ASX/Media Release

Immutep's Efti in Combination with KEYTRUDA® Generates Excellent Overall Survival Benefit in Patients with Metastatic Non-Small Cell Lung Cancer

- *Median Overall Survival reaches 35.5 months in first-line treatment of metastatic non-small cell lung cancer patients expressing PD-L1 (TPS ≥1%), 23.4 months in patients with low PD-L1 expression (TPS 1-49%), and has not been reached in patients with high PD-L1 expression (TPS ≥50%), exceeding expectations*
- *Promising Overall Survival, Overall Response Rate, Progression Free Survival, and Duration of Response visible across all PD-L1 subgroups (TPS <1%, ≥1%, 1-49%, and ≥50%), differentiates efti in combination with KEYTRUDA® from other chemotherapy-free immuno-oncology combinations in non-small cell lung cancer*
- *Exceptional durability and quality of responses exhibited through overall survival (OS) and progression free survival rates across patients expressing PD-L1, including 3-year OS rates of 45.6%, 31%, and 63.6% in TPS ≥1%, 1-49%, and ≥50%, respectively*
- *Immutep to host webcast to discuss ESMO 2023 clinical data on Monday, October 23rd, at 8AM AEDT (Sunday, October 22nd, at 5PM ET)*

SYDNEY, AUSTRALIA – 23 October 2023 – Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, today announces excellent new clinical data from the TACTI-002 / KEYNOTE-798 Phase II trial evaluating eftilagimod alpha ("efti"), a soluble LAG-3 protein and first-in-class MHC Class II agonist, in combination with MSD's (Merck & Co., Inc., Rahway, NJ., USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) as first-line treatment for patients with previously untreated unresectable or metastatic non-small cell lung cancer (NSCLC).

The updated TACTI-002 data, with a cut-off date of August 15, 2023 and a median follow up of over 2 years (25.1 months), was presented by Dr. Enric Carcereny, Catalan Institute of Oncology (ICO), Badalona, Spain, during a Mini Oral session (#1312MO) at ESMO Congress 2023 on Saturday, October 21st. Key takeaways from the oral presentation detailing results from efti in combination with KEYTRUDA® for frontline treatment of advanced or metastatic NSCLC in the TACTI-002 Phase II trial[1] include:

- Promising Overall Survival (OS), Overall Response Rate (ORR), Progression Free Survival (PFS), and Duration of Response (DOR) are visible across all PD-L1 subgroups (Tumor Proportion Score [TPS] <1%, ≥1%, 1-49%, and ≥50%), which clearly differentiates efti in combination with KEYTRUDA® from other chemo-free immuno-oncology (IO) combinations for first-line treatment of NSCLC.
- A significant overall survival benefit was achieved, with a 35.5-month median Overall Survival (mOS) in patients with TPS ≥1%, 23.4-month mOS in TPS 1-49%, and mOS not yet reached in TPS ≥50%. Notably, the mOS in TPS ≥1% was attained with central assessment of PD-L1 (N=58) and a larger patient group with central + local assessment of PD-L1 (N=71), and the 35.5-month mOS compares very favourably to standard-of-care IO, IO-IO, IO-chemo, and IO-IO-chemo therapies *(Table 1).*

- Exceptional durability and quality of responses are increasingly evident with strong overall survival (OS) and progression free survival (PFS) rates across patients expressing PD-L1. The 3-year OS rates are 45.6%, 31.0%, and 63.6% in TPS ≥1%, TPS 1-49%, and TPS ≥50%, respectively. The 12-month PFS rates are 46.8%, 42.1%, and 55.0% for TPS ≥1%, TPS 1-49%, and TPS ≥50%, respectively.
- The entire patient population regardless of PD-L1 expression (N=114) showed encouraging efficacy with 20.2-month mOS, 21.6-month mDoR, and a 36-month OS rate of 36% despite ~75% of patients having negative or low PD-L1 expression.

Table 1: Overall Survival of Efti + KEYTRUDA® versus standard-of-care IO, IO-IO, IO-chemo, and IO-IO-chemo therapies for first-line treatment of advanced non-small cell lung cancer patients with PD-L1 TPS ≥1%

Therapy	Median Overall Survival[2]
Efti + Pembrolizumab	**35.5 months**
Pembro + Doublet Chemo (NSQ)*	**23.3 months**
Pembro + Doublet Chemo (SQ)*	**18.9 months**
Ipilimumab + Nivolumab[3]	**17.1 months**
Pembrolizumab monotherapy[3]	**16.4 months**
Ipi + Nivo + 2 cycles Doublet Chemo	**15.8 months**

** NSQ = Non-squamous; SQ = Squamous*

In NSCLC patients with ≥1% PD-L1 expression, a key area for efti's future development where it has FDA Fast Track status, the ORR (48.3%), mPFS (11.2 months), mDOR (24.2 months), and mOS (35.5 months) compare overall favourably to historical results of anti-PD-1 monotherapy, as well as to historical results of approved anti-PD-1 + chemo-containing regimens. Collectively, the breadth of efficacy and safety data from the large number of metastatic NSCLC patients in the Phase II TACTI-002 trial offers compelling evidence of efti's substantial impact in safely stimulating the patients' immune response to fight cancer.

