

# **ASX/Media Release**

#### **OPERATIONAL UPDATE**

- TACTI-002 patient recruitment update
- Three patients now enrolled and dosed in INSIGHT-004, recruitment ongoing
- Significant eftilagimod alpha clinical data expected in coming months:
  - o AIPAC Phase II first data expected in Q1 calendar year 2020
  - TACTI-002 Phase II first data in Q3 calendar year 2019
  - o TACTI-mel Phase I final data expected in Q4 calendar year 2019
  - INSIGHT-004 Phase I initial data expected in Q4 calendar year 2019
- Equity financing announced in July to raise approximately A\$10 million, via a Placement and a fully underwritten Entitlement Offer which will include management team and director participation from Immutep

**SYDNEY, AUSTRALIA – July 26, 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 as well as its equity financing, announced 9 July 2019.

## Eftilagimod alpha ("efti" or "IMP321") Clinical Update

### AIPAC - Phase IIb clinical trial

In late June, Immutep completed patient enrolment of its late stage clinical trial, AIPAC, which is evaluating efti in patients with metastatic breast cancer. The Phase IIb study has enrolled 227 patients at more than 30 clinical trial sites in Europe.

The Company expects to report progression-free survival data in Q1 of calendar year 2020. AIPAC is a potentially pivotal clinical trial, meaning it could serve as a basis to pursue the appropriate regulatory approval pathways for efti, subject to sufficient and clinically meaningful data from the trial and regulatory interactions.

#### TACTI-002 - Phase II clinical trial

Immutep completed the recruitment of the initial 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 may be expanded to include an additional number of patients if the predefined number of patient responses to the combination treatment of efti with KEYTRUDA® (or pembrolizumab, an anti-PD-1 therapy) are observed.

Recruitment is ongoing for Parts B (second line non-small cell lung cancer) and Part C (second line head and neck squamous cell carcinoma), where 4 and 5 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 26 patients have been recruited across all three groups in TACTI-002.

Immutep expects to report first data from the open label TACTI-002 study in Q3 calendar year 2019.

#### TACTI-mel - Phase I clinical trial

Immutep's TACTI-mel trial is ongoing with two melanoma patients continuing to receive the combination treatment of efti and KEYTRUDA while the remaining 22 patients are either receiving pembrolizumab monotherapy or have completed the study (total of 24 patients).

Following encouraging interim data which was presented earlier in the year, Immutep expects to report final data from this trial in Q4 of calendar year 2019.

### **INSIGHT-004 - Phase I clinical trial**

In June, 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 (known as Stratum D) which is being conducted in collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. Three patients are now participating in the initial cohort (6 mg of efti) of the study, with a further three to be recruited. The second cohort (12 mg of efti) will recruit six patients, bringing the total participants in the study to 12 patients.

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

# **INSIGHT - Phase I clinical trial**

In June, Prof. Salah-Eddin Al-Batran, MD, from the Institute of Clinical Research (IKF) in Frankfurt, Germany presented a single patient case study in a Key Opinion Leader call, hosted by Immutep.

A male metastatic gastric cancer patient commenced escalating intratumoural injections of efti into a stomach tumour in September 2017. Following seven injections, the tumour was observed as stable and the patient completed participation in the study. Encouragingly, he has continued to survive for nearly 2 years from the commencement of treatment, beyond the usual median 2-4-month survival timeframe typical of such patients.

Further data is expected to be presented by IKF, the sponsor of the study, in late 2019.

# **IMP761 Update**

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. IMP761 has demonstrated potential as a new therapy that could treat the causes of autoimmune diseases, such as inflammatory bowel diseases, rheumatoid arthritis, and multiple sclerosis, rather than just treating the symptoms.



# **Update on Programs Fully Funded by Immutep's Licensing Partners**

# Glaxo Smith Kline (GSK) – Phase I and II clinical trials

In May, Immutep's partner, GSK initiated its Phase II clinical study evaluating GSK2831781 (derived from Immutep's IMP731 antibody) in 280 ulcerative colitis patients. The new study is expected to complete in August 2022 and follows GSK's completed phase I clinical trial of GSK2831781 in psoriasis.

In June, GSK also commenced a Phase I study to evaluate the safety and tolerability, pharmacokinetics, and pharmacodynamics of GSK2831781 in 36 healthy volunteers in Japan. This study is expected to complete in January 2020. The new trials bring the total number of clinical trials of GSK2831781 to three.

#### 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, 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

Patient recruitment is ongoing for Immutep's partner and Chinese licensee, EOC Pharma, for a Phase I clinical study of efti for the treatment of metastatic breast cancer. Further progress from EOC Pharma is expected in late 2019.

# **Funding Update**

In early July, Immutep announced an equity financing to raise approximately A\$10 million, comprising of a Placement and a fully underwritten pro rata non-renounceable Entitlement Offer.

Under the Placement, 190.5 million new fully paid ordinary shares have been issued to multiple new and existing Australian and foreign institutional and professional investors at an issue price of A\$0.021 per share, raising a total of A\$4 million before transaction-related expenses. The Placement included support from Platinum Investment Management (trading as Platinum Asset Management), Australian Ethical Investment and Altium Capital Management.

The Company also opened a 1 for 11.8 fully underwritten pro rata non-renounceable Entitlement Offer of new Shares at the same price as the Placement to raise approximately A\$6 million. The Entitlement Offer is due to close on 30 July 2019 and the Company will provide the final details in due course.

The Entitlement Offer will include management team and director participation from Immutep.



# **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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