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Immutep Clinical Development Update for its First-in-Class LAG-3 Antigen Presenting Cell Activator Candidate Eftilagimod Alpha

- **Encouraging Phase II data supports broad therapeutic potential of eftilagimod alpha in non-small cell lung cancer (NSCLC), head and neck squamous cell cancer (HNSCC) and metastatic breast cancer (MBC)**
- **Planning and regulatory interactions ongoing with a focus now prioritising first-line NSCLC**
- **New and important clinical data in first-line NSCLC expected in Q4 2022**
- **Continued expansion of efti in additional indications and combinations planned**
- **Strong balance sheet provides cash runway into early 2024**

Sydney, Australia, September 14, 2022 - [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 a clinical development update for its first-in-class LAG-3 antigen-presenting cell (APC) activator product candidate, eftilagimod alpha ("efti").

Immutep CEO Marc Voigt said: "Efti is an innovative LAG-3-based clinical candidate with broad therapeutic potential supported by encouraging activity and well-tolerated safety in multiple Phase II trials in solid tumor indications including NSCLC, HNSCC and MBC. Recent data from TACTI-002, a frontline, PD-L1 all-comer trial in NSCLC, demonstrated that efti in combination with anti-PD-1 therapy delivered a clinical benefit in patients across all levels of PD-L1 expression, including patients with negative PD-L1. Based on this compelling data, coupled with the large market opportunity and high unmet need for more durable and tolerable options, our late-stage clinical development efforts will focus on frontline NSCLC in combination with anti-PD-1 therapy. We look forward to providing additional clinical data in 1L NSCLC later this year. Regulatory interactions and late-stage planning to evaluate efti in MBC, another attractive opportunity for efti, will also continue."

Dr. Frederic Triebel, Immutep's CSO and CMO added: "Well-tolerated treatment options that can synergise with standards of care to improve outcomes across the PD-L1 spectrum remain a high unmet need in NSCLC. We are particularly encouraged by the ability of efti to demonstrate benefit across all levels of PD-L1 status, and particularly in patients with negative or low PD-L1 levels who typically respond poorly to checkpoint treatment. This could be explained by the orthogonal therapeutic approach in TACTI-002 where efti first activates innate immunity via monocytes, dendritic cells, and NK cells and leads to the activation of more T cells, enhancing the effect of anti-PD-1 therapy. Data from TACTI-002 support the potential of this IO-IO combination to not only offer a chemotherapy-free option for a broad range of NSCLC patients but also expand the potential market opportunities of current immune checkpoints approaches. We look forward to maximizing the full treatment potential of efti in patients with advanced solid tumors."

Late-Stage Efti Clinical Development Updates

Pathway in Lung Cancer (anti-PD-1 combination with or without chemo)

Immutep is prioritising 1L NSCLC in terms of late-stage clinical strategy, based on compelling data, coupled with the large market opportunity and continued high unmet need for more durable and tolerable options. In combination with top selling drug in oncology, Keytruda(R), efti has been delivering strong results, especially in patients known to respond less than optimally/sub-optimally to anti-PD-1 treatment (e.g. patients with negative or low PD-L1

expression levels). Immutep's next steps in NSCLC will be shaped by the maturing TACTI- 002 data, with additional data expected in Q4 2022 and feedback from regulatory authorities.

Initial results from Immutep's ongoing INSIGHT-003 trial evaluating efti in combination with anti-PD-1 therapy and chemotherapy are also expected in Q4 2022. These results may help to further inform the design of our late-stage trial in 1L NSCLC.

Pathway in Head and Neck Cancer (anti-PD-1 combination)

Currently, 47/154 patients (approximately 30 percent) have been recruited into Immutep's ongoing randomised Phase IIb TACTI-003 trial in 1L HNSCC. Recruitment is accelerating as further sites have been activated. The trial is being conducted in collaboration with Merck and Co., Inc., Rahway, NJ, USA (known as "MSD" outside the United States and Canada). Efti in first-line HNSCC has Fast Track designation by the FDA, which provides Immutep with access to more frequent meetings and communications with the FDA, and potentially enables Rolling Review of a Biologic License Application. In addition, Fast Track designation may provide Accelerated Approval and Priority Review if relevant criteria are met, for efti in HNSCC.

Pathway in Breast Cancer (chemo combination)

Immutep will continue with preparations for future clinical development in MBC, including engagement with the regulators, Contract Research Organisations and other stakeholders, each of which are progressing. Efti has shown encouraging clinical data in combination with chemotherapy in this indication, including statistically significant improvements in overall survival (OS) across several pre-defined subgroups. As such, MBC remains an attractive opportunity for efti.

Ultimately, Immutep will aim to obtain marketing authorisation of efti in multiple indications, positioning the Company, or a potential partner, strongly to fully exploit the compelling potential of this unique clinical candidate to help a wide range of cancer patients.

Upcoming Clinical Data Updates

Immutep plans to provide further clinical trial updates in Q4 2022, as follows:

- more data from TACTI-002 in 1L NSCLC,
- first results from the INSIGHT-003 study, and
- an update from the TACTI-003 study.

New Clinical Trials

In addition to Immutep's current development program, the company is also engaged in discussions with a number of external parties to test efti in new settings. The expansion of clinical settings will help to further explore the potential of efti and enhance its value. A first example is the recently announced new Phase II investigator-initiated study in soft tissue sarcoma with efti in combination with pembrolizumab and radiotherapy in the neoadjuvant setting. We hope to have further updates regarding these potential new settings in the coming weeks.

Including the planned program expansion, Immutep remains well-funded with AUD 80 million in cash as of 30 June 2022, providing a cash runway into early CY2024.

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 maximise 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. 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