

Immutep Receives Positive Scientific Advice from European Medicines Agency

Sydney, Australia, August 1, 2023 - Immutep Limited (ASX: IMM; NASDAQ: IMM) ("Immutep" or "the Company"), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, today announces it has received positive scientific advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the continued development of efitlagimod alpha (efti), the Company's soluble LAG-3 protein and first-in-class MHC Class II agonist.

In May 2023, Immutep requested scientific advice from the EMA regarding future development of efti, and in particular whether further toxicity studies would be required before the Company could seek marketing authorisation for efti in Europe. Based on the available clinical data and acknowledgement that additional studies in animal models are unlikely to provide relevant information, the CHMP advised that further toxicology studies are not needed for a future Marketing Authorisation Application (MAA). Similar advice was received from the US Food and Drug Administration (FDA) as it relates to a potential future Biologics License Application (BLA).

Immutep continues to be encouraged with its constructive interaction with regulatory agencies regarding its expanding late-stage clinical pipeline with efti. As recently reported, Immutep has also received positive feedback from the FDA regarding the [upcoming TACTI-004 Phase III trial](#) in 1st line non-small cell lung cancer as well as for the [AIPAC-003 Phase II/III trial](#) in metastatic breast cancer, which began [dosing patients](#) during the second quarter of CY2023.

About Scientific Advice

Scientific Advice is a procedure offered by the EMA to medicine developers for clarification of questions arising during development of medicinal products. The EMA provides scientific advice to support the timely and sound development of high-quality, effective and safe medicines, for the benefit of patients. Scientific Advice is prospective in nature and focuses on development strategies rather than pre-evaluation of data to support a Marketing Authorisation Application (MAA). Scientific Advice is legally nonbinding and is based on the current scientific knowledge, which may be subject to future changes.

About Efitlagimod Alpha (Efti)

Efti is Immutep's proprietary soluble LAG-3 protein and MHC Class II agonist that stimulates both innate and adaptive immunity for the treatment of cancer. As a first-in-class antigen presenting cell (APC) activator, efti binds to MHC (major histocompatibility complex) Class II molecules on APC leading to activation and proliferation of CD8+ cytotoxic T cells, CD4+ helper T cells, dendritic cells, NK cells, and monocytes. It also upregulates the expression of key biological molecules like IFN- γ and CXCL10 that further boost the immune system's ability to fight cancer.

Efti is under evaluation for a variety of solid tumours including non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), and metastatic breast cancer. Its favourable safety profile enables various combinations, including with anti-PD-[L]1 immunotherapy and/or chemotherapy. Efti has received Fast Track Designation in 1st line HNSCC and in 1st line NSCLC from the United States Food and Drug Administration (FDA).

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 market for patients in need and to maximise value for shareholders. For more information, please visit www.immutep.com.