Dr. Enric Carcereny stated, "The strong efficacy data across all levels of PD-L1 expression in TACTI-002, especially in PD-L1 low (1-49%) and PD-L1 negative (<1%) patients, differentiates efti in combination with anti-PD-1 from other chemo-free immuno-oncology combinations in the frontline treatment of advanced or metastatic non-small cell lung cancer. Unlike other IO-IO combinations that only work in high PD-L1 expressing patients or IO-chemo combinations that rely on toxic chemotherapy to drive better efficacy, efti is clearly enabling deep, durable responses for patients regardless of PD-L1 expression with a favourable safety profile that's in line with anti-PD-1 monotherapy."

Marc Voigt, Immutep CEO stated, "We are extremely pleased to report these excellent overall survival results, the gold standard benchmark within oncology, in patients with metastatic non-small cell lung cancer, and believe these are among the strongest ever delivered in a sizable Phase II clinical trial like TACTI-002 evaluating a dual immuno-oncology approach. The strength of the data positions us well as we continue to plan and prepare for our Phase III trial that we expect to launch next year."

Conference Call and Webcast Details
Immutep will host a conference call and webcast to discuss the clinical data presented at ESMO 2023 and provide an overview on future clinical development plans for efti in 1st line non-small cell lung cancer. The event will feature CEO Marc Voigt, CSO Dr Frederic Triebel, CMO Dr Florian Vogl, and Christian Mueller, Senior Vice President Strategic Development. An open question & answer session with all presenters will conclude the event. A replay of the webcast will be available under the Events section of Immutep's website.

- Date/Time: Monday, October 23rd, at 8AM AEDT (Sunday, October 22nd, at 5PM ET)
- Register: Link to register here.
- Questions: Investors are invited to submit questions in advance via immutep@citadelmagnus.com.

Lung cancer is the second most common cancer. Non-small cell lung cancer accounts for approximately 80-85% of all lung cancers, impacting an estimated 1.87 million people annually, and is the highest cause of death among all cancers[4-6].

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About Eftilagimod Alpha (Efti)
Efti is Immutep's proprietary soluble LAG-3 protein and MHC Class II agonist that stimulates both innate and adaptive immunity for the treatment of cancer. As a first-in-class antigen presenting cell (APC) activator, efti binds to MHC (major histocompatibility complex) Class II molecules on APC leading to activation and proliferation of CD8+ cytotoxic T cells, CD4+ helper T cells, dendritic cells, NK cells, and monocytes. It also upregulates the expression of key biological molecules like IFN-γ and CXCL10 that further boost the immune system's ability to fight cancer.

Efti is under evaluation for a variety of solid tumours including non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), and metastatic breast cancer. Its favourable safety profile enables various combinations, including with anti-PD-[L]1 immunotherapy and/or chemotherapy. Efti has received Fast Track Designation in 1st line HNSCC and in 1st line NSCLC from the United States Food and Drug Administration (FDA).

About Immutep
Immutep is a clinical-stage biotechnology company developing novel LAG-3 immunotherapy for cancer and autoimmune disease. We are pioneers in the understanding and advancement of therapeutics related to Lymphocyte Activation Gene-3 (LAG-3), and our diversified product portfolio harnesses its unique ability to stimulate or suppress the immune response. Immutep is dedicated to leveraging its expertise to bring innovative treatment options to patients in need and to maximise value for shareholders. For more information, please visit www.immutep.com.

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1) Clinical data according to iRECIST. Comparable results by RECIST1.1.
2) Arrow lengths in Table 1 are proportional representations of OS data. Data for standard-of-care therapies taken from publications of respective registrational trials (e.g., KN-042, KN-189, KN-407, CM-227, CM-9LA), and comparison of data is from different clinical trials.
3) Ipi+ Nivo approved in US for 1L NSCLC PD-L1 TPS ≥1% but not in EU; Pembro monotherapy not approved in Europe for TPS 1-49%.
4) The Global Cancer Observatory, Lung Cancer Fact Sheet
5) American Cancer Society, About Lung Cancer
6) CDC, Lung Cancer Statistics

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