

ASX/Media Release

Enrollment completed for the INSIGHT-004 Study

SYDNEY, AUSTRALIA – April 22, 2020 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, announced that the last patient has been enrolled and safely dosed for the second cohort of the INSIGHT-004 Phase I clinical trial. This completes enrollment for the study.

The trial evaluates the combination of efitlagimod alpha (“efti” or “IMP321”), an antigen presenting cell activator, with a standard dose of avelumab, a human anti-PD-L1 antibody, in patients with advanced solid malignancies. Avelumab is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc. Initial results from the cohort of the INSIGHT-004 study are expected to be presented at a major medical conference in the second quarter of 2020.

Prof. Dr. Salah-Eddin Al-Batran, lead investigator of INSIGHT-004, commented: “We are pleased with the pace at which IKF was able to complete enrollment for the INSIGHT-004 study, especially considering the majority of the patients in the second Cohort were enrolled in just the past few weeks as the world continues to deal with the COVID-19 pandemic. We are excited by the opportunity to build on the data announced to date from the first cohort of the INSIGHT-004 study, as the second cohort offers a much higher dose, 30 mg, of efti to patients.”

The first cohort of six patients in the INSIGHT-004 study received a standard dose of avelumab and a 6 mg dose of efti with no new safety signals or dose limiting toxicities. The observed safety profile also aligns with the known safety profile of the monotherapies. Participants enrolled in the INSIGHT-004 trial are patients with late-stage cancer who have been heavily pre-treated for advanced, metastatic solid tumors. Typically, they have no other therapy options available.

INSIGHT-004 is the fourth arm of the INSIGHT trial which is being conducted by Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany (IKF). It is being conducted under Immutep’s collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer Inc., and is evaluating the safety, tolerability and recommended Phase II dose of Immutep’s lead immunotherapy product candidate efti when given in combination with avelumab in 12 patients with advanced solid malignancies.

About INSIGHT-004

INSIGHT-004 is being conducted as an amendment to the ongoing INSIGHT Phase I clinical trial. The Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany (“IKF”) is the sponsor of the clinical trial which is being conducted under the existing protocol of the ongoing INSIGHT clinical study. Prof. Dr. Salah-Eddin Al-Batran, the lead investigator of INSIGHT and member of Immutep’s clinical advisory board, is the lead investigator of INSIGHT-004.

For more information regarding the INSIGHT-004 which forms part of the INSIGHT trial, visit clinicaltrials.gov (INSIGHT identifier NCT03252938). INSIGHT-004 refers to the fourth arm of the INSIGHT trial where IMP321 is given in combination with avelumab.

Avelumab Approved Indications

Avelumab (BAVENCIO®) in combination with axitinib is indicated in the US, EU, Japan and other countries for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

The US Food and Drug Administration (FDA) also granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab is currently approved for patients with mMCC in more than 50 countries globally, with the majority of these approvals in a broad indication that is not limited to a specific line of treatment.

Avelumab Important Safety Information from the US FDA-Approved Label

The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis and hepatitis [including fatal cases], colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions [which can be severe and have included fatal cases]), infusion-related reactions, hepatotoxicity, major adverse cardiovascular events (MACE) [which can be severe and have included fatal cases], and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO® monotherapy include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash. Common adverse reactions (reported in at least 20% of patients) in patients receiving BAVENCIO® in combination with axitinib include diarrhea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, cough, dyspnea, abdominal pain and headache. Grade 3-4 clinical chemistry and hematology laboratory value abnormalities reported in at least 10% of patients treated with BAVENCIO® monotherapy include hyponatremia, lymphopenia, GGT increased; in patients receiving BAVENCIO® in combination with axitinib, grade 3-4 clinical chemistry and hematology laboratory value abnormalities included blood triglyceride increased and lipase increased.

For full Prescribing Information and Medication Guide for BAVENCIO®, please see www.BAVENCIO.com

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 efitlagimod alpha ("efti" or "IMP321"), a soluble LAG-3 protein (LAG-3lg) 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 to evaluate a combination of efti with KEYTRUDA[®] (or 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).

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 www.immutep.com or by contacting:

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