

ASX/Media Announcement

## Immutep Reports Positive Phase II TACTI-002 Data

- Increasing benefit reported from patients with first line Non-Small Cell Lung Cancer (NSCLC):
  - Improving Overall Response Rate (ORR) of 53% (earlier data indicated 47%)
  - Improving Progression free Survival (PFS) now at more than 8 months, median PFS not yet reached
  - 71% patients with tumour shrinkage
- Encouraging results also from patients with second line Head and Neck Squamous Cell Carcinoma (HNSCC):
  - ORR of 33% (consistent with earlier data) without substantial additional toxicity so far
  - 50% of patients still under therapy, median PFS not yet reached
  - 44% patients with tumour shrinkage

**SYDNEY, AUSTRALIA – April 28, 2020 – [Immutep Limited](#)** (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, announces further positive interim data from its ongoing Phase II TACTI-002 study. The data relates to the data cut-off date of 20 March 2020 and shows improving efficacy results.

The results are being presented today as a poster short talk audio presentation as part of the high-impact paper presentation program by TACTI-002 Principle Investigator, Dr Martin Forster of University College London Hospitals NHS Foundation at the American Association for Cancer Research (AACR) Virtual Annual Meeting.

TACTI-002 is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada). It is evaluating the combination of the Company’s lead product candidate eftilagimod alpha (“efti” or “IMP321”) with MSD’s KEYTRUDA® (pembrolizumab) in up to 109 patients with second line HNSCC or NSCLC in first and second line.

**Immutep CSO and CMO, Dr Frederic Triebel said:** “These very positive results for stage 1 demonstrate the benefits for NSCLC patients in receiving efti in combination with pembrolizumab. 53% of patients are now responding and we expect PFS to be more than 9 months. These consolidated results, with more tumour responses being confirmed by a second CT-scan and a longer follow up, are remarkable given that usually only 20% of patients respond to pembrolizumab monotherapy, if not pre-selected for high PD-L1 expression. It is also encouraging to see that 33% of HNSCC patients are responding, almost double the proportion that respond to pembrolizumab monotherapy and that the median PFS hasn’t yet been reached for this group.”

**Immutep CEO, Marc Voigt stated:** “Efti is showing remarkable results for patients with NSCLC and HNSCC. These are multi-billion-dollar markets, with NSCLC expected to reach US\$33.9 billion and HNSCC US\$2.8

billion by 2026 respectively<sup>1</sup>. As the treatment duration continues, we will update ORR and PFS, positioning the Company strongly to advance efi in these indications.”

**Key Findings** (Data cut-off: 20 March 2020)

**Stage 1 Part A (1<sup>st</sup> line NSCLC, N=17):**

- Increasing ORR of 53% (earlier data 47%), with 9 out of 17 patients reporting a Partial Response according to iRECIST. 6 now confirmed with at least a 2nd CT scan. 1 out of 9 of these patients has progressed thus far.
- Remarkably, 2 patients responded after 8 and 11 months (late responders are quite unusual with pembrolizumab alone)
- 71% (12 out of 17) patients with target lesion decrease (includes 3 patients with Stable Disease and 9 with a Partial Response)
- Improving PFS with majority (9 out of 17, or 53%) of NSCLC patients still under treatment at 8+ months. Median PFS is not yet reached with all patients having passed the 8+ month mark already
- PD-L1 distribution as expected (see table) → ~30% with ≥ 50% PD-L1, indicating the PD-L1 all comer trial (please see *About the TACTI-002 Trial* section for background on PD-L1 expression)
- Tumour responses continue to be reported across all three PD-L1 expression level groups (< 1%, 1-49% and ≥50%) for NSCLC. 4 out of the 9 responders had a PD-L1 expression <50%.
- Responses in all PD-L1 subgroups are detailed below:

