ImmunOs Therapeutics Receives Regulatory Approval for First-In-Human Trial of IOS-1002

- Lead compound IOS-1002 to be studied as mono and combination therapy in patients with advanced solid tumors
- First patients to be enrolled in Q1, 2023

Schlieren (Zurich Area), Switzerland – January 17, 2023 – ImmunOs Therapeutics AG, a biopharmaceutical company leveraging its HLA-based technology platform to develop first-in-class therapeutics for the treatment of cancer and autoimmune diseases, today announced that the Company has received full ethical institutional approval from the Human Research Ethics Committee (HREC) and regulatory approval from the Therapeutic Goods Administration (TGA) to conduct a Phase 1 trial of its lead program IOS-1002 in Australia. The first patients are expected to be enrolled in Q1, 2023.

Primary endpoints of the Phase 1, first-in-human, open-label, non-randomized, multicenter, dose-escalation cohort expansion study will be the safety and tolerability of the compound, while secondary endpoints include efficacy, immunogenicity, pharmacokinetics, and pharmacodynamics of IOS-1002. In the trial, the compound will be administered at various dose levels to patients with advanced solid tumors either as monotherapy or in combination with a PD-1 monoclonal antibody. The trial is expected to enroll up to 140 patients.

"Advancing our lead compound IOS-1002 into a first-in-human trial is a major milestone for our team and provides a potential new option for patients," said Sean R. Smith, CEO of ImmunOs Therapeutics. "Our goal is not only to determine the safety, tolerability and activity of IOS-1002, but also to assess its clinical potential as both monotherapy and in combination with anti-PD-1 therapy, as supported by preclinical data."

IOS-1002 is a first-in-class, multi-functional agent based on a naturally occurring human leukocyte antigen (HLA) that targets multiple immune checkpoints to activate both innate and adaptive immune cells, thereby leading to profound anti-tumor activity.

"In preclinical trials, we have demonstrated the ability of IOS-1002 to bind to three different immune checkpoint targets, LILRB1 (ILT2), LILRB2 (ILT4) and KIR3DL1, leading to significantly increased anti-tumor responses of human macrophages, T cells, and NK cells," said Prof. Dr. Christoph Renner, Chief Medical Officer of ImmunOs Therapeutics. "We are excited about the opportunity to evaluate IOS-1002 in patients, as the compound addresses key challenges in cancer immunotherapy. We believe it has the potential to help patients with advanced solid tumors who have no further treatment options."

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About ImmunOs Therapeutics AG
ImmunOs Therapeutics AG leverages its HLA-based technology platform to develop first-in-class therapeutics for the treatment of cancer and autoimmune diseases. The Company has identified specific HLA molecules known to activate the immune system and is utilizing these HLA molecules as the backbone of novel therapies capable of stimulating both the innate and the adaptive immune systems of cancer patients to eliminate tumor cells. ImmunOs' lead program is a multi-functional fusion protein that blocks specific LILRB (leukocyte immunoglobulin-like) and KIR (killer cell immunoglobulin-like) receptors and activates anti-tumor responses. ImmunOs is also developing antibodies to block the activation of specific HLA protein molecules associated with autoimmune diseases.

The Company is supported by leading international investors including Samsara BioCapital, Lightspeed Venture Partners, Gimv, Pfizer Ventures, BioMed Partners, Schroder Adveq, Mission BioCapital, GL Capital, PEAK6, and Fiscus. ImmunOs is located in Schlieren, Switzerland, and Gaithersburg, MD, USA.

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