



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

*- Data Safety Committee reviewed Cohort 1 safety data from intratumoral patients and cleared dosing for the next intratumoral and intravenous cohorts -*

**PITTSBURGH, PA (May 20, 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 its STEALTH-001 study, a Phase 1/1b clinical trial of VET3-TGI for patients with incurable, advanced solid tumors.

VET3-TGI is a novel oncolytic immunotherapy designed to target and selectively kill tumor cells while also expressing an immuno-stimulatory transgene payload consisting of interleukin-12 and a TGFbeta inhibitor. The Data Safety Committee, charged with monitoring the safety and overall risk-benefit of treatment on the STEALTH-001 ([NCT06444815](#)) clinical study, convened following dosing of the first cohort in the dose-escalation portion of the study, and approved continuation of dosing for the next intratumoral (IT) and intravenous (IV) infusion cohorts.

"The safety profile demonstrated in our initial first-in- human cohort is critical as it opens up expanded dosing in both the study's IV infusion and IT injection arms which will continue in parallel on study STEALTH-001. We are excited to assess not only the safety of VET3-TGI but further investigate both proof of concept and anti-tumor activity moving forward," said James Burke, M.D., Chief Medical Officer of KaliVir Immunotherapeutics.

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.

"Completing this first cohort reinforces our commitment to advancing our VET platform and its potential to address significant unmet needs in oncology," said Helena Chaye, Ph.D., CEO of KaliVir Immunotherapeutics. "We remain focused on our mission to develop novel oncolytic virus candidates with the potential to transform the treatment landscape for patients with advanced cancer."

**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.

The Company is actively expanding its pipeline using the VET™ platform, with its capabilities validated through strategic global partnerships with Astellas Pharma and Roche. Currently, the Company has two product candidates in Phase 1 clinical trials: ASP1012, exclusively licensed and led by Astellas Pharma, and its internal lead candidate, VET3-TGI. With multiple therapeutic candidates progressing through clinical development, KaliVir is positioned as a leader in innovative cancer therapies.

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

###

Media Contact:

Lauren Arnold

LA Communications

[Lauren@LACommunications.net](mailto:Lauren@LACommunications.net)