Patients by PD-L1 category	No. of Responses <sup>2</sup>	ORR <sup>1</sup>	Frequency in TACTI-002 N (%) <sup>3</sup>	Historical <sup>4</sup> Distribution
Low (< 1%)	1	33%	3 (23%)	35%
Medium (1-49%)	3	50%	6 (46%)	35%
High (≥ 50%)	3	75%	4 (31%)	30%
NE <sup>5</sup>	2	50%	4 (n/a)	n/a
<b>Overall</b>	<b>9</b>	<b>52.9%</b>	<b>17</b>	

1 Estimation of Datamonitor Healthcare, Informa Pharma Intelligence for US, Jap, EU (5) and KBV Research

2 According to iRECIST

3 Percentage refers to evaluable subjects (n=13)

4 Garon et al N Engl J Med 2015; 372:2018-28

5 NE= not evaluable by central lab using standard kit

### Stage 1 Part C (2<sup>nd</sup> line HNSCC):

- Maintained interim ORR of 33% with 6 out of 18 patients reporting a Partial Response according to iRECIST. All 6 patients with iPR still under therapy and five of the six responses confirmed.
- 1 patient with outstanding imaging
- 44% (8 out of 18) patients with target lesion decrease (includes 2 patients with Stable Disease and 6 with a Partial Response)
- 1 patient responded after 8 months (late responder, again quite unusual for pembrolizumab alone)
- 50% of patients (9 out of 18) still under treatment. Median PFS is not yet reached
- PD-L1 distribution across all expression levels, indicating PD-L1 all comer trial (please see *About the TACTI-002 Trial* section)

### Safety:

The combination treatment continues to be safe and well tolerated with no new safety signals reported thus far.

### TACTI-002 Recruitment Update

Trial recruitment continues to progress well, with 76 patients out of up to 109 already enrolled at 12 clinical sites across Australia, Europe, the UK and US. Recruitment details for each Part are below and are current as at the date of today's announcement (not the data cut-off date of 20 March).

	Stage 1 (N) Actual/target	Stage 2 (N) Actual / target
Part A (1st line NSCLC)	17/17	17/19
Part B (2nd line NSCLC)	18/23	-/13
Part C (2nd line HNSCC)	18/18	6/19

### AACR Virtual Annual Meeting

A replay of the audio poster presentation with the presentation slides entitled, "*Initial results from a phase II study (TACTI-002) in metastatic non-small cell lung or head and neck carcinoma patients receiving eftilagimod alpha (soluble lag-3 protein) and pembrolizumab*", is available on the Company's website at [www.immutep.com](http://www.immutep.com).

### About the TACT-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® (or pembrolizumab, an anti-PD-1 therapy) in up to 109 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 the U.S., Europe, UK and Australia.

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. PD-L1 expression is typically reported in three groups for NSCLC: < 1%, 1-49% and ≥50% (Tumour Proportion Score or TPS). Patients with a high PD-L1 status are typically more responsive to anti-PD-1 monotherapy 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.

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 efitlagimod alpha ("efti" or "IMP321"), a soluble LAG-3 protein (LAG-3lg) based on the LAG-3 immune control mechanism. This mechanism plays a vital role in the regulation of the T cell immune response. Efti is currently in a Phase IIb clinical trial as a chemoimmunotherapy for metastatic breast cancer termed AIPAC (clinicaltrials.gov identifier NCT02614833); a Phase II clinical trial being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada) referred to as TACTI-002 to evaluate a combination of efti with KEYTRUDA® (pembrolizumab) in several different solid tumours (clinicaltrials.gov identifier NCT03625323); a Phase I clinical trial being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. referred to as INSIGHT-004 to evaluate a combination of efti with avelumab (clinicaltrials.gov identifier NCT03252938); and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT02676869).

Additional LAG-3 products, including antibodies, for immune response modulation in autoimmunity and cancer are being developed by Immutep's large pharmaceutical partners. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

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

Further information can be found on the Company's website [www.immutep.com](http://www.immutep.com) or by contacting:

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