KaliVir Immunotherapeutics Doses First Patient in Phase 1/1b Trial of VET3-TGI for Incurable, Advanced, Solid Tumors

Novel oncolytic immunotherapy being evaluated via IV and intratumoral delivery, both as monotherapy and in combination with checkpoint inhibitors

PITTSBURGH, PA (October 8, 2024) – KaliVir Immunotherapeutics, Inc., a clinical-stage biotechnology company developing cutting-edge, multi-mechanistic oncolytic viral immunotherapy therapeutics, today announced that the first patient has been dosed 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 which is 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 dosing of our first patient in the STEALTH-001 study marks a significant milestone for KaliVir and our innovative VET3-TGI program," said James Burke, M.D., Chief Medical Officer of KaliVir Immunotherapeutics. "The unique engineering of this platform to selectively target the tumor even in the face of anti-viral immunity holds great promise in delivering potent immune stimulatory cargo intravenously in patients with advanced solid tumors. Both VET3-TGI monotherapy and combination with checkpoint inhibition will be explored in this initial study."

About the STEALTH-001 Clinical Trial

STEALTH-001 (ClinicalTrials.gov No. NCT06444815) is a dose escalation and expansion study with VET3-TGI administered by direct injection into tumor(s) or by intravenous infusion. The dose escalation will determine the highest tolerated dose of VET3-TGI when injected directly into the tumor(s), given intravenously and when combined with the checkpoint blockade. Once the maximum tolerated dose is found for each of these groups, expansion cohorts will be initiated to further evaluate the safety and efficacy of VET3-TGI. The study is enrolling patients with pathologically confirmed, advanced, unresectable or metastatic solid tumors.

"VET3-TGI has the potential to reshape our approach to treating advanced tumors and provide a new path forward for patients who urgently need better treatment options," said Jorge Nieva, M.D., Associate Professor of Clinical Medicine at the Keck School of Medicine of the University of Southern California and Section Head of Lung and Head/Neck Tumors at the Norris Comprehensive Cancer Center and a member of KaliVir's Medical Advisory Board. "This is a pivotal milestone and I look forward to seeing the continued progress of VET3-TGI as a monotherapy and in combination with checkpoint inhibitor therapy."

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 kalivir.com.

###

Media Contact:
Lauren Arnold
LA Communications
Lauren@LACommunications.net