



AlloVir Announces Positive Final Results in Phase 2 Posoleucel Multi-Virus Prevention Study In Oral Presentation at the 64th ASH Annual Meeting and Exposition

December 10, 2022

23 of 26 (88%) patients remained free of clinically significant infections caused by any of six common viruses that posoleucel targets through the Week 14 primary endpoint

3 of 26 (12%) patients had clinically significant infections despite 22 of 26 (85%) patients reactivating one or more of six potentially devastating viruses

Biomarker data support the clinical results by demonstrating expansion of functional virus-specific T cells coincident with viral load declines

Enrollment progressing in Phase 3 posoleucel multi-virus prevention registrational trial in the U.S., Europe and Asia

Company to host investor webcast with external KOLs on December 14, 2022, at 4:30 p.m. EST

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 10, 2022-- AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T-cell immunotherapy company, today announced final data from the Phase 2 study of posoleucel, an investigational, allogeneic, off-the-shelf, multi-virus specific T cell therapy, for the prevention of clinically significant infections or diseases from six common and devastating viruses in allogeneic hematopoietic cell transplant (allo-HCT) recipients – adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). These final data demonstrated a substantial reduction in the expected rate of clinically significant viral infections or diseases in this high-risk patient population despite the expected high rates of viral reactivation. Biomarker data demonstrated the persistence of posoleucel and association between expansion of functional virus-specific T cells (VSTs) and viral control. Repeat dosing of posoleucel was generally well tolerated in the study. These data were highlighted in an oral presentation ([Abstract 362](#)) at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition in New Orleans today.

The majority of allo-HCT recipients reactivate one or more of posoleucel's six target viruses post allo-HCT, which can lead to clinically significant infections, prolonged morbidity, hospitalization and premature death. There are currently no effective preventive therapies that can target these viruses simultaneously to block the progression of viral reactivation to clinically significant infections. When given as preventative therapy, posoleucel is designed to serve as an immunologic bridge, covering patients through the high-risk, post-transplant window when patients' own immune systems are rebuilding. Posoleucel selectively expands in the presence of antigens from the six target viruses, controls viral replication and contracts after viral control and the reconstitution of patients' own immune systems.

"Allogeneic hematopoietic cell transplant recipients are highly vulnerable to potentially devastating viral infections, particularly in the first 100-180 days post-transplant. The downstream effects of these viral infections can be life-threatening, and there are very few treatment options that can control these infections and their sequelae," said Sanjeet Singh Dadwal, M.D., Chief, Division of Infectious Diseases, and Professor of Medicine, City of Hope, and lead investigator of the posoleucel multi-virus prevention Phase 2 study. "Preventing the progression of viral reactivation into clinically significant infections or disease and avoiding the devastating consequences of these infections for patients, either through a prophylactic or preemptive treatment approach with posoleucel, would be a significant advance in the management of allo-HCT patients."

"We are excited to see the durability of posoleucel efficacy and safety in this final data set from the Phase 2 multi-virus prevention study, which reinforces the preliminary data previously reported. The additional biomarker data presented today on the expansion of functional VSTs against all six target viruses provide additional insight into the mechanism of action and role of posoleucel in preventing the progression of these ubiquitous viruses into clinically significant infections or end-organ disease," said Diana Brainard, M.D., CEO, AlloVir. "Multi-virus prevention against six common, potentially devastating pathogens represents a highly transformative use of posoleucel. We continue to urgently enroll our ongoing global Phase 3 multi-virus prevention study, with the goal of delivering this therapy to patients as quickly as possible."

Phase 2 Multi-Virus Prevention Study

This open-label Phase 2 study evaluated the efficacy and safety of posoleucel for the prevention of clinically significant viral infections or disease caused by six target viruses: AdV, BKV, CMV, EBV, HHV-6 and JCV. The prevention study encompassed both the prophylaxis of patients at high risk for viral reactivation and the preemptive treatment of patients with viral reactivation who had not yet developed clinically significant infections or disease.

Patients received up to seven biweekly posoleucel infusions and were tested for viremia by polymerase chain reaction (PCR) on a weekly basis against all six viruses over a period of 14 weeks. Following this dosing period, patients received follow-up through Week 26. The primary study endpoint was the number of new onset clinically significant infections or end-organ disease through Week 14.

