AlloVir Receives the European Medicines Agency PRIME Designation for Viralym-M, an Allogeneic, Off-the-Shelf, Multi-Virus Specific T-Cell Therapy

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Viralym-M pivotal and proof-of-concept studies to be initiated in 2020 for treatment and prevention of severe and life-threatening viral diseases

Cambridge, MA, February 12, 2020 – AlloVir, a late-clinical stage T-cell immunotherapy company, today announced that the European Medicines Agency (EMA) has granted PRIority MEdicines (PRIME) designation to Viralym-M (ALVR105), the company's lead allogeneic, off-the-shelf, multi-virus specific T-cell therapy, for the treatment of serious infections with BK virus, cytomegalovirus, human herpes virus-6, Epstein Barr virus, and/or adenovirus in allogeneic hematopoietic stem cell transplantation (HSCT) recipients.

PRIME designation offers an accelerated regulatory pathway for Viralym-M in Europe, under the EMA's program to accelerate review of promising therapies targeting unmet medical needs. Designation for Viralym-M was granted based on data from a positive Phase 2 proof-of-concept study that showed greater than 90% of patients who failed conventional treatment and received Viralym-M had a complete or partial clinical response based on predefined criteria, with most patients achieving complete resolution of major clinical symptoms. These data were published in the *Journal of Clinical Oncology* (Tzannou, JCO, 2017). AlloVir plans to initiate Phase 3 pivotal and Phase 2 proof-of-concept studies with Viralym-M in 2020 targeting six common, devastating viral pathogens.

AlloVir previously received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) for Viralym-M for the treatment of hemorrhagic cystitis (HC) caused by BK virus in adults and children following allogeneic HSCT. The company holds worldwide development and commercialization rights to Viralym-M. AlloVir is dedicated to developing and delivering transformative cell therapies for patients suffering from life-threatening viral diseases.

"For immunocompromised patients, viral diseases can cause devastating and life-threatening consequences and today's PRIME designation acknowledges the urgent medical need for these patients," said David Hallal, Chief Executive Officer of AlloVir and co-founder of ElevateBio. "We believe Viralym-M has the potential to fundamentally transform the lives of patients with viral diseases by substantially reducing or preventing disease morbidity and dramatically improving patient outcomes. We look forward to advancing pivotal and proof-of-concept studies for Viralym-M in multiple indications this year, and we hope that PRIME designation by the European Medicines Agency speeds our efforts to get treatment to patients in need."

The PRIME program aims to optimize development plans and speed up evaluation of medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options. The PRIME designation is awarded by the EMA to promising medicines that target an unmet medical need. To be eligible and accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data coupled with non-clinical data. Through the PRIME program, the EMA offers enhanced support to medicine developers including early interaction and dialogue, and a pathway for accelerated evaluation by the agency. The program is intended to optimize development plans and expedite the review and approval process so that these medicines may reach patients as early as possible.

About Opportunistic Viral Diseases

In healthy individuals, virus-specific T-cells (VSTs) from the body's natural defense system provide protection against numerous disease-causing viruses. However, in patients with a weakened immune system these viruses may be uncontrolled. Viral diseases are common, with potentially devastating and life-threatening consequences in immunocompromised patients. For example, up to 90% of patients will reactivate at least one virus following an allogeneic stem cell transplant and two-thirds of these patients reactivate more than one virus, resulting in significant and prolonged morbidity, hospitalization and premature death. Typically, when viruses infect immunocompromised patients, standard antiviral treatment does not address the underlying problem of a weakened immune system and therefore, many patients suffer with life-threatening outcomes such as multi-organ damage and failure, and even death.

About Viralym-M (ALVR105)

Viralym-M is the lead investigational therapy in AlloVir's pipeline of allogeneic, off-the shelf multi-virus specific T-cell therapies designed to treat active viral diseases in immunocompromised patients, including in patients following HSCT, solid organ transplant, or in patients suffering with primary immunodeficiencies, cancer, or HIV. In a positive Phase 2 proof-of-concept study, published in the *Journal of Clinical Oncology* (Tzannou, JCO, 2017), greater than 90% of patients who failed conventional treatment and received Viralym-M demonstrated a complete or partial clinical response, and most exhibited complete resolution of major clinical symptoms. Viralym-M has the potential to fight or prevent a range of severe and life-threatening viral diseases in patients while they are immunocompromised.

About AlloVir

AlloVir (formerly ViraCyte), founded in 2013 by researchers at Baylor College of Medicine's Center for Cell and Gene Therapy, is the leader in the development of novel cell therapies with a focus on restoring and maintaining virus-specific T-cell immunity in patients suffering from, or at risk for, life-threatening viral diseases. The company's technology platforms deliver commercially scalable solutions by leveraging off-the-shelf, allogeneic, multi-virus specific T-cells targeting devastating viral pathogens for patients under viral attack. AlloVir's technology and manufacturing process enables the potential for the treatment and/or prevention of up to six devastating viruses with its lead allogeneic product, Viralym-M (ALVR105), and allows potentially hundreds of patients to be treated with virus-specific T-cells manufactured from a single donor, using a proprietary cell selection strategy to match the company's bank of donor-derived cell lines to patients. AlloVir is advancing multiple mid- and late-stage clinical trials across its

product portfolio.

AlloVir is an ElevateBio portfolio company. More information can be found at allovir.com.

About ElevateBio

ElevateBio, LLC, is a Cambridge-based biotechnology company, established to create and operate a broad portfolio of cell and gene therapy companies with leading academic researchers, medical centers and entrepreneurs. ElevateBio builds single- and multi-product companies by providing scientific founders with fully integrated bench-to-bedside capabilities including world-class scientists, manufacturing facilities, drug developers and commercial expertise. ElevateBio BaseCamp, a company-owned Cell and Gene Therapy Center of Innovation, will serve as the R&D, process development and manufacturing hub across the entire ElevateBio portfolio while also supporting selected strategic partners. For more information, please visit https://www.elevate.bio.

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