



## KaliVir Immunotherapeutics Announces FDA Clearance of Investigational New Drug (IND) for Systemic Oncolytic Virus ASP1012 for Phase I Clinical Trials for Locally Advanced or Metastatic Solid Tumors

*Licensed to Astellas, ASP1012, delivered by IV, reaches and destroys cancer cells and activates anti-cancer immunity through expression of therapeutic transgenes*

**PITTSBURGH, PA (October 24, 2023)** – [KaliVir Immunotherapeutics, Inc.](#), a biotech company developing cutting-edge, multi-mechanistic oncolytic viral immunotherapy programs, today announced clearance of an Investigational New Drug (IND) application by the United States Food and Drug Administration (FDA) to initiate a Phase 1 clinical study of ASP1012 in participants with locally advanced or metastatic solid tumors.

Discovered and developed by Kalivir and [licensed](#) to Astellas Pharma Inc. in December 2020, ASP1012 (formerly named VET2-L2) is a systemic oncolytic vaccinia virus therapy in which the virus is delivered intravenously and expresses Leptin-IL2 fusion protein as a therapeutic payload. The trial is expected to begin in Q1 2024.

“ASP1012 was the first candidate built from our unique Vaccinia Enhanced Template (VET™) platform and we are thrilled to reach this important milestone,” said Steve Thorne, Ph.D, Chief Scientific Officer and founder of Kalivir. “Our partnership with Astellas underscores our mission to bring critical cancer therapies to patients and we look forward to continued collaborations.”

“Immuno-oncology is a core focus of the Astellas R&D strategy and enriching our pipeline with the oncolytic virus ASP1012 is a testament to our commitment to provide new options to treat cancers where there are no effective treatment options,” said Peter Sandor, M.D., MBA, Senior Vice President and Primary Focus Lead, Immuno-Oncology, Astellas. “The combination of KaliVir’s expertise in oncolytic viruses and Astellas’ drug development capabilities has been a great partnership and it’s exciting to see the collaboration move forward in this way, bringing us one step closer to developing an immuno-oncology therapy for patients.”

### **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 [www.kalivir.com](http://www.kalivir.com).

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