

ASX/Media Release

Immutep enters into a New Collaboration with Merck KGaA, Darmstadt, Germany for LAG-3 Therapy, Efti

- Collaboration with Merck KGaA, Darmstadt, Germany to evaluate eftilagimod alpha in combination with bintrafusp alfa
- New investigator-initiated explorative, multi-centre, open-labelled Phase I/IIa trial in 12 previously treated patients with different solid tumours, called INSIGHT-005
- First patient is expected to be enrolled and dosed in H2 of calendar year 2021

SYDNEY, AUSTRALIA – 1 June 2021 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMPP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune disease, announces a new collaboration and supply agreement with Merck KGaA, Darmstadt, Germany for a Phase I/IIa clinical trial in patients with solid tumours, called INSIGHT-005.

The trial will evaluate the feasibility, safety and efficacy of Immutep’s lead product candidate, eftilagimod alpha (efti or IMP321), when given in combination with bintrafusp alfa (M7824), an investigational bifunctional fusion protein immunotherapy being jointly developed by Merck, Darmstadt, Germany and GlaxoSmithKline. Bintrafusp alfa aims to block two immunosuppressive pathways, TGF- β and PD-L1, while efti activates antigen presenting cells, via the LAG-3 – MHC II pathway.

“Through INSIGHT-005, we plan to explore the effect of releasing the brakes and pushing the accelerator of the body’s immune system in three different positions of the cancer immunity cycle. The new trial builds on our knowledge and the encouraging data from the INSIGHT trial of efti, also in solid tumours. We are excited about this new clinical collaboration which allows us to extend and strengthen our relationship with an existing partner in a new and exciting setting, particularly at a time when there is growing awareness and validation of the LAG-3 MHC class II interaction,” said Immutep CEO Marc Voigt.

INSIGHT-005 will be conducted by the Institute of Clinical Cancer Research, at Krankenhaus Nordwest in Frankfurt, Germany (IKF) as an investigator-initiated trial, with Prof. Dr. Salah-Eddin Al-Batran as lead investigator. The study will be run as an amendment to the protocol of the ongoing Phase I INSIGHT trial as the fifth arm (Stratum E). Prof. Al-Batran is also the lead investigator of INSIGHT and INSIGHT-004 and a member of Immutep’s clinical advisory board.

“We are very pleased to be expanding our involvement with Immutep to explore efti in a new combination with bintrafusp alfa. Our experience and knowledge of efti, combined with our extensive nationwide network of more than 500 German clinical facilities, means we are well equipped to lead the INSIGHT-005 study,” said Prof. Al-Batran, lead investigator of INSIGHT-005.

INSIGHT-005 is planned to take place in 2 clinical sites in Germany. Immunetep is financially supporting the trial to be run by IKF, and Merck, Darmstadt, Germany is financially contributing to the biomarker-related work. Subject to regulatory and ethics committee approval, the first patient is expected to be enrolled in mid-2021 and the trial is expected to deliver first data in early 2022.

About Immunetep

Immunetep 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. Immunetep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximize value to shareholders. Immunetep is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Immunetep'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. Immunetep 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 Immunetep's large pharmaceutical partners.

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

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This announcement was authorised for release by the board of Immunetep Limited.

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