%, with 26% of patients being progression free at the 6-month landmark. These patients are a challenging population to treat, having progressed after previous lines of immunotherapy or chemo-immunotherapy and have limited options available for further treatment. So, it is pleasing to see the potential that efti in combination with pembrolizumab has to provide meaningful benefit in this patient group."

### **Condition of the patients as they entered the trial**

A total of 36 patients were enrolled and treated. Patients were advanced in their disease. They had progressed after prior standard of care treatment with either anti-PD-(L)1 mono therapy (28%) or a combination of chemotherapy and anti-PD-(L)1 therapy (72%) and are referred to as PD-X refractory. Disease progression was confirmed by two consecutive CT-scans at least four weeks apart, eliminating the possibility of pseudo-progressions.<sup>1</sup> The majority of patients (69%) had a PD-L1 tumour proportion score (TPS) of less than 50% at baseline, making them generally less likely to respond to anti-PD-(L)1 therapy.

### **Key Findings – data cut-off date 21 January 2022**

- 73.7% of evaluable patients (14/19) had tumour shrinkage or tumour growth deceleration, according to tumour growth kinetics analysis
- 73% of patients alive at 6 months landmark in this difficult-to-treat patient population
- DCR of 36.1% (13/36), with 26% being progression free at the 6-month landmark
- ORR of 5.6% (2/36) with two patients reporting confirmed and durable partial responses, participating in the study for over 9 months and 23 months, respectively
- 6 patients still under therapy in the trial
- Median OS has not yet been reached, which is encouraging given the advanced nature of the disease in this patient population

*Table 1 – TACTI-002 Interim Results for Part B of TACTI-002*

Tumour Response	Part B 2nd line NSCLC <sup>2</sup>
Best Overall Response as per iRECIST	Stage 1 & 2 N (%) Total N=36
Complete Response (CR)	0 (0)
Partial Response (PR)	2 (5.6)
Stable Disease (SD)	11 (30.6)
Progressive Disease (PD)	22 (61.1)
Not Evaluable	1 (2.8)
<b>Overall Response Rate (ITT)</b>	<b>2/36 (5.6)</b>
<b>Disease Control Rate (ITT)</b>	<b>13/36 (36.1)</b>
<b>Overall Response Rate (evaluable patients)</b>	<b>2/35 (5.7)</b>
<b>Disease Control Rate (evaluable patients)</b>	<b>13/35 (37.1)</b>

<sup>1</sup> A pseudo-progression refers to an increase in the apparent size of a tumour or number of metastases on an imaging test, that can falsely create the appearance of disease progression. This may be caused by the infiltration of immune cells into the tumour site or a delay in the development of an adaptive immune response following immunotherapy.

<sup>2</sup> As assessed by local investigator read.

### **Safety**

The combination of efti plus pembrolizumab is safe and well-tolerated, continuing efti's good safety profile to date and compares favourably to standard of care chemotherapy options.

### **Conclusion**

The interim data from the TACTI-002 study shows that efti in combination with pembrolizumab is demonstrating encouraging early signs of antitumour activity in 2<sup>nd</sup> line confirmed PD-X refractory, NSCLC patients.

### **Next results**

More mature data from the 2nd line NSCLC cohort is planned to be presented later this year, along with other data from the TACTI-002 trial.

### **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<sup>®</sup> (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 efitagimod 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.