

ASX/Media Release

Positive Initial Clinical Data Reported from Immutep's Efti Combined with Radiotherapy and Checkpoint Inhibitor from Phase II Trial in Soft Tissue Sarcoma

- Novel triple combination of efti with radiotherapy and anti-PD-1 therapy is well tolerated and has led to encouraging initial efficacy data in EFTISARC-NEO Phase II trial
- Four of six patients treated have very good, near-complete pathologic responses (primary endpoint of study) that are rarely observed with standard therapies
- Soft tissue sarcoma is a hard-to-treat orphan disease with poor prognosis & high unmet medical need
- Additional data from EFTISARC-NEO planned for a medical conference in H2 CY2024

SYDNEY, AUSTRALIA – 2 May 2024 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, today announces initial encouraging data from EFTISARC-NEO, a Phase II investigator-initiated trial of eftilagimod alpha (efti) in combination with radiotherapy, a standard-of-care treatment, plus KEYTRUDA® (pembrolizumab) for patients with soft tissue sarcoma (STS).

The EFTISARC-NEO study is the first to evaluate efti in a neoadjuvant setting, which takes place before intended surgery, and the first to combine efti with radiotherapy. Importantly, the neoadjuvant setting allows for the impact of this novel combination to be assessed in the tumour microenvironment (TME).

The triple combination has revealed no new safety findings and has been well tolerated in the first six patients who have completed the 10 weeks of treatment followed by surgery 2-3 weeks later. Initial efficacy data is very encouraging with 4 of 6 patients (67%) having near-complete responses according to EORTC-STBSDG, which measures responses via tissue pathology after surgery. These deep responses are rarely seen in STS patients with standard therapeutic approaches including radiotherapy.

Katarzyna Kozak, M.D., Ph.D., and Paweł Sobczuk, M.D., Ph.D., medical oncologists at the Department of Soft Tissue/Bone Sarcoma and Melanoma at MSCNRIO (Warsaw), and the trial's principal investigators stated: "The initial pathologic responses from this novel combination are very encouraging and supportive of the potential synergistic effects of this new therapeutic approach. Indeed we have seen a high degree of hyalinization/fibrosis in the surgical samples which we rarely see with standard treatments. We look forward to continuing this study."

Frédéric Triebel, M.D., Ph.D, Immutep's Chief Scientific Officer, added: "We are pleased to see these early results from EFTISARC-NEO, which has allowed efti for the first time to be clinically evaluated in

a non-metastatic cancer setting. The ability to evaluate tumour specimens is helping elucidate the significant anti-cancer immune response efiti drives through its direct maturation and activation of antigen-presenting cells as an MHC Class II agonist. If the positive trend of strong pathological responses continues in this rare orphan disease, we will pursue all available avenues to bring this innovative therapy to soft tissue sarcoma patients in need of new, effective therapies in an expeditious manner.”

Efiti’s targeting and unique activation of dendritic cells, the most potent professional antigen-presenting cells, as a MHC Class II agonist leads to broad adaptive and innate immunity to fight cancer, including proliferation of CD8+ cytotoxic T cells that can be armed with radiotherapy-induced tumour antigens. The combination of efiti with radiotherapy and anti-PD-1 therapy has the potential to generate a robust anti-tumour immune response in the immunosuppressed tumour microenvironment of soft tissue sarcoma.

The open-label EFTISARC-NEO Phase II study will treat up to 40 patients and is being conducted by the Maria Skłodowska-Curie National Research Institute of Oncology (MSCNRIO) in Warsaw. The trial is primarily funded with an approved grant from the Polish government awarded by the Polish Medical Research Agency program. The study’s primary endpoint is the pathologic response rate (defined as percentage of tumor hyalinization/fibrosis) to the treatment assessed at the time of surgical resection. The lower the number of viable tumor cells and the higher the extent of hyalinization/fibrosis observed in patients’ tumor specimens will determine the therapy’s effectiveness. For more information, visit clinicaltrials.gov (NCT06128863).

The trial is ongoing with 14 patients now enrolled and additional clinical data is planned to be presented at a medical conference in H2 CY2024.

About Soft Tissue Sarcoma

Soft tissue sarcoma (STS), an orphan disease, represents a high unmet medical need with a poor prognosis. The incidence of STS varies in different regions, with approximately 23,400 cases annually and a crude incidence of 4.7 per 100,000 in Europe, according to the RARECARE project. In the United States, the number of new cases is estimated to be 13,400 annually with 5,140 deaths, according to the American Cancer Society.

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 clinical-stage biotechnology company developing novel LAG-3 immunotherapy for cancer and autoimmune disease. We are pioneers in the understanding and advancement of therapeutics related to Lymphocyte Activation Gene-3 (LAG-3), and our diversified product portfolio harnesses its unique ability to stimulate or suppress the immune response. Immutep is dedicated to leveraging its expertise to bring innovative treatment options to patients in need and to maximise value for shareholders. For more information, please visit www.immutep.com.

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