

ASX/Media Announcement

Immutep Reports Supportive Efficacy Data from the Phase IIb AIPAC Study; Overall Survival Data Expected in Late 2020

- Progression Free Survival (PFS) Hazard Ratio improvement for eftilagimod alpha (efti) group versus placebo at the 6-month landmark
- Increased Overall Response Rate (ORR) of 48.3% in the efti group versus 38.4% in the placebo group
- Immutep will advance discussions with regulatory authorities regarding the next clinical development steps for efti
- Global webcast at 8am AEDT on Thursday March 26th / 5pm US EDT on Wednesday March 25th, webcast details below

SYDNEY, AUSTRALIA – March 25, 2020 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel LAG-3-related immunotherapy treatments for cancer and autoimmune diseases, announces data from its Phase IIb AIPAC clinical trial in HER2-negative / Hormone Receptor positive (HR⁺) metastatic breast cancer (MBC).

AIPAC is a multicentre, placebo-controlled, double-blind, randomised study evaluating the Company’s lead product candidate, eftilagimod alpha (efti, LAG-3Ig or IMP321) in combination with paclitaxel, a taxane standard of care chemotherapy, in 227 MBC patients to boost the T-cell immune responses against tumours.

63% of patients who received paclitaxel plus efti were progression-free at the 6-month landmark (at the end of the chemo-immunotherapy combination phase) and according to RECIST 1.1 based on blinded independent central readers (BICR). This compares favourably to 54% of patients who received paclitaxel plus placebo. The PFS data yielded an unadjusted hazard ratio (HR) of 0.93. The secondary endpoint of Overall Response Rate (ORR) increased to 48.3% in the efti group, from 38.4% in the placebo group.

Favourable results were reported in multiple predefined patient subgroups, e.g.:

- A) patients with low monocytes count at baseline had a positive HR of 0.61 (median PFS of 5.45 vs. 7.29 months) favouring efti
- B) patients with a more aggressive, more immunogenic luminal B type had a positive HR of 0.65 (median PFS of 5.45 vs. 7.29 months) favouring efti
- C) patients with lower general performance status at baseline had a positive HR of 0.76 (median PFS of 6.67 vs. 7.13 months) favouring efti

The combination of efti and paclitaxel chemotherapy was overall safe and well tolerated, further building upon efti’s strong safety profile to date.

These results, together with consideration of the Overall Survival (OS) and the immuno-monitoring data expected to be reported later this year, could allow the Company to build a platform to commence planning for a phase III clinical trial of efti in metastatic breast carcinoma. This will include the hypotheses for the primary and secondary endpoints and the appropriate stratification for different patient subgroups. Immutep will advance its discussions with the regulatory authorities accordingly.

Immutep CSO and CMO, Dr Frederic Triebel said: “The PFS results reported from the AIPAC study in a randomised clinical setting indicate an overall trend for clinical efficacy in HR-positive metastatic breast carcinoma, which is not a particularly immunogenic tumor and very interesting results in some meaningful subgroups. We would like to thank the patients and their families, along with the investigators for participating in this important study.”

Immutep CEO, Marc Voigt stated: “We are pleased to see a clinical benefit for patients receiving efti in HR-positive metastatic breast carcinoma in multiple patient subgroups. This is just one of the four advanced solid tumor indications targeted in our efti clinical development program. We are pleased to see an efficacy trend and will carefully assess the data for further development of efti given our positive data in patient subgroups. More AIPAC results should become available in the coming months, including immuno-monitoring data and Overall Survival data.”

“Another piece of evidence for efti efficacy in cancer patients comes from the interim results we are seeing from our ongoing phase II TACTI-002 trial of efti. In TACTI-002, 47% of first line non-small cell lung cancer patients responding to the combination treatment of efti with pembrolizumab, an anti-PD-1 therapy. These results are remarkable given that usually only 20% of patients respond to pembrolizumab monotherapy in this PDL-1 all comer trial indication.”

AIPAC Principal Investigator, Hans Wildiers of University Hospitals Leuven, Leuven, Belgium, said: “I am pleased to see this innovative chemo-immunotherapy approach in AIPAC is well tolerated by patients, while showing a numerically (non-significant) higher progression free survival rate compared to chemotherapy alone. Hormone receptor positive breast tumours represent the majority of metastatic breast cancer patients and any active well tolerated adjunct to the weekly paclitaxel standard of care regimen, is desirable. This combination warrants further investigation in larger and more biomarker selected populations.”

Further Reporting from AIPAC

The Company expects to present these clinical results in more detail at an upcoming conference. Patients are continuing in the follow up phase of the study enabling OS data to be collected. Immutep expects to report OS data in late-2020.

Webcast Details

Immutep will present this AIPAC data in a global webcast, details are as follows:

Date & Time: Thursday, March 26th, 8am Australian Eastern Daylight Time / Wednesday, March 25th, 5pm US Eastern Daylight Time

Register: Interested parties can register via a link to the webcast on the Company's website or via the following link: <http://public.viavid.com/index.php?id=138665>

Questions: Investors are invited to submit questions in advance via immunetep@citadelmagnus.com.

A replay of the webcast will also be available at www.immunetep.com from the day after the event.

About the AIPAC trial

Active Immunotherapy PAClitaxel (AIPAC) is a Phase IIb clinical trial in HER2-negative/ HR positive metastatic breast cancer. Based on Immunetep's LAG-3 technology, the study evaluates the combination of the Company's lead product candidate, eftilagimod alpha (efti, LAG-3Ig or IMP321), and a taxane chemotherapy, called paclitaxel, as an immunotherapy. This combination is aimed at boosting the immune response against tumour cells compared to chemotherapy alone. In AIPAC, 227 hormone receptor positive metastatic breast cancer patients are randomised 1:1 to treatment A (paclitaxel chemotherapy plus placebo) or treatment B (paclitaxel chemotherapy plus eftilagimod alpha) for six months.

Patients receive weekly paclitaxel at Days 1, 8 and 15 with either efti or placebo injected subcutaneously, on Days 2 and 16 of each 4-week cycle, repeated for 6 cycles. Thereafter, patients pass over to the maintenance phase with efti alone.

The primary end point is to determine progression-free survival (PFS) and key secondary objectives include overall survival, safety, quality of life and objective response rate.

For more information regarding the AIPAC trial, visit clinicaltrials.gov (identifier NCT02614833) and <https://www.ncbi.nlm.nih.gov/pubmed/30977393>).

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 eftilagimod alpha ("efti" or "IMP321"), a soluble LAG-3 protein (LAG-3Ig) 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 (clinicaltrials.gov identifier NCT02614833); 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 (clinical trials.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 Immunetep's large pharmaceutical partners. Immunetep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

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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