

ASX/Media Announcement

Immutep Receives Second IND approval for Efti from US FDA

- Enables Immutep to initiate its AIPAC-002 study, in metastatic breast cancer
- AIPAC-002 to expedite the possible use of efti for patients in the US

SYDNEY, AUSTRALIA – March 9, 2020 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, announces the approval of its Investigational New Drug (“IND”) application by the United States Food and Drug Administration (“FDA”) for eftilagimod alpha (“efti” or “IMP321”).

The FDA approval of the IND allows Immutep to initiate its planned AIPAC-002 Phase I clinical study in metastatic breast cancer (MBC) patients. Immutep will commence the study, subject to the completion of other preparatory steps and pending positive results from its larger AIPAC Phase IIb study, which are expected to be reported by the end of March 2020.

Immutep CEO, Marc Voigt stated: “Receiving our second IND approval for efti from the FDA is a crucial step forward for Immutep. The IND allows us to initiate, effectively, a small bridging study called AIPAC-002 that enables us to further interact with the FDA in terms of efti in metastatic breast cancer. The results of our larger AIPAC trial will be reported this month. If they are positive, we will proceed with the final preparations and more importantly, will advance our discussions with regulators in order to make key strategic decisions about efti.”

Overview of AIPAC-002

AIPAC-002 is a Phase I trial evaluating efti in combination with a taxane-based standard of care chemotherapy, called paclitaxel, in 24 patients with MBC in the US and the EU to boost the T-cell immune responses against tumours. This is the same combination therapy being investigated in Immutep’s Phase IIb AIPAC study. The trial forms part of Immutep’s strategy to expedite the possible use of efti for MBC patients in the US.

The IND application allows Immutep to ship efti across US state borders to US clinical investigators participating in the AIPAC-002 clinical study.

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 eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3 protein (LAG-3lg) based on the LAG-3 immune control mechanism. This mechanism plays a vital role in the regulation of the T cell immune response. Efti is currently in a Phase IIb clinical trial as a chemoimmunotherapy for metastatic breast cancer termed AIPAC; a Phase II clinical trial being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as "MSD" outside the United States and Canada) referred to as TACTI-002 (Two ACTIVE Immunotherapies) to evaluate a combination of efti with KEYTRUDA[®] (or pembrolizumab, an anti-PD-1 therapy) in several different solid tumours (clinicaltrials.gov identifier NCT03625323); a Phase I clinical trial being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. referred to as INSIGHT-004 to evaluate a combination of efti with avelumab (clinicaltrials.gov identifier NCT03252938); and a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier NCT02676869).

Additional LAG-3 products, including antibodies, for immune response modulation in autoimmunity and cancer are being developed by Immutep's large pharmaceutical partners. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

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.