



## **KaliVir Immunotherapeutics Announces Completion of First Intravenous Patient Cohort of STEALTH-001 Study Evaluating VET3-TGI in Patients with Advanced Solid Tumors**

*Milestone marks first systemic delivery of KaliVir's multi-mechanistic oncolytic virus in patients with advanced solid tumors*

**PITTSBURGH, PA (October 1, 2025)** – [KaliVir Immunotherapeutics, Inc.](#), a clinical-stage biotechnology company developing cutting-edge, multi-mechanistic oncolytic immunotherapy programs, today announced the successful completion of the first cohort in the intravenous (IV) infusion arm of its STEALTH-001 ([NCT06444815](#)) clinical study, a Phase 1/1b clinical trial of VET3-TGI for patients with incurable, advanced solid tumors.

Patients received VET3-TGI, the Company's lead oncolytic immunotherapy candidate, which is designed to selectively kill tumor cells and remodel the tumor microenvironment by delivering a potent immuno-stimulatory transgene payload composed of interleukin-12 (IL-12) and a TGFbeta inhibitor.

"The dosing of patients in the IV arm marks a significant advancement for the STEALTH-001 study and the broader field of systemic oncolytic viral immunotherapy," said Dr. Yana Najjar, MD, Associate Professor in the Department of Medicine at the University of Pittsburgh and Director of the Clinical and Translational Research Center at UPMC Hillman Cancer Center. "Delivering VET3-TGI intravenously opens the door to using oncolytic virotherapy to treat patients with tumors that are not easily accessible for direct injection, expanding the potential reach of this therapeutic approach."

The continuation of IV dosing complements continued enrollment in the intratumoral (IT) arm of the Phase 1/1b trial, where patients are now being treated in cohort 3, and supports plans for combining VET3-TGI with checkpoint inhibitor therapy. The STEALTH-001 trial is evaluating VET3-TGI as both a monotherapy and in combination with a checkpoint inhibitor in patients with advanced, unresectable, or metastatic solid tumors.

"Systemic delivery of VET3-TGI is essential to realizing its full therapeutic potential, and this first IV dose brings us closer to that goal," said James Burke, MD, Chief Medical Officer of KaliVir Immunotherapeutics. "VET3-TGI was engineered to selectively infect tumor cells and deliver a potent combination of IL-12 and a TGFbeta inhibitor, stimulate a strong immune response and overcome tumor-driven immunosuppression. This milestone supports our broader goal of developing multi-mechanistic oncolytic immunotherapies that can address a wide range of solid tumors."

**About VET3-TGI and the STEALTH-001 Study**

VET3-TGI is a novel oncolytic virus developed using KaliVir's proprietary VET™ platform. It is designed to selectively replicate in tumor cells, stimulate local immune responses, and remodel the immunosuppressive tumor microenvironment through the expression of IL-12 and a TGFβ inhibitor. The STEALTH-001 study is a first-in-human, open-label, dose escalation and expansion Phase 1/1b trial assessing both intratumoral and intravenous administration of VET3-TGI.VE

The STEALTH-001 trial is a dose escalation and expansion study evaluating VET3-TGI administered through direct IT injection and IV infusion. The trial is evaluating VET3-TGI as a monotherapy and in combination with a checkpoint inhibitor in patients with pathologically confirmed, advanced, unresectable or metastatic solid tumors. The study continues to progress as planned through its dose escalation phase.

**About KaliVir Immunotherapeutics, Inc.**

KaliVir Immunotherapeutics is a clinical-stage biotechnology company at the forefront of developing next-generation oncolytic immunotherapies. By harnessing the unique advantages of the vaccinia platform, KaliVir engineers optimized viral backbones to create innovative candidates for cancer treatment. The Company's proprietary Vaccinia Enhanced Template (VET™) platform integrates multiple genetic modifications, allowing for the systemic delivery of oncolytic vaccinia candidates and the targeted expression of therapeutic transgenes within tumors.

Headquartered in Pittsburgh, Pennsylvania, KaliVir is committed to revolutionizing cancer treatment. For more information, visit [www.kalivir.com](http://www.kalivir.com).

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