



ASX/Media Announcement

# Immutep's Partner, EOC Pharma, Reports Completion of Recruitment of Phase I Study of Efti

- Last patient enrolled and safely dosed, completing patient recruitment for EOC Pharma's phase I study in metastatic breast cancer (MBC)
- Data expected throughout 2020, with study completion in Q4 CY2020
- · Registration trial in MBC in China is planned

**SYDNEY, AUSTRALIA – March 20, 2020 – Immutep Limited** (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), is pleased to report that it has been informed its Chinese partner, EOC Pharma, has completed patient recruitment for the ongoing EOC202A1101 study being conducted in China. EOC Pharma is an oncology focused specialty pharmaceutical company headquartered in Shanghai, China, and is the exclusive licensee of eftilagimod alpha ("efti" or "IMP321") from Immutep for the Chinese market. The last patient was enrolled and safely dosed in February 2020, bringing the total number of participating patients to 12.

The EOC202A1101 study is taking place at the Fudan University Shanghai Cancer Center in China and is a single-center, open label, fixed dose-escalation phase I study in MBC patients. Under the license, EOC Pharma is evaluating Immutep's lead product candidate, efti, in combination with chemotherapy agent, paclitaxel, in Chinese patients. Participants are receiving either 6 mg or 30 mg doses of efti over the six-month treatment period to determine the safety, tolerability and efficacy of the combination treatment, along with the appropriate dose for a potential phase II study.

Efti continues to have a good safety profile supported by the interim safety data from the trial. No serious adverse events were reported from the combination therapy and no dose limiting toxicity events were observed in either dose group. Based on interim data and Immutep's published MBC data from Caucasian patients, the 30 mg dose of efti has already been recommended for a registration clinical trial in Europe (Immutep's AIPAC trial).

**EOC Pharma CEO, Xiaoming Zou, said:** "Our EOC202A1101 study is progressing well. The safety data so far is supportive of the 30 mg dose of efti for a potential registration trial in China. We look forward to seeing the readout of Immutep's phase IIb AIPAC trial in MBC patients in March. If the AIPAC results are also positive, we will have confidence to move forward with our plans for the registration trial, deepening our partnership with Immutep."

**EOC202A1101** Principle Investigator, Prof. Xichun HU, Director of Medical Oncology at Fudan University, said: "It is encouraging to see the combination therapy continues to demonstrate a good safety profile, consistent with other trials. As the study continues and more patients complete their treatment courses, we will be able to report efficacy data."





**Immutep CEO, Marc Voigt stated:** "EOC Pharma are our partner for efti in China and we are excited to see such strong progress being reported from their trial in MBC, particularly as we prepare to report results from our own late-stage breast cancer trial, AIPAC, this month."

Data is expected to be reported from EOC202A1101 during 2020, with study completion in Q4 CY2020. EOC Pharma holds the exclusive development and commercialisation rights for efti in China, including Hong Kong, Macau, and Taiwan via a licensing agreement with Immutep. EOC Pharma will make further milestone payments to Immutep if efti achieves specific development milestones as well as undisclosed royalties on sales. EOC Pharma refers to efti as "EOC202".

## About the EOC202A1101 Trial

The EOC202A1101 study is taking place at the Fudan University Shanghai Cancer Center in China and is a single-center, open label, fixed dose-escalation phase I study in 12 metastatic breast carcinoma patients. The study is evaluating Immutep's lead product candidate, eftilagimod alpha ("efti" or "IMP321"), in combination with chemotherapy agent, paclitaxel, in Chinese patients. Participants are receiving either 6 mg or 30 mg doses of efti over the six-month treatment period to determine the safety, tolerability and efficacy of the combination treatment, along with the appropriate dose for a potential phase II study. The Chinese IND application for EOC202 (efti) was approved by the Chinese National Medical Products Administration (NMPA) in December 2017.

# **About EOC Pharma**

EOC Pharma is patient centric organisation, combining products, capabilities and healthcare industry partners to support an integrated structure focused on the manufacturing, development and commercialisation of innovative oncology products. EOC strives to be the preferred oncology partner of global biopharma and pharmaceutical companies, taking full advantage of the improving regulatory environment and strengthening clinical infrastructure in China in order to benefit the millions of patients who currently have limited access to high quality oncology treatments.

#### **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 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 (clinicaltrials.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 Immutep's large pharmaceutical partners. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

Further information can be found on the Company's website <a href="www.immutep.com">www.immutep.com</a> or by contacting:

## Australian Investors/Media:

Catherine Strong, Citadel-MAGNUS +61 (0)406 759 268; cstrong@citadelmagnus.com

## U.S. Media:

Garth Russell, LifeSci Advisors +1 (646) 876-3613; garth@lifesciadvisors.com

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