KaliVir Immunotherapeutics Reports 71% Objective Response Rate in Patients with Advanced, Cutaneous Malignancies in Phase 1/1b STEALTH-001 Trial

Preliminary data from intratumoral VET3-TGI presented in oral session at SITC 2026; abstract recognized among SITC's top 150 abstracts

Responses observed in non-injected lesions, suggesting systemic antitumor activity following intratumoral administration

PITTSBURGH, PA (November 6, 2026) – KaliVir Immunotherapeutics, Inc., a clinical-stage biotechnology company developing multi-mechanistic oncolytic immunotherapy programs, today announced preliminary clinical results from its Phase 1/1b STEALTH-001 trial evaluating intratumoral VET3-TGI alone or in combination with atezolizumab (NCT06444815) in patients with advanced solid tumors. The objective response rate (ORR) was 71% (5 of 7) in the response-evaluable cutaneous cancer subgroup and 41.7% (5 of 12) across the overall response-evaluable population. All seven patients with cutaneous cancers had progressed on prior anti-PD-1/PD-L1 therapy.

Yana Najjar, MD, Director of the Clinical and Translational Research Center at UPMC Hillman Cancer Center, presented the findings today during an oral presentation at the Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting. The complete disappearance of lesions, along with tumor shrinkage, was observed in both injected and non-injected lesions, suggesting the potential for systemic antitumor activity following local, intratumoral administration. VET3-TGI is an investigational oncolytic vaccinia virus engineered to express interleukin-12 (IL-12) and a transforming growth factor-beta (TGF-β) inhibitor.

"Patients with advanced cutaneous cancers who progress on checkpoint inhibitors have limited treatment options," said Najjar, MD, also Associate Professor of Medicine at the University of Pittsburgh, and presenting investigator for STEALTH-001. "The responses observed in patients with immunotherapy resistant Merkel cell carcinoma and melanoma are encouraging, particularly given their prior treatment histories. We also observed responses in tumors that were not injected, suggesting VET3-TGI may have activity beyond the site of administration. Our translational data from non-injected tumors also support this."

Summary of Preliminary Clinical Data

The evaluable patient data set presented included 12 patients with advanced solid tumors including a subset of seven patients with advanced checkpoint inhibitor refractory cutaneous cancers.

Antitumor Activity

- 71% ORR (5 of 7) was observed in patients with advanced cutaneous cancers, including responses in all three patients with Merkel cell carcinoma and two of three patients with advanced melanoma
- One patient with Merkel cell carcinoma achieved a complete response (CR)
- Four of the five responders received VET3-TGI monotherapy, while the fifth achieved a response to VET3-TGI in combination with atezolizumab
- Across all 12 evaluable patients with advanced solid tumors, the ORR was 41.7% (5 of 12) and the disease control rate 75% (9/12)
- Responses were observed in non-injected lesions, suggesting systemic antitumor activity following intratumoral VET3-TGI administration
- All five responders remained on study treatment at the data cutoff, with treatment durations ranging from 10 to 19 months. Responses continued to deepen in some patients

Patient Population

- The seven patients with advanced cutaneous cancers included three with Merkel cell carcinoma, three with advanced melanoma and one with cutaneous squamous cell carcinoma
- All patients had received at least one prior line of systemic therapy
- All seven patients with cutaneous cancers had progressed on prior anti-PD-1/PD-L1 therapy

Safety and Tolerability

- No dose-limiting toxicities were observed
- Treatment-related adverse events were predominantly Grade 1 or 2
- No treatment-related deaths were reported

"These early findings provide encouraging evidence of anti-tumor activity with VET3-TGI in patients who have progressed on prior immunotherapy," said James M. Burke, MD, Chief Medical Officer of KaliVir Immunotherapeutics. "The response rates, durability observed to date and activity in non-injected lesions support continued evaluation of VET3-TGI in cutaneous cancers as we advance the STEALTH-001 trial."

SITC 2026 Presentation details

The STEALTH-001 abstract was selected for an oral presentation and recognized among SITC's Top 150 abstracts.

- **Title:** A Phase 1 Study of VET3-TGI, an Oncolytic Vaccinia Virus Encoding TGFb Inhibitor and IL-12, for the Treatment of Advanced Solid Tumors
- **Abstract number:** 572
- **Session:** Biotech Session: The Next Generation of Off-the-Shelf IO
- **Date and time:** Friday, November 6, 2026, 4:50–5:00 p.m. MST
- **Presenter:** Yana Najjar, MD, UPMC Hillman Cancer Center

The presentation will be available on KaliVir's website following the meeting.

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.

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