

ASX/Media Announcement

Immutep Announces Investigator-Initiated Phase II Trial Evaluating LAG-3 Candidate Eftilagimod Alpha (Efti) in Soft Tissue Sarcoma

- Expansion of the efti clinical development pipeline with a new Phase II setting
- Efti Phase II trial awarded €1.5M (~A\$2.2M) in funding as part of the Polish Medical Research Agency program funded by the Polish government
- Collaboration with the Maria Skłodowska-Curie National Research Institute to evaluate efti in triple combination with Keytruda (pembrolizumab) and radiotherapy, followed by surgery
- First patient dose anticipated by H1 2023

SYDNEY, AUSTRALIA – 6 September 2022 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), is pleased to announce it has signed a Material Transfer Agreement (“Agreement”) with the Maria Skłodowska-Curie National Research Institute of Oncology in Warsaw, Poland to enable an investigator-initiated open label Phase II clinical trial. The trial will evaluate Immutep’s lead product candidate efti in combination with pembrolizumab and radiotherapy in the neoadjuvant setting (prior to surgery) in up to 40 patients with select soft tissue sarcoma (STS).

Subject to the necessary approvals from the Polish State Institute for Drug Control and ethics committee, the dosing of the first patient is anticipated in the first half of calendar year 2023, with initial interim data expected in the fourth quarter of CY 2024.

Under the Agreement, the Maria Skłodowska-Curie National Research Institute of Oncology will primarily fund the study with an approved grant from the Polish government of €1.5M (~A\$2.2M) awarded by the Polish Medical Research Agency program. Immutep will provide efti at no cost to the Maria Skłodowska-Curie National Research Institute of Oncology and will technically support the trial. The trial will be led by Principal Investigators, Dr. Katarzyna Kozak, M.D. PhD., and Paweł Sobczuk, M.D., medical oncologists at the Department of Soft Tissue/Bone Sarcoma and Melanoma at the Maria Skłodowska-Curie National Research Institute of Oncology.

Immutep CEO, Marc Voigt, said: “We were delighted to be approached by Dr Paweł Sobczuk and Dr. Katarzyna Kozak to form this collaboration with the Maria Skłodowska-Curie National Research Institute of Oncology to explore the potential of efti in combination with pembrolizumab and radiotherapy in soft tissue sarcoma. We thank the Polish government for granting €1.5M in non-dilutive cash funding for this trial. Recurrence and lack of deep and durable responses are challenges with the limited standards of care available for this rare and difficult-to-treat disease. Efti’s novel mechanism of action offers potential to enhance anti-tumour responses for these patients. This latest expansion of the efti pipeline is further evidence of the increased interest from a variety of interested parties to investigate the broad potential of efti to improve patient outcomes in yet another cancer indication and treatment regimen.”

Immutep CSO and CMO, Dr Frederic Triebel said: “Efti stimulates the immune system through a differentiated mechanism that targets LAG-3-driven activation of antigen-presenting cells. By working upstream of T cells, efti has potential to generate a broad and robust anti-tumour immune response even in the immunosuppressed tumour microenvironment of soft tissue sarcomas. Therefore, we are very pleased to be collaborating with our colleagues at the Maria Skłodowska-Curie National Research Institute of Oncology.”

Maria Skłodowska-Curie National Research Institute of Oncology, Medical Oncology Fellow and Co-Principal Investigator, Dr. Paweł Sobczuk said: “The need for new approaches in this rare and aggressive disease is evident by the still dismal responses with current standards of care including surgery, radiotherapy and chemotherapy. Clinical data in other solid tumours suggest that efti can synergize with radiotherapy and pembrolizumab for robust responses across PD-L1 status, supporting the potential of this combination to mount effective immunity against aggressive malignancies like soft tissue sarcoma and replace the need for chemotherapy.”

Efti’s Mechanism of Action

Efti is a first-in-class antigen presenting cell (APC) activator currently being developed by Immutep for the treatment of cancer. Efti binds to antigen presenting cells such as dendritic cells, monocytes and macrophages via MHC II molecules. This activates the APCs causing them to become professional antigen presenting cells, thereby presenting antigen to the adaptive immune system. This leads to activation and proliferation of CD4+ (helper) and CD8+ (cytotoxic) T cells. Thus, the aim of efti is to “push the gas” on the body’s innate and adaptive immune systems making it a suitable candidate to evaluate not only for the treatment of cancer, but also for the treatment of infectious diseases.

About The Maria Skłodowska-Curie National Research Institute of Oncology

The Maria Skłodowska Curie National Research Institute of Oncology is the leading Polish comprehensive cancer centre, as well as the primary government research institution devoted solely to oncology. Founded in 1932 by Maria Skłodowska-Curie, it is currently divided into 28 specialised clinical departments responsible for the diagnostics and therapy of different tumour types such as: Breast Cancer Clinic, Head and Neck Cancer Clinic, General and Visceral Surgery, Thoracic Surgery, Urology, Gynaecology, Haematology, Soft Tissue/Bone Sarcoma and Melanoma Clinic, Radiation Oncology, Brachytherapy and Diagnostic Radiology, Pathology and Molecular Medicine and Cell Research. Oncology, Gastroenterology, Cancer Epidemiology and Prevention Division and others.

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 efitigimod alpha (“efti” or “IMP321”), a soluble LAG-3 fusion protein (LAG-3Ig), which is a first-in-class antigen presenting cell (APC) activator being explored in cancer. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

Additional LAG-3 products, including antibodies for immune response modulation, are being developed by Immutep's large pharmaceutical partners.

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.