

## Immutep Announces First Clinical Data from 90mg Dosing of Efti

- Data from the safety lead-in of the AIPAC-003 trial shows 90mg efti in combination with paclitaxel is safe and well tolerated
- Encouraging initial efficacy in six metastatic breast cancer patients, who exhausted all endocrine therapy including CDK4/6 inhibitors, demonstrated by a 50% overall response rate, including one complete response, and a 100% disease control rate

**SYDNEY, AUSTRALIA – March 05, 2024** – [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 safety and initial efficacy data from the first ever 90mg dosing of eftilagimod alpha (efti) in combination with weekly paclitaxel in patients from the safety lead-in (N=6) of the AIPAC-003 Phase II/III trial.

Updated safety data from patients with HR-positive/HER2-negative/low metastatic breast cancer (MBC) treated with this innovative immuno-oncology (IO)-chemotherapy combination reveal no treatment-emergent serious adverse events. Additionally, all treatment-emergent adverse events during the safety observation period to date have been of mild severity.

Initial efficacy reports show these six MBC patients, who exhausted all endocrine therapy including cyclin-dependent kinase 4/6 (CDK4/6) inhibitors, exhibited encouraging results achieving a 50% overall response rate, including one complete response and two partial responses, and a 100% disease control rate overall with the remaining three patients having stable disease as best response.

Acknowledging the early nature of these results, efti with paclitaxel historically has shown a dose-dependent effect in MBC and has in some cases also led to stable disease patients becoming partial responders after six months. The biologically active 30mg efti dose, previously the highest dose of efti ever tested, has demonstrated a stronger immune response and greater efficacy than lower dosing levels (1mg, 6mg) in multiple clinical trials.

The ongoing randomized Phase II portion of the trial, which will include up to 58 evaluable patients, is focused on whether 90mg efti dosing is safe and more efficacious than 30mg dosing. This portion of the trial has enrolled 23 patients to date. Importantly, the determination of the optimal biological dose in AIPAC-003 is directly tied to the [FDA’s Project Optimus](#) initiative and is relevant for the entire efti program.

Further updates from AIPAC-003 will be provided in CY2024. For more information on the trial, please visit [clinicaltrials.gov \(NCT05747794\)](https://clinicaltrials.gov/NCT05747794).

### **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- $\gamma$  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 first line HNSCC and in first 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](http://www.immutep.com).

### **Australian Investors/Media:**

Catherine Strong, Citadel-MAGNUS  
+61 (0)406 759 268; [cstrong@citadelmagnus.com](mailto:cstrong@citadelmagnus.com)

### **U.S. Media:**

Chris Basta, VP, Investor Relations and Corporate Communications  
+1 (631) 318 4000; [chris.basta@immune.com](mailto:chris.basta@immune.com)

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