

## **Immutep Receives Positive Feedback from FDA on Late-Stage Clinical Development of Eftilagimod Alfa in Head and Neck Cancer with CPS <1**

**SYDNEY, AUSTRALIA – August 5th, 2025** – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a late-stage immunotherapy company targeting cancer and autoimmune diseases, today announces it has received positive and constructive feedback from the US Food and Drug Administration (FDA), regarding future clinical development of its first-in-class MHC Class II agonist, eftilagimod alfa (“efti”), for first line treatment of recurrent/metastatic head and neck squamous cell carcinoma (1L HNSCC) patients who have PD-L1 expression below 1 (Combined Positive Score [CPS] <1).

Based on its review of the encouraging data in 1L HNSCC with CPS <1 from the TACTI-003 (KEYNOTE-C34) Phase IIb trial evaluating efti in combination with MSD’s (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 KEYTRUDA® (pembrolizumab), the FDA agreed on the potential of efti in combination with KEYTRUDA to address the high unmet need in this CPS <1 patient segment and is supportive of the combination’s further development.

Paths for future clinical development and potential accelerated approval in light of the FDA’s Project FrontRunner include a randomised registrational trial evaluating efti in combination with KEYTRUDA against standard-of-care therapy or alternatively a smaller single-arm study (e.g. 70 - 90 patients) with safety, response rate, and duration of response as key endpoints, followed by a confirmatory randomised study that builds on the existing data.

“We are pleased with the FDA’s feedback and guidance that underscores the high unmet need of head and neck cancer patients whose PD-L1 expression level is below one. The FDA feedback positions Immutep to evaluate options for future collaborative clinical development paths to bring a new, effective and safe treatment option to this underserved patient population,” said Marc Voigt, CEO of Immutep.

“Our primary focus clearly remains the pivotal TACTI-004 Phase III evaluating efti as first line therapy for non-small cell lung cancer and we are excited with its progress to date and the consistent, encouraging feedback we hear from physicians. This focus and additional considerations will be reviewed internally and discussed with stakeholders and potential strategic partners in regards to forward paths in head and neck cancer,” added Mr Voigt.

[Project FrontRunner](#) is an FDA Oncology Center of Excellence (OCE) initiative to encourage drug sponsors to consider when it may be appropriate to develop and seek approval of cancer drugs for advanced/metastatic disease, in an earlier clinical setting rather than the usual approach to develop and seek approval of a drug for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options. In this setting, advancing new effective therapies has the greatest potential to significantly improve quantity and quality of patients’ lives.

Patients with CPS <1 in 1L HNSCC represent a treatment population with high unmet medical need. Up to 20% of 1L HNSCC patients have CPS <1 and despite immunotherapy’s progress in fighting



cancer, anti-PD-1 therapy alone (without chemotherapy) is only approved for patients who express PD-L1 (CPS  $\geq 1$ ). All currently available treatment options for patients with PD-L1 CPS  $< 1$  include chemotherapy.

### **About Immutep**

Immutep is a late-stage biotechnology company developing novel immunotherapies for cancer and autoimmune disease. The Company is a pioneer in the understanding and advancement of therapeutics related to Lymphocyte Activation Gene-3 (LAG-3), and its diversified product portfolio harnesses LAG-3's ability to stimulate or suppress the immune response. Immutep is dedicated to leveraging its expertise to bring innovative treatment options to patients in need and to maximise value for shareholders. For more information, please visit [www.immutep.com](http://www.immutep.com).

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

