AlloVir Research Presented at the 2021 Transplantation & Cellular Therapy Meeting Digital Experience

February 11, 2021

- Subgroup analysis of Phase 2 CHARMS study shows rapid resolution of macroscopic hematuria in patients with virus-associated hemorrhagic cystitis treated with Viralym-M

- Real world claims data analyses demonstrate worse clinical outcomes, and significantly higher healthcare costs and health resource utilization in allogeneic HSCT recipients with virus-associated hemorrhagic cystitis and dsDNA viral infections

- ALVR109 preclinical data highlights opportunity to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus infected cells

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 11, 2021-- AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, today announced results of a subgroup analysis from a Phase 2, proof-of-concept study (CHARMS) evaluating the company's lead product candidate, Viralym-M (ALVR105), an allogeneic, off-the-shelf, multi-virus specific investigational T-cell therapy (VST), in allogeneic hematopoietic stem cell transplant (allo-HSCT) recipients with virus-associated hemorrhagic cystitis (V-HC). These data are being presented in an oral presentation during the Transplantation & Cellular Therapy (TCT) Meeting of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR). Additionally, two separate oral presentations characterize the high economic and clinical burden of V-HC and double-stranded (ds) DNA viral infections in allo-HSCT recipients. Preclinical data was also presented in a poster presentation on ALVR109, AlloVir's virus-specific T-cell therapy targeting SARS-CoV-2, the virus responsible for COVID-19.

"The data from the Phase 2 CHARMS study highlight Viralym-M's potential to treat and possibly prevent multiple viral infections and viral diseases. The findings presented at TCT show that this novel virus-specific T cell therapy has the potential to rapidly and effectively resolve macroscopic hematuria in allo-HSCT recipients with virus-associated hemorrhagic cystitis – a disease that currently has no effective treatment options and causes significant morbidity and increased risk of mortality," said Agustin Melian, MD, Chief Medical Officer and Head of Global Medical Sciences of AlloVir. "We have recently initiated our Phase 3, pivotal study of Viralym-M for the treatment of virus-associated hemorrhagic cystitis and look forward to advancing this therapy through development for patients in need."

Data of Viralym-M in fifty-eight allo-HSCT recipients with at least one treatment-refractory viral infection caused by BK virus (BKV), cytomegalovirus (CMV), adenovirus (AdV), Epstein Barr virus (EBV), human herpesvirus 6 (HHV-6), and/or JC virus (JCV) were evaluated in the CHARMS Phase 2 study. The subgroup analysis presented at TCT included 26 patients who received intravenous VST infusions for the treatment of V-HC due to infection with BKV (n=23), AdV (n=2) and BKV and AdV (n=1). Infusions were well tolerated with mild, grade 1, de novo skin rash from graft-versus-host disease (GVHD) occurring in 15% of patients (n=4). In the 20 patients with available V-HC grading, resolution of macroscopic hematuria was observed in 60% and 80% of patients at two- and six-weeks post-infusion, respectively. In comparison, resolution of macroscopic hematuria was observed in <10% and 30% of patients at weeks two and six, respectively, in a contemporary cohort of allo-HSCT recipients (n=33) with V-HC who were not treated with Viralym-M.

Health economic outcomes data was also presented in two separate oral presentations at the conference. The two presentations analyzed U.S. claims data to compare health care reimbursement, health resource utilization, and clinical outcomes in pediatric and adult allo-HSCT recipients with V-HC and those without V-HC, and allo-HSCT recipients with or without dsDNA infections, respectively. Both studies found that allo-HSCT recipients with V-HC and those with any dsDNA infection had higher reimbursement costs, increased hospital and ICU length of stay, and increased hospital readmission rates. The presence of V-HC or any dsDNA viral infection was associated with a higher risk of mortality.

In addition, a poster presentation at the conference demonstrated the in vitro effector and safety profile of ALVR109, an allogeneic, off-the-shelf investigational VST therapy designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19. These data suggest the potential for using these VSTs to treat COVID-19 in hospitalized high-risk patients to prevent the development of severe disease. A clinical trial evaluating these banked, off-the-shelf SARS-CoV-2 specific T cells has been initiated at the Center for Cell and Gene Therapy, Baylor College of Medicine (BCM), Texas Children's Hospital, and Houston Methodist Hospital.

Viral Infections in Immunocompromised Patients

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 and can cause 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.

Viralym-M

Viralym-M (ALVR105) is an allogeneic, off-the-shelf, multi-virus specific investigational T-cell therapy targeting five devastating viral pathogens: BK virus, cytomegalovirus, adenovirus, Epstein-Barr virus, and human herpesvirus 6. Viralym-M has the potential to transform care for transplant recipients as well as individuals who are at high risk for opportunistic viral infections by reducing or preventing disease morbidity and dramatically

improving patient outcomes. Three pivotal and proof-of-concept clinical (POC) trials are ongoing and actively recruiting patients in indications such as treatment of virus-associated hemorrhagic cystitis and multi-virus prevention following allo-HSCT, and preemptive treatment of BK viremia in adult kidney transplant recipients. Additional pivotal and POC trials are expected to initiate for the treatment of CMV and the treatment of AdV in allo-HSCT recipients and in CMV for solid organ transplant recipients, respectively. For more information on the ongoing clinical trials visit clinicaltrials.gov.

Viralym-M has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA), as well as PRIority MEdicines (PRIME) and Orphan Drug Designations (ODD) from the European Medicines Agency.

About AlloVir

AlloVir is a leading late clinical-stage cell therapy company with a focus on restoring natural immunity against life-threatening viral diseases in pediatric and adult patients with weakened immune systems. The company's innovative and proprietary technology platforms leverage off-the-shelf, allogeneic, multi-virus specific T-cells targeting devastating viruses for patients with T-cell deficiencies who are at risk from the life-threatening consequences of viral diseases. AlloVir's technology and manufacturing process enables the potential for the treatment and prevention of a spectrum of devastating viruses with each single allogeneic cell therapy. The company is advancing multiple mid- and late-stage clinical trials across its product portfolio. For more information visit http://www.allovir.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding AlloVir's development and regulatory status of our product candidates, the planned conduct of its preclinical studies and clinical trials and its prospects for success in those studies and trials, and its strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to AlloVir's financial results, the timing for the initiation and successful completion of AlloVir's clinical trials of its product candidates, whether and when, if at all, AlloVir's product candidates will receive approval from the U.S. Food and Drug Administration, or FDA, or other foreign regulatory authorities, competition from other biopharmaceutical companies, the impact of the COVID-19 pandemic on AlloVir's product development plans, supply chain, and business operations and other risks identified in AlloVir's SEC filings. AlloVir cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. AlloVir disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent AlloVir's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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Source: AlloVir