

## Immutep's AGM 2024 Chairman's Address

22 November 2024

Dear Fellow Shareholders,

On behalf of the Board of Directors, I am pleased to welcome you to Immutep Limited's Annual General Meeting for the 2024 financial year. Thank you to all our shareholders who have joined us, both in person and virtually.

It's my pleasure to provide you with an overview of Immutep's progress during the last financial year, a year of notable advancements in our clinical trials, significant regulatory achievements, and continued strong financial management. This has put our Company in a very strong position to continue to advance our lead candidate, eftilagimod alpha (efti) toward market approvals in Europe and the US and in addition, to progress our autoimmune candidate, IMP761 through early clinical trials following its recent entry into the clinic.

As you may know, efti is a soluble LAG-3 fusion protein, with a unique mechanism of action as an MHC Class II agonist. It is the only LAG-3 product that activates both the adaptive and innate immune systems to drive a broad immune response to fight cancer. Another key differentiator is efti's strong safety profile which enables it to be paired with a variety of other cancer therapies, including anti-PD-(L)1 therapies, radiotherapy, and chemotherapy without generating a new safety signal for combined therapy. Its versatility, with exceptional promise in multiple oncology indications, opens up multiple strategic opportunities for Immutep.

Immutep's strategic options include the opportunity to partner with one of our existing collaboration partners, or to partner with the owner of any of the other cancer therapies efti is already being tested with, or, we could potentially pursue commercialisation ourselves. Delivering the best outcome for patients and shareholders will be a key determinant of our eventual pathway.

In financial year 2024, we made significant strides advancing efti in later-stage clinical trials in three large oncology indications. Our lead indication is first line non-small cell lung cancer (NSCLC). We are also evaluating efti in first line head and neck squamous cell carcinoma (HNSCC) and metastatic breast cancer. In addition to these later-stage studies, earlier stage trials in soft tissue sarcoma and urothelial cancer are also underway with clinical collaborators.

Before I take you through the highlights of this work, I would like to extend the Board's appreciation to Immutep's team whose dedication has enabled us to achieve so many milestones this year. Immutep has welcomed a number of new team members this year. We now have 46 talented professionals across the globe, experts in research, development and regulatory affairs in our key markets.

During the year, we were pleased to sign our third and most important clinical trial collaboration and supply agreement with MSD, also known as Merck & Co. This clinical trial will assess efti in combination with Merck's anti-PD-1 therapy, KEYTRUDA® plus chemotherapy, as a first-line treatment for metastatic NSCLC. This pivotal Phase III trial is called TACTI-004. MSD's KEYTRUDA became the world's top-selling drug in 2023, and lung



cancer was estimated to represent over 35% of KEYTRUDA's US\$25 billion in sales last year. Success with TACTI-004 would provide our company with significant commercial leverage.

The TACTI-004 trial will enroll approximately 750 patients, irrespective of PD-L1 expression, to address the full scope of the first-line NSCLC market eligible for anti-PD-1 therapy. We were delighted to receive positive feedback from the US Food and Drug Administration on this trial following the end of the financial year, completing the preparatory regulatory interactions needed to start the trial.

In other areas, our TACTI-003 trial for first-line HNSCC has made strong progress, completing recruitment and reporting initial clinical results. This Phase IIb trial has reported promising efficacy across all levels of PD-L1 expression, especially in the PD-L1 negative cohort. Remarkably, these results have been achieved without chemotherapy in a PD-L1 negative HNSCC population, a patient subgroup traditionally challenging to treat. Immutep continues to track patient outcomes and looks forward to providing an update on HNSCC patients with negative PD-L1 expression in a few weeks at the ESMO Immuno-Oncology conference.

The AIPAC-003 Phase II/III study in metastatic breast cancer is also progressing well. Patient recruitment continued through the financial year. In October 2024 we announced the Phase II portion was fully enrolled. Early data from the safety lead in phase was encouraging. We look forward to reporting further data and determining efti's optimal biological dose – which will be either 30 or 90 mg - in light of project Optimus guidance from the FDA.

Our new collaboration with MSD builds on previous collaborations, including the TACTI-002 trial in NSCLC and HNSCC, where we've reported compelling improvements in patient survival and response rates. In Part A of TACTI-002 we have shown efti is enabling deep, durable responses for patients regardless of PD-L1 expression. We have a favourable safety profile in line with anti-PD-1 monotherapy and, most importantly, this treatment drives a relatively high median overall survival benefit for our patients.

Finally, Immutep recently reported promising interim results from the INSIGHT-003 trial in first-line non-small cell lung cancer (NSCLC) and from the EFTISARC-NEO Phase II trial in soft tissue sarcoma (STS). We are excited about the excellent data in NSCLC and STS represents an area of high unmet need. These advancements across Immutep's broader clinical programs underscore efti's potential to improve therapeutic outcomes for a variety patients facing challenging cancer types.

FY24 has also been a pivotal year for regulatory achievements. Both the European Medicines Agency (EMA) and the U.S. FDA provided positive feedback on efti's development pathway. The EMA confirmed additional toxicology studies are not required for the anticipated potential Marketing Authorisation Application (MAA), while the FDA offered similar support regarding a potential Biologics License Application (BLA). This stengthens the approval pathway for efti.

On the manufacturing front, Immutep secured regulatory approval for efti made under its commercial 2,000L scale process designed for clinical use in multiple European countries, as well as in the US. This manufacturing milestone positions Immutep to meet future demand as the company advances toward commercialisation.



Immutep's second program, with IMP761, the world's first LAG-3 agonist designed for autoimmune diseases, has also made significant progress. The initiation of first-in-human trials started mid this year. The first healthy participant was successfully dosed subsequent to the financial year end and the trial is progressing well. IMP761 holds great promise due to its potential to address the underlying causes of autoimmune disorders, and is an exciting, emerging part of our development pipeline.

Throughout all this clinical activity, Immutep's financial position has remained very robust, thanks to the ongoing and strong support we have received from our shareholders. During FY24, new and existing shareholders enabled Immutep to raise \$100.2 million (~US\$63 million) via a fully underwritten issue of new equity. We closed FY24 with a strong balance in cash, cash equivalents and term deposits of approximately A\$181.8 million. Our financial strategy has been disciplined and growth-oriented, ensuring we can expect a strong runway to the end of calendar 2026.

Immutep's share price and market capitalisation is often affected by the broader biotech and pharma market, as well as other global forces that are always changing. Following our recent INSIGHT-003 data, we are more confident than ever in our path to conduct our pivotal Phase III study, TACTI- 004, for the largest global cancer market, NSCLC. We believe efti can add significant clinical benefit to the standard of care for patients receiving the world's commercially most successful drug, Keytruda, and that our combination trial will translate into tremendous value for Immutep and its partners and will well reward our long-standing shareholders.

Looking ahead, FY25 is poised to be another year of meaningful progress. Our primary focus will be to develop efti in first line NSCLC via the TACTI-004 phase III trial. We anticipate initiation of the trial in late 2024 or early 2025. In addition, we will continue to explore the paths forward for first line HNSCC and metastatic breast cancer, and we are eagerly awaiting results from the first-in-human study of our autoimmune candidate, IMP761.

We are grateful for the continued support of our shareholders, whose trust enables us to advance these life-changing LAG-3 therapeutics. Thank you for your ongoing confidence in Immutep as we work to make a lasting difference in the lives of patients and their families worldwide.

Yours sincerely,
Dr Russell Howard
Chairman
Immutep Limited

## **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 <a href="https://www.immutep.com">www.immutep.com</a>.



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