KaliVir Immunotherapeutics Announces FDA Clearance of Investigational New Drug (IND) for Oncolytic Immunotherapy VET3-TGI for Solid Tumors

Phase 1/1b study of VET3-TGI, alone and in combination with checkpoint inhibitor therapy, for advanced solid tumors

PITTSBURGH, PA (July 1, 2024) – KaliVir Immunotherapeutics, Inc., a biotech company developing cutting-edge, multi-mechanistic oncolytic viral immunotherapy programs, today announced that the FDA has cleared the Investigational New Drug (IND) application for the STEALTH-001 study of VET3-TGI in patients with incurable, advanced solid tumors.

VET3-TGI is a novel oncolytic immunotherapy which in nonclinical studies specifically targets and preferentially kills tumor cells directly while stimulating anti-cancer immunity by expressing its therapeutic payload consisting of the transgenes for interleukin-12 and a TGFbeta inhibitor. The Phase 1/1b study (ClinicalTrials.gov ID NCT06444815) will evaluate the safety profile and efficacy of VET3-TGI when administered through intravenous infusion or intratumoral injection in patients with advanced, incurable solid tumors. The trial will assess VET3-TGI both as a monotherapy and in combination with checkpoint inhibitor therapy.

“The initiation of this Phase 1/1b clinical study marks a pivotal moment in our continued journey to redefine cancer treatment with oncolytic virus therapy and combat advanced, unresectable or metastatic solid tumors,” said Helena Chaye, Ph.D., CEO of KaliVir Immunotherapeutics. “This marks our second initiation of a clinical trial from the VET platform, having announced in 2023 the progress with ASP1012 exclusively licensed to Astellas. We remain fully committed to pushing the boundaries on what is possible with cancer therapies and develop safer, more effective options that have the potential to transform the treatment landscape of oncology.”

About KaliVir Immunotherapeutics, Inc.
KaliVir Immunotherapeutics is a privately held biotech company developing cutting-edge, multi-mechanistic oncolytic viral immunotherapy programs. The company has developed a unique vaccinia virus-based platform, Vaccinia Enhanced Template “VET” Platform, that can generate potent novel oncolytic vaccinia viruses with modifications to maximize viral replication and to enhance intravenous delivery and spread. VET™ platform utilizes the large transgene capacity of the vaccinia virus to deliver therapeutics matched to tumor immunophenotypes to stimulate patients’ immune systems and modify the tumor microenvironment. KaliVir’s oncolytic virus candidates are designed to be safe, potent and systemically deliverable to treat cancer patients across multiple tumor types. KaliVir has separate collaborations with Roche and Astellas Pharma to design and generate novel oncolytic vaccinia viruses derived from the VET™ platform. In addition, Astellas entered into a world-wide exclusive license to develop and

commercialize KaliVir's initial lead clinical candidate VET2-L2 oncolytic vaccinia virus. KaliVir is currently advancing multiple therapeutic candidates toward the clinic. For more information, please visit Kalivir.com.

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