

ASX Announcement

IMMUTEP ACTIVITIES REPORT

- First progression-free survival (“PFS”) data expected from late-stage Phase IIb metastatic breast cancer study, AIPAC, in March 2020
- More mature data expected from TACTI-002 in February 2020
- Sufficiently funded to deliver key upcoming catalysts

SYDNEY, AUSTRALIA – January 29, 2020 – [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, efitlagimod alpha (“efti” or “IMP321”) and IMP761.

Commenting on the quarter and the period ahead, Immutep CEO Marc Voigt said:

“Immutep has continued to report encouraging data from its trials of efti, with first data from TACTI-002 and INSIGHT-004, along with final efficacy data from our TACTI-mel trial. Building on this momentum, we have entered into a very important and decisive quarter especially as we prepare to report our first PFS data from late-stage AIPAC study in metastatic breast cancer, expected in March 2020.

“If positive, AIPAC results could help to validate an entirely new class of products in immuno-oncology: antigen presenting cell activators, along with the “pushing the gas” concept. This would be a landmark medical achievement, with metastatic breast cancer just being the first indication of possibly many others to follow. It would also arm the Company with the data it needs to make strategic decisions, paving the way for the creation of very significant value for Immutep and its shareholders.”

Efitlagimod alpha Clinical Update

AIPAC - Phase IIb clinical trial

Immutep’s largest and most advanced clinical trial, AIPAC, is continuing to advance towards first progression-free survival (PFS) and overall response rate (ORR) data read-out, which is expected to be reported in March 2020.

AIPAC evaluates efti in combination with paclitaxel, a standard of care chemotherapy, as a chemo-immunotherapy combination in 227 HR+ metastatic breast cancer patients in a randomised, double blinded, placebo-controlled clinical trial. This combination is designed to boost the immune response against tumour cells compared to chemotherapy plus placebo. The trial is taking place across 30 clinical trial sites across Germany, the UK, France, Hungary, Belgium, Poland and the Netherlands.

The primary endpoint of AIPAC is PFS according to RECIST. Additional efficacy endpoints are overall response rate (ORR) and overall survival (OS).

In light of the upcoming AIPAC readout, Immutep is undertaking regulatory steps to expedite the possible use of efti for metastatic breast cancer (MBC) patients in the US, pending the AIPAC results. This includes a small bridging trial evaluating the combination efti with paclitaxel in 24 patients in the US and the EU which will take place pending the first AIPAC results. For that purpose, Immutep plans to file an IND in MBC which would enable Immutep to discuss regulatory strategies based on AIPAC results also in the US.

TACTI-002 - Phase II clinical trial

During the period, Immutep reported positive first preliminary safety and efficacy data from its TACTI-002 study. Patients in stage 1 of Part A (first line non-small cell lung cancer (NSCLC)) reported an encouraging preliminary Overall Response Rate (ORR) of 41%.

The requisite number of predefined patient responses have been observed in stage 1 for both Parts A and C (second line head and neck squamous cell carcinoma (HNSCC)). The Data Monitoring Committee recommended opening stage 2 recruitment for both these Parts, following its review of the preliminary safety and efficacy data.

Accordingly, Immutep is recruiting an additional 19 patients to both Part A and Part C, forming stage 2 of these Parts. For stage 2 of Part A, 6 out of 19 patients are now participating. Recruitment has commenced for stage 2 of Part C and is ongoing for stage 1 of Part B (second line NSCLC) with 12 out of 23 patients now participating.

The below table summarises the number of patients recruited to date for the TACTI-002 cohorts.

	Stage 1 (recruited to date/ targeted total)	Stage 2 (recruited to date/ targeted total)
Group A (1st line NSCLC)	17 / 17	6 / 19
Group B (2nd line NSCLC)	12 / 23	0 / 13
Group C (2nd line HNSCC)	18 / 18	0 / 19

Immutep expects to report more mature data from TACTI-002 at the German Cancer Congress in mid February 2020.

TACTI-002 is being conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada). It is evaluating the combination of efti with MSD’s KEYTRUDA® (or pembrolizumab, an anti-PD-1 therapy) in up to 109 patients with second line HNSCC or NSCLC in first and second line.

TACTI-mel - Phase I clinical trial

In October 2019, Immutep reported positive final efficacy data for its TACTI-mel trial. The data confirmed 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 and efti.

The TACTI-mel trial evaluates efti with MSD's KEYTRUDA® in melanoma patients, the same combination as TACTI-002.

INSIGHT-004 - Phase I clinical trial

In December 2019, Immutep completed the recruitment of the first cohort of 6 patients for its INSIGHT-004 phase 1 study. These patients are receiving a standard dose of avelumab with efti (6 mg). One patient has experienced a partial response according to RECIST 1.1. from this cohort and another patient has been reported as having stable disease, which is encouraging given the late disease stage and pretreatment of these patients. Importantly, no new safety signals or dose limiting toxicities have been reported from the first cohort of patients.

Recruitment is ongoing for the second cohort of 6 patients to receive the standard dose of avelumab, with a higher 30 mg dose of efti.

More data from the study is expected to be reported in H1 CY2020.

INSIGHT-004 evaluates the combination of efti with avelumab, a human anti-PD-L1 antibody, in 12 patients with advanced solid malignancies. It is being conducted as the 4th arm of the INSIGHT trial.

IMP761

Immutep is continuing cell line development and the manufacturing steps for its preclinical candidate, IMP761, in preparation for clinical studies. This follows the encouraging preclinical results reported from the Company's preclinical studies in autoimmune disease studies of IMP761 in early 2019. In January 2020 research results were published in the peer reviewed Journal of Immunology (refer <https://www.jimmunol.org/content/early/2020/01/04/jimmunol.1900823>).

Financials

Cash receipts for the last quarter ended 31 December 2019 was \$7.29 million, representing a significant increase on the previous quarter ended 30 September 2019 (i.e. Q1 FY2020; \$0.11 million), which was mainly due to receipt of the GSK milestone payment of £4 million.

During the last quarter, the company also received €1,568,399 from the research and development tax incentive payment from the French Government under its Crédit d'Impôt Recherche scheme.

The net cash used in Research and Development activities in the last quarter was \$6.19 million compared to \$5.19 million in Q1 FY2020. The increase of 19% was mainly due to the increased activities in clinical and preclinical studies.

The net cash used in G&A activities in the last quarter was \$1.43 million compared to \$0.5 million in Q1 FY2020. The increase was mainly due to the prepayment of some annual corporate expenses due for the 2020 calendar year.

Total net cash inflows from operating activities in the last quarter was \$1.22 million. In comparison, total net cash used in operating activities was \$6.46 million in Q1 FY2020.

The cash balance as at 31 December 2019 was \$20.5 million compared to balance of \$19.6 million as at 30 September 2019. Immutep is in a solid financial position ahead of the crucial catalysts in Q1 of calendar year 2020.

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[®] (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).

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.