

ASX/Media Release

## **ImmuteP Successfully Achieves Commercial Scale in Manufacturing of Eftilagimod Alpha**

*First 2,000L Manufacturing Run of its First-in-Class Soluble LAG-3 Protein  
Completed by WuXi Biologics*

**SYDNEY, AUSTRALIA – 8 December, 2022** – [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 the successful scale-up of the manufacturing of its lead product candidate eftilagimod alpha (“efti” or “IMP321”), a first-in-class soluble LAG-3 protein, with the completion of a 2,000L manufacturing run.

In preparation for late-stage clinical trials and commercial production, ImmuteP has been working with WuXi Biologics to increase the efti manufacturing process from 200L to 2,000L capacity single-use bioreactors at the manufacturing plant in Wuxi city, China. The first 2,000L manufacturing run has been performed successfully with all predefined release criteria met.

**Marc Voigt, CEO of ImmuteP said:** “Following compelling results from the TACTI-002 Phase II trial and promising initial clinical data from INSIGHT-003 recently presented at SITC 2022, we are pleased to announce this significant achievement reaching commercial scale in efti’s manufacturing by WuXi Biologics, an important long-term partner of ImmuteP. With potential registrational trials in multiple indications for our first-in-class soluble LAG-3 protein, including our ongoing randomised TACTI-003 Phase IIb trial in 1<sup>st</sup> line head and neck cancer, this represents an important step towards potential commercial production of efti.”

**Chris Chen, CEO of WuXi Biologics stated:** “We are very pleased to be moving the scale up process forward for efti with ImmuteP. WuXi Biologics and ImmuteP have been working together for many years and we are excited to continue supporting them as they advance towards potential commercialisation of efti.”

Subject to feedback from competent authorities, ImmuteP plans to introduce the material manufactured by the 2,000L scale process into ongoing and future Phase II/III clinical trials.

### **About Eftilagimod Alpha (Efti)**

Efti is ImmuteP’s proprietary soluble LAG-3 clinical stage candidate that is a first-in-class antigen presenting cell (APC) activator for the treatment of cancer, capitalising on LAG-3’s unique characteristics to stimulate both innate and adaptive immunity. Efti binds to and activates antigen presenting cells via MHC II molecules leading to expansion 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 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 HER2–/HR+ 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 WuXi Biologics**

WuXi Biologics is a leading global Contract Research, Development and Manufacturing Organisation (CRDMO) offering end-to-end solutions that enable partners to discover, develop and manufacture biologics from concept to commercialisation for the benefit of patients worldwide.

With over 10,000 skilled employees in China, the United States, Ireland, Germany and Singapore, WuXi Biologics leverages its technologies and expertise to provide customers with efficient and cost-effective biologics discovery, development and manufacturing solutions.

#### **About Immutep**

Immutep is a clinical stage biotechnology company leading the development of LAG-3 related immunotherapy products for the treatment of cancer and autoimmune disease. The Company is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximize value to shareholders.

Immutep’s lead product candidate is efitlagimod 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 in multiple clinical trials. The Company is also developing an agonist of LAG-3 (IMP761) for autoimmune disease. Additional LAG-3 product candidates, including antibodies for immune response modulation, are licensed to and being developed by Immutep’s large pharmaceutical partners.

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

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