

ASX/Media Release

OPERATIONAL UPDATE

- TACTI-002 patient recruitment update
- Six patients now enrolled and dosed in INSIGHT-004, 6 mg cohort complete
- Significant eftilagimod alpha clinical data expected in coming months:
 - AIPAC Phase II - data expected in Q1 calendar year 2020
 - TACTI-002 Phase II - data at SITC in Nov 2019 and in Q1 in 2020
 - TACTI-mel Phase I - final safety data expected in H1 2020
 - INSIGHT-004 Phase I - initial safety data expected in Q4 calendar year 2019
- Scale up to 2,000L for commercial manufacturing started
- Solid financial position following receipt of \$7.4m GSK milestone payment, with expected cash runway at least to the end of calendar year 2020, well beyond above data catalysts

SYDNEY, AUSTRALIA – October 28, 2019 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, provides an update on the ongoing development of its product candidates.

Eftilagimod alpha (“efti” or “IMP321”) Clinical Update

AIPAC - Phase IIb clinical trial

The Company is fully on track to report progression-free survival data and overall response rate data in Q1 of calendar year 2020. AIPAC is potentially a pivotal clinical trial, meaning it could serve as the basis to pursue appropriate regulatory approval pathways for efti, subject to sufficient and clinically meaningful data from the trial and regulatory interactions. Importantly AIPAC would be the first successful randomised trial in solid tumors for an antigen presenting cell activator and would be a very significant step in validating this new class of products.

TACTI-002 - Phase II clinical trial

Immutep presented initial encouraging data of the first cohort of 17 patients for Part A (patients with first line non-small cell lung cancer) of its TACTI-002 Phase II study, which is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada), in June. Part A has been expanded by the data monitoring committee in September to include 19 additional patients.

Recruitment is ongoing for Part B (second line non-small cell lung cancer) and Part C (second line head and neck squamous cell carcinoma), where 6 and 12 patients have been recruited, respectively. There is also potential to expand Parts B and C, subject to the required number of predefined patient responses being observed in these groups. Hence, in total 35 patients have been recruited across all three groups in TACTI-002.

ImmuteP will report data updates from the open label TACTI-002 study at SITC on 8 November, at 7.00am EST, as well as in Q1 2020.

TACTI-mel - Phase I clinical trial

ImmuteP's CSO and CMO presented final efficacy data at the World Immunotherapy Congress in Basel on 15 October 2019. The key findings were efti has a favourable safety profile in combination with pembrolizumab with no dose-limiting toxicities and the recommended dosage level for a Phase II trial is 30 mg of efti (this is the dosage level currently being evaluated in the ongoing TACTI-002 Phase II trial).

In addition, final efficacy data has been reported, confirming deep durable responses have been observed, with 12 patients (50%) having a decrease of $\geq 75\%$ in the target lesions and 9 patients (38%) being treated for ≥ 12 months with pembrolizumab plus efti.

Final safety data is expected to be presented in H1 2020.

INSIGHT-004 - Phase I clinical trial

In June 2019, the first patient was enrolled in Germany and has received the first dose of treatment in INSIGHT-004, the fourth arm of the INSIGHT trial (INSIGHT-004 is also known as Stratum D of INSIGHT) which is being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. The first cohort (6 mg of efti) is now fully recruited with six patients in total. The second cohort (30 mg of efti) will recruit six patients, bringing the total participants in the study to 12 patients.

Initial safety data from the study is expected to be reported in Q4 2019.

Efti Manufacturing

The company is also working on upscaling the manufacturing process from 200L to 2,000L single-use bioreactors at the WuXi Biologics manufacturing plant (Wuxi, China) in order to be better prepared for potential commercial manufacturing and additional registration trials in multiple indications.

IMP761 Update

IMP761

ImmuteP is continuing cell line development and the associated manufacturing steps of its IMP761 product candidate following encouraging preclinical results that demonstrated the immunosuppressive activity of IMP761.

Update on Programs Fully Funded by ImmuteP's Licensing Partners

GlaxoSmithKline (GSK) – Phase I and II clinical trials

In September, ImmuteP announced that it will receive a milestone payment from GSK of £4 million (~A\$7.39 million) related to the first patient being dosed in GSK's Phase II clinical trial evaluating GSK2831781 in ulcerative colitis. This milestone payment was received by ImmuteP from GSK in October.

Novartis – Phase I and II clinical trials

Immutep’s partner Novartis, is conducting five trials of LAG525, derived from IMP701, which is licensed from Immutep. Earlier this year, it commenced the recruitment of 220 patients for its combinatory Phase Ib clinical trial in triple negative breast cancer.

Recruitment is also ongoing for its Phase II study in advanced triple negative breast cancer and its Phase II study in melanoma. A further two trials are active, namely a Phase I/II trial in advanced solid tumors and a Phase II trial in a range of advanced malignancies.

Eddingpharm (EOC Pharma) – Phase I clinical trial

The Phase I clinical study is ongoing with efti for the treatment of metastatic breast cancer.

About Immutep

Immutep is a globally active biotechnology company that is a leader in the development of 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 eftilagimod alpha (“efti” or “IMP321”), a soluble LAG-3Ig fusion protein 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; 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[®] (pembrolizumab) 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).

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

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