

**ASX/Media Release**

**IMMUTEP RECEIVES CONSTRUCTIVE FEEDBACK FROM US FDA ON ITS  
CLINICAL DEVELOPMENT PROGRAM FOR EFTI IN METASTATIC BREAST CANCER**

**SYDNEY, AUSTRALIA – 10 March 2022** – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), is pleased to announce it has received constructive feedback from the US Food and Drug Administration (FDA) regarding its clinical development program for lead product candidate, eftilagimod alpha (efti or IMP321), in metastatic breast cancer (MBC).

In particular, the FDA has supported Immutep’s view to continue exploring the development of efti in MBC in a new registrational trial. The FDA’s feedback was based on clinical data presented by Immutep, including final overall survival data from its phase IIb AIPAC trial reported at the SITC 2021 conference (see announcements dated 10 and 15 November 2021).

The advice from the FDA follows the receipt of feedback from the European Medicines Agency (EMA) regarding Immutep’s clinical development program for efti, as announced in October 2021.

The planned new registrational trial, AIPAC-003, will be based on Immutep’s completed AIPAC trial, but with an optimized design and directed to patients who are likely to benefit most from the treatment. As the new trial is intended to take place across multiple countries, additional regulatory interactions are ongoing, including with the FDA and EMA. Immutep is also consulting key opinion leaders and its clinical advisory board, and will consolidate this advice with the ongoing feedback from the regulatory interactions to generate a final study design.

**Immutep CEO, Marc Voigt, commented:** “We are pleased to receive constructive feedback from the US FDA regarding the advancement of efti in metastatic breast cancer. The FDA’s advice builds on the feedback we received from the EMA in October 2021 and will help solidify the optimal trial design. Interactions with the FDA and other regulatory agencies will continue and we will keep the market informed of our progress as we plan for our registrational trial for efti.”

**Immutep CSO & CMO, Dr. Frederic Triebel, also commented:** “We are very pleased to have now received feedback from both the FDA and the EMA as part of our ongoing process to design a new registrational trial in MBC. As we have noted previously, many of these patients do not respond well to conventional immune checkpoint inhibitors and so it is important that we continue to advance efti, with its unique mechanism of action, with a carefully designed trial.”

**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

maximize 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 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 and infectious disease. 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](http://www.immutep.com) or by contacting:

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