The study enrolled 26 high-risk allo-HCT patients. Of these patients, 12 (46%) received transplanted cells from haploidentical donors, nine (35%) from mismatched unrelated donors, four (15%) from matched unrelated donors with T cell depletion or with lymphopenia, and one (4%) from umbilical cord blood.

Out of 26 high-risk allo-HCT patients who received posoleucel in this open-label study, 22 (85%) patients experienced reactivation of at least one of posoleucel's target viruses. Despite these expected high rates of viral reactivation, only three clinically significant infections were observed through Week 14; two asymptomatic patients initiated preemptive CMV treatment with valganciclovir following withdrawal of letermovir, and one patient started

rituximab for EBV-associated post-transplant lymphoproliferative disease in the setting of receiving high-dose steroids.

Biomarker analyses demonstrated that viral control was associated with expansion of functional VSTs. An increase in frequency of functional VSTs, when evaluating change from baseline (Pre) to peak response through the 14-week treatment period (Post), was observed via ELISpot. This increased frequency of functional VSTs was associated with a reduction in viremia during the same timeframe. Cell persistence was evaluated with T cell receptor sequencing, with the presence of posoleucel confirmed both during the infusion period and up to 14 weeks after the last infusion.

Treatment of up to seven doses of posoleucel over 12 weeks was generally well tolerated with no unanticipated safety signals. Rates of GVHD (19%) were similar in frequency and severity to those expected in this high-risk allo-HCT population. Three (12%) treatment-related serious adverse events were reported. No episodes of cytokine release syndrome were reported.

Based on preliminary data from this study released earlier this year, AlloVir commenced a global, registrational Phase 3 multicenter, randomized, double-blind, placebo-controlled clinical trial ([NCT05305040](https://clinicaltrials.gov/ct2/show/study/NCT05305040)) of posoleucel for multi-virus prevention. The study is enrolling patients in the U.S., Europe and Asia.

Investor Webcast Details

The company will host an investor webcast on Wednesday, December 14, 2022, at 4:30 p.m. EST to discuss the unmet medical need for and clinical value of a multi-virus prevention approach in the management of allo-HCT patients. The webcast will feature remarks from AlloVir CEO Diana Brainard; infectious disease specialist Sanjeet Singh Dadwal, M.D., City of Hope; and hematologist-oncologist and transplant specialist Joseph McGuirk, D.O., University of Kansas Medical Center.

A live audio webcast of the presentation will be available on the Investors & Press section of the AlloVir website at <https://ir.allovir.com/events-and-presentations>. An archived replay of the presentation will be available on the website for 30 days following the event.

About Posoleucel

AlloVir's lead product, posoleucel, is in late-stage clinical development as an allogeneic, off-the-shelf, multi-virus specific T-cell therapy targeting six viral pathogens in immunocompromised individuals: adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). In the positive Phase 2 proof-of-concept CHARMS study, more than 90% of patients who failed conventional treatment and received posoleucel demonstrated a complete or partial clinical response based on predefined criteria, most with complete elimination of detectable virus in the blood and resolution of major clinical symptoms.

Based on the strength of the posoleucel Phase 2 data for both treatment and prevention, the FDA has granted posoleucel Regenerative Medicine Advanced Therapy (RMAT) designation for each of the three indications being evaluated in Phase 3 clinical trials – for the treatment of hemorrhagic cystitis (HC) caused by BKV, for the treatment of AdV infection in adults and children following allo-HCT, and for the prevention of clinically significant infections and disease caused by posoleucel's six target viruses. The FDA also granted posoleucel Orphan Drug Designation for the treatment of virus-associated HC. The European Medicines Agency has granted posoleucel PRiority Medicines (PRIME) designation for the treatment of serious infections with AdV, BKV, CMV, EBV and HHV-6, and Orphan Medicinal Product designation as a potential treatment of viral diseases and infections in patients undergoing HCT.

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 efficacy of posoleucel as a treatment for the prevention of clinically significant infections or diseases, AlloVir's development plans and the regulatory status of AlloVir's 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, including but not limited to the risks discussed in AlloVir's Annual Report on Form 10-K for the year ended December 31, 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20221210005012/en/): <https://www.businesswire.com/news/home/20221210005012/en/>

Media and Investor Contact:

Sonia Choi
AlloVir
schoi@allovir.com

Source: AlloVir