AlloVir Announces Positive Results Including Long-Term Mortality Data in Phase 2 Posoleucel Multi-Virus Prevention Study in Oral Presentation at EBMT 2023

April 26, 2023

Day 400 non-relapse mortality was 0%

Previously reported data from the 14-week primary endpoint showed low rates of clinically significant viral infections and diseases in this high-risk patient population despite the expected high rates of viral reactivation

Global Phase 3 pivotal posoleucel trials continue to progress with robust patient enrollment in the US, Europe and Asia with data readouts on track for 2024

WALTHAM, Mass.--(BUSINESS WIRE)--Apr. 26, 2023-- AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today announced the presentation of positive long-term, follow-up data from the Phase 2 study of posoleucel for the prevention of clinically significant infections from six common and devastating viruses in allogeneic hematopoietic cell transplant (allo-HCT) recipients. Posoleucel is the company's investigational, allogeneic, off-the-shelf, multi-virus specific T cell therapy, designed to target adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). These new findings demonstrate that the high-risk allo-HCT patients who received posoleucel experienced continued low rates of clinically significant infections and end-organ disease and 0% non-relapse mortality. These data were highlighted today in an oral presentation (Abstract OS08-03) at the 49th annual meeting of the European Society for Blood and Marrow Transplantation (EBMT 2023).

"The data presented today provide further evidence supporting the potential benefits of using posoleucel to prevent viral infection in high-risk allo-HCT patients. The non-relapse mortality rate in patients receiving posoleucel was 0% through week 52 which compares favorably with published non-relapse mortality rates among allo-HCT patients ranging from 9 percent to over 15 percent," said Diana Brainard, MD, CEO, AlloVir. "Our global, registrational Phase 3 clinical trial further exploring the potential of posoleucel for multi-virus prevention is well underway and we anticipate data from this registrational study in 2024. If successful, an option that prevents viral infection, such as posoleucel, could transform the care of allo-HCT patients."

"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," said Sanjeet Singh Dadwal, MD, Chief, Division of Infectious Diseases, and Professor of Medicine, at City of Hope, one of the largest cancer research and treatment organizations in the United States, and lead investigator of the posoleucel multi-virus prevention Phase 2 study. "This long-term 0% non-relapse mortality result builds upon the positive data through week 26 post-HCT, which was reported at the end of last year. These long-term follow-up data suggest that posoleucel could significantly impact patient outcomes. When available, I look forward to seeing the larger data set from the ongoing Phase 3 program."

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 and 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. After this dosing period, patients were followed through Week 26. The primary study endpoint was the number of new onset clinically significant infections or end-organ disease through Week 14. Details from the Phase 2 study were reported in December 2022 and can be found here.

The study also included a 52-week follow-up visit, data from which were presented today at EBMT. These new data demonstrate that, of the 26 patients dosed with posoleucel, the five deaths were all related to relapse/progression of underlying disease; none were due to infection or deemed treatment-related, resulting in 0% non-relapse mortality.

More information on the ongoing, global, registrational, Phase 3, multicenter, randomized, double-blind, placebo-controlled clinical trial of posoleucel for multi-virus prevention can be found on clinicaltrials.gov under the study ID (NCT05305040).

References:
1. Marty F, et al. N Engl J Med. 2017;377:2433-44.
2. McDonald GB, et al. Ann Intern Med. 2020;172:229-39.
3. Su Y, et al. Clin Infect Dis. 2022;75:795-804.

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 allogeneic T cell immunotherapy 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 caused by AdV, BKV, CMV, EBV, HHV-6 and JCV and as a treatment to prevent viral infection in high-risk allo-HCT patients, 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, the planned enrollment of clinical trials, the anticipated timing of data readouts and completion of its clinical 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 the potential of posoleucel as a treatment for the prevention of clinically significant infection or diseases, the potential of posoleucel as a treatment option to prevent viral infection in high-risk allo-HCT patients, 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 (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, 2022, 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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