

ASX/Media Release

Immutep receives positive EMA scientific advice for further clinical development of efti in MBC including Phase III

- Positive feedback for the general clinical development program including the planned registrational Phase III trial in metastatic breast cancer (MBC)
- Other regulatory engagement ongoing, including with the US Food and Drug Administration (FDA)

SYDNEY, AUSTRALIA – 29 October 2021 – [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, is pleased to announce it has received positive feedback from the European Medicines Agency (EMA) regarding its clinical development program for lead product candidate, eftilagimod alpha (efti), including the planned Phase III trial in MBC.

In its scientific advice the EMA has supported the Company’s view to continue the development of efti in MBC in a Phase III clinical trial, based on clinical data presented in December 2020 at SABCS. The trial will be built on the Company’s ongoing Phase IIb AIPAC trial, which reported encouraging interim results in key patient subgroup populations. Final overall survival data from the Phase IIb AIPAC trial will be reported in mid November at SITC 2021 as a *late breaker* poster presentation.

As the planned Phase III trial is intended to take place across multiple countries, additional interactions with the EMA and other regulators, including with the US FDA to generate a final study design are ongoing.

Immutep CEO, Marc Voigt, noted: “Receiving positive and constructive EMA advice on our clinical development program for efti, including the planned Phase III trial in metastatic breast cancer is an exciting achievement for Immutep. We now look forward to further engagement with the EMA and other regulators, including the US FDA to solidify our trial plans.”

About Scientific Advice

Scientific Advice is a procedure offered by the EMA to medicine developers for clarification of questions arising during development of medicinal products. The EMA provides scientific advice to support the timely and sound development of high-quality, effective and safe medicines, for the benefit of patients. Scientific Advice is prospective in nature and focuses on development strategies rather than pre-evaluation of data to support a Marketing Authorisation Application (MAA). Scientific Advice is legally nonbinding and is based on the current scientific knowledge which may be subject to future changes. Nevertheless, the advice provided is taken into consideration during MAA and any deviations from the advice given need to be well justified.

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’s current lead product candidate is eftilagimod alpha (efti or IMP321), a soluble LAG-3 fusion protein (LAG-3lg), 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.

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Additional LAG-3 products, including antibodies for immune response modulation, are being developed by Immutep's large pharmaceutical partners.

Immutep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Further information can be found on the Company's website www.immutep.com or by contacting:

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

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