

ASX/Media Release

**IMMUTEP ACHIEVES FAST TRACK DESIGNATION FROM US FDA  
FOR EFTI, A SOLUBLE LAG-3 PROTEIN, IN FIRST LINE RECURRENT/METASTATIC HEAD & NECK  
CANCER**

- Fast Track designation opens the potential for expedited development and review with the US FDA
- Fast Track was granted based on the promising data package from Immutep, including from Immutep's Phase II TACTI-002 trial (Keynote-798) in head and neck squamous cell carcinoma (HNSCC)
- Start-up preparations for Immutep's new Phase IIb TACTI-003 trial in 1<sup>st</sup> line HNSCC are advancing well

**SYDNEY, AUSTRALIA – 8 April 2021 – [Immutep Limited](#)** (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a biotechnology company developing novel immunotherapy treatments for cancer, infectious disease and autoimmune disease, announces its lead product candidate eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3 protein, has received Fast Track designation in 1<sup>st</sup> line recurrent or metastatic HNSCC from the United States Food and Drug Administration (FDA).

Fast Track has been granted for the development program of efti for 1<sup>st</sup> line treatment of recurrent or metastatic HNSCC due to its potential to address an unmet medical need, as evidenced by encouraging data indicating a positive risk benefit ratio.

The data package evaluated by the FDA included the promising results from Part C of Immutep's Phase II TACTI-002 trial evaluating efti in combination with KEYTRUDA<sup>®</sup> (pembrolizumab) 2nd line PD-X naive HNSCC, and its plans for a trial in 1<sup>st</sup> line HNSCC (TACTI-003). Interim clinical data from TACTI-002 was presented at the Society for Immunotherapy of Cancer (SITC) in November 2020. The Overall Response Rate (ORR) reported at SITC was approximately 36% (approximately 44% in evaluable patients) for 28 patients receiving efti in combination with KEYTRUDA.

On 16 March 2021, Immutep announced that it had entered into a second collaboration with MSD (Merck & Co. Inc., Kenilworth, NJ, USA) to evaluate efti in combination with KEYTRUDA in a new Phase IIb trial in 1<sup>st</sup> line HNSCC, TACTI-003. Planning for this trial is advancing well and the study is expected to start in mid-2021.

**About Fast Track designation**

FDA Fast Track designation is awarded to help important new therapies reach patients earlier. It is designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fill an unmet medical need. Importantly, Immutep will now have access to more frequent meetings and communications with the FDA, potentially receive Rolling Review of its Biologic License Application (once submitted) and may be eligible for Accelerated Approval and Priority Review, if relevant criteria are met, for efti in HNSCC.

More information on Fast Track designation is available on the US FDA's website.

### **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, infectious disease, 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.