Data Presented at IDWeek™ 2021 Demonstrate that ALVR109, AlloVir's Investigational SARS-CoV-2-Specific T Cell Therapy, Is Reactive Against a Broad Range of Variants, Including Delta

September 29, 2021

Early clinical data show expansion and persistence of cells and support the efficacy and safety profile of ALVR109 in transplant and non-transplant patients with COVID-19

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 29, 2021-- AlloVir, Inc. (Nasdaq: ALVR), a late clinical-stage cell therapy company, today announced preclinical and early clinical data demonstrating that ALVR109, an investigational, allogeneic, off-the-shelf, virus-specific T cell (VST) therapy targeting SARS-CoV-2, provides antiviral activity and coverage against multiple variant strains, including Delta. The data were featured today in an oral presentation at IDWeek™ 2021

Preclinical research from Baylor College of Medicine demonstrated the ability to rapidly characterize the cellular immune response to SARS-CoV-2 in convalescent individuals and to develop VSTs targeting immunodominant T cell target antigens within the virus. This research enabled the study of ALVR109 in four patients who were hospitalized with COVID-19 with at least two risk factors for poor outcomes. Two of these patients were not prior recipients of a stem cell transplant.

"The preclinical data presented today underscore the power of AlloVir's virus-specific T cell therapy platform, demonstrating the speed at which we can identify target antigens, advance these to our manufacturing process and generate highly potent VSTs that are effective against a broad range of SARS-CoV-2 variant strains, including the Delta variant," said Ann Leen, Ph.D., Chief Scientific Officer of AlloVir, and an author on the presentation. "These cells are capable of targeting not only spike, including the majority of spike-mutated T cell epitopes present in clinically important variant strains, but also four additional structural and non-structural proteins. This broad immune reactivity minimizes the potential risk of immune escape from our therapy."

When advanced into clinical study, ALVR109 was well tolerated and was associated with clinical improvement in the four enrolled transplant and non-transplant patients, with cells that expanded and persisted post-infusion. Given the profile of ALVR109 from these clinical and preclinical data and the unmet medical need in immunocompromised patients with COVID-19, AlloVir continues to make ALVR109 available to physicians in response to compassionate use requests.

Beyond SARS-CoV-2, the early clinical data presented at IDWeek reinforce the potential for AlloVir's VST therapies to address the major public health issue posed by ubiquitous respiratory viruses. The company plans to initiate a proof-of-concept study for its multi-respiratory virus-specific T cell therapy, ALVR106, targeting respiratory syncytial virus, influenza, parainfluenza and human metapneumovirus later this year.

About the Preclinical Data

Researchers screened peripheral blood mononuclear cells (PBMCs) from convalescent donors who had naturally controlled and cleared the SARS-CoV-2 virus to identify immunogenic and protective SARS-CoV-2 antigens. Of the proteins screened, a subset was identified as immunodominant and was advanced for VST manufacturing using AlloVir's proprietary, clinically validated and commercially scalable manufacturing and cell culture process.

Though initially generated against the reference strain (Wuhan), AlloVir's ALVR109 recognized other clinically important variants in *in vitro* testing, including Alpha, Beta, Gamma, Epsilon, Kappa and, most notably, Delta. These data demonstrate that polyclonal, diverse VSTs targeting multiple antigens and epitopes can minimize the risk of immune escape due to viral mutation.

About the Clinical Data

A Phase 1b clinical trial enrolled adult, high-risk, hospitalized patients with at least two risk factors for poor outcomes, including age, history of malignancy, diabetes, hypertension and prior stem cell transplant. All four patients received standard of care and a single infusion of ALVR109, which was given at one of two dose levels. ALVR109 was well-tolerated, with only one serious adverse event of cytokine release syndrome 13 days after ALVR109 infusion; this event was transient and most likely attributable to COVID-19 disease progression. All four patients experienced clinical improvement after administration of ALVR109. One patient experienced clinical improvement after administration but subsequently experienced a late COVID-19 recurrence and died nearly four weeks following treatment with ALVR109. Three of the four patients experienced clinical improvement and remain well and virus-free.

Researchers also performed exploratory studies to examine the *in vivo* expansion and persistence of the ALVR109 infused cells. In all four patients, substantial increases in SARS-CoV-2 specific T cells following administration were observed, and ALVR109 VSTs were detected out to at least three months post-infusion in two of the four patients.

Spyridoula Vasileiou, Ph.D., from the Center for Cell and Gene Therapy, Baylor College of Medicine, Texas Children's Hospital, and presenting author said, "The data demonstrate that polyclonal SARS-CoV-2 VSTs can provide coverage against variant strains and, when administered to patients with COVID-19, these cells expand and persist *in vivo*."

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, single and multi-virus-specific T-cells for patients with T-cell deficiencies who are at risk from the life-threatening consequences of viral diseases. AlloVir's technology and manufacturing process enable 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 www.allovir.com or follow us on Twitter or LinkedIn.

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 the potential for AlloVir's VST therapies to address the major public health issue posed by ubiquitous respiratory viruses, the development and regulatory status of our product candidates, the planned conduct of its 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, including but not limited to the risks discussed in AlloVir's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and in our other filings with the SEC. 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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Sonia Choi
AlloVir
schoi@allovir.com

Source: AlloVir, Inc.