

ASX/Media Release

Immutep Reports Positive Final Data from the INSIGHT-004 Phase I Study of LAG-3 Therapy, Efti, at ASCO 2021

- Encouraging activity signals from the combination of efti and avelumab with a response rate of 41.7% in different solid tumours (DCR 50%) acc. to RECIST 1.1
- No selection of patients for immunogenic markers (e.g. PD-L1 expression levels, MSI high or TMB)
- 9 out of 12 patients still alive
- Deep and durable responses also in patients with low or no PD-L1 expression and typically IO insensitive indications like gastroesophageal or cervical cancer which typically do not respond to immune checkpoint therapy
- Continued good safety profile and promising activity signals warrant further clinical evaluation

SYDNEY, AUSTRALIA – 4 June 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, announces encouraging final data from its Phase I INSIGHT-004 study.

The data will be presented in a poster presentation by Dr Thorsten Goetze, Krankenhaus Nordwest, University Cancer Center Frankfurt, Germany at the American Society of Clinical Oncology's (ASCO) 2021 Annual Meeting in an on-demand session available from 9 am on 4 June 2021, US Eastern Time at this year's virtual conference. The poster will also be made available on Immutep's website from that time at:

<https://www.immutep.com/investors-media/presentations.html>

INSIGHT-004 is evaluating the combination of Immutep's lead product candidate, efitilagimod alpha ("efti" or "IMP321") with avelumab (Bavencio®), an anti-PD-L1 antibody, in 12 patients with different solid tumours. It is being conducted under Immutep's collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer Inc., which are co-developing and co-commercialising avelumab. INSIGHT-004 is the fourth arm (Stratum D) of the investigator-initiated INSIGHT trial which is conducted by the Institute of Clinical Cancer Research (IKF) in Frankfurt, Germany.

Immutep CSO and CMO, Dr Frederic Triebel said: "The final results of the INSIGHT-004 study show promising activity signals from efti in combination with avelumab in a variety of solid cancers, primarily gastrointestinal. Overall, 41.7% of patients responded to the therapy and half showed disease control. Importantly, it continues to be well tolerated. These encouraging results are supportive of further clinical evaluation of this new combination, efti plus anti-PD-L1 therapy."

Prof Salah-Eddin Al-Batran, INSIGHT-004 trial investigator and Director of IKF said: "Efti and avelumab could represent a potent combination for enhancing the immune system in patients with different solid tumours. We are particularly encouraged to see the deep and durable responses in patients with solid tumors including PD-L1-negative cancers."

Final Results Summary

- Objective Response Rate of 41.7% (5/12) demonstrates encouraging early activity signals from this all-comer trial. All responders (5/12) reported a partial response (PR) to the combination therapy according to RECIST 1.1
- Disease Control was seen in 50% of patients (6/12)
- 75% of patients (9/12) are still alive in this partly heavily pretreated patient population

Tumor response – according to RECIST 1.1	Total N (%) Total (N=12)
Complete Response (CR)	0 (0)
Partial Response (PR)	5 (41.7%)
Stable Disease (SD)	1 (8.3%)
Progressive Disease (PD)	6 (50.0%)
Objective Response Rate (ORR)	5 (41.7%)
Disease Control Rate (DCR)	6 (50%)

Safety

The combination treatment of efti and avelumab in this trial is well tolerated with no dose limiting toxicities, building on efti's strong safety profile to date.

Conclusion

The final efficacy and safety data from INSIGHT-004 is promising and warrants further clinical evaluation of this new combination, efti plus anti-PDL-1 therapy, with distinct tumor indications.

About INSIGHT-004

INSIGHT-004 is the fourth arm of the investigator-initiated INSIGHT trial, which is being conducted by the Institute of Clinical Cancer Research IKF at Krankenhaus Nordwest in Frankfurt. It is being conducted under ImmuteP's collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer Inc., and is evaluating the safety, tolerability and recommended Phase II dose of efti when given in combination with avelumab. It is the first combination trial of an approved and marketed anti-PD-L1 drug and efti.

Patients in cohort 1 received 6mg doses of efti every two weeks for six months with the standard dose of avelumab (800 mg every two weeks), while patients in cohort 2 received a higher dose of efti, 30 mg, with avelumab for six months. Thereafter, patients enter the maintenance phase and received avelumab monotherapy.

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 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 or by contacting:

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