

Commercial manufacturing of Eftilagimod Alpha at 2000L scale granted authorization for clinical trial use

Comparability of drug substance and drug product manufactured at 2,000L scale achieved

Sydney, Australia, September 21, 2023 - Immunetep Limited (ASX: IMM; NASDAQ: IMM) ("Immunetep" or "the Company"), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, today announces the regulatory authorization of eftilagimod alpha ("efti") manufactured at commercial 2,000L scale for use in clinical trials across multiple European countries including Germany, Belgium, Denmark, and the United Kingdom.

After successfully scaling up the manufacturing process of efti to commercial scale at WuXi Biologics, the process-related changes were presented in a substantial amendment of the Investigational Medicinal Product Dossier (IMPD). Overall comparability of the first 2,000L and the previous 200L scale clinical stage manufacturing process was achieved. Immunetep plans to introduce efti manufactured by the 2,000L scale process into current and future clinical trials.

Marc Voigt, CEO of Immunetep, said: "With late-stage clinical development underway for our first-in-class soluble LAG-3 protein and MHC Class II agonist in non-small cell lung cancer, head and neck cancer, and metastatic breast cancer, commercial scale manufacturing of efti for use in clinical trials is a significant achievement and brings us closer to realizing efti's potential to help cancer patients worldwide."

About Eftilagimod Alpha (Efti)

Efti is Immunetep'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 Immunetep

Immunetep 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. Immunetep 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.immunetep.com.