AlloVir Announces Plans to Complete Enrollment in Three Phase 3 Posoleucel Studies in 2023

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Positive final posoleucel Phase 2 clinical data presented at ASH 2022 underscore potential as multi-virus prevention therapy and support ongoing global Phase 3 registration trial

Completion of enrollment of all three posoleucel Phase 3 registrational trials anticipated by the end of 2023 and data readouts in 2024

Topline results of posoleucel Phase 2 BKV treatment study in kidney transplant patients expected in 1Q 2023

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 9, 2023-- AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage, allogeneic T-cell immunotherapy company, today announced the company's 2023 priorities and anticipated future milestones across its pipeline of virus-specific T cell therapies, including its lead investigational therapy posoleucel. These updates will be the focus of a corporate presentation by Chief Executive Officer Diana Brainard, M.D., at the 41st Annual J.P. Morgan Healthcare Conference on Tuesday, January 10, at 2:15 pm PT / 5:15 pm ET. A live webcast and archived replay of the presentation will be available in the Investors & Press section of the AlloVir website at https://ir.allovir.com.

"The positive posoleucel Phase 2 data we reported in 2022 and the enthusiasm we are seeing from transplant centers give us further confidence in our Phase 3 strategy for posoleucel and our ability to execute on our trials in 2023," said Dr. Brainard. "Our Phase 2 multi-virus prevention study data underscore the potential for posoleucel to be transformative for allo-HCT patients by substantially reducing clinically significant infections from six viruses that are devastating for this vulnerable population. Viral infections are a leading cause of non-relapse mortality, generate substantial healthcare expenditures, exact a significant emotional burden on patients and their caregivers, and unfortunately most viruses targeted by posoleucel currently have no preventive therapies."

Posoleucel is an investigational T cell therapy that targets multiple viruses that commonly reactivate in patients who have received allogeneic hematopoietic cell transplants (allo-HCTs) or solid organ transplants. The therapy is being evaluated in three Phase 3 registrational studies for three distinct indications — the prevention of clinically significant infections or disease from adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV), the treatment of virus-associated hemorrhagic cystitis (vHC), and the treatment of AdV infection, all in allo-HCT patients. These viral infections have limited to no approved preventive therapies and treatment options, threatening patient survival.

Posoleucel

Multi-Virus Prevention in Allo-HCT Patients

Multi-virus prevention represents the most transformational potential use of posoleucel, moving upstream to prevent the progression of viral reactivations to clinically significant infections and avoid the deleterious downstream effects of these infections. Final data from the open-label, Phase 2 multi-virus prevention study of posoleucel were recently presented at the 64th ASH Annual Meeting and Exposition. Results showed that high-risk allo-HCT patients who received posoleucel had substantially lower than expected rates of clinically significant viral infections from posoleucel's six target viruses, and that repeat dosing was generally safe and well tolerated.

The posoleucel Phase 3 multi-virus prevention trial (NCT05305040) is enrolling adult and pediatric patients in the U.S., Europe, Asia, Australia and Canada. Enrollment is expected to complete by year-end 2023, enabling topline data in mid-2024.

vHC and AdV Treatment in Allo-HCT Patients

Global enrollment is ongoing in Phase 3 registrational studies of posoleucel for the treatment of vHC (NCT04390113) and AdV infection (NCT05179057), both in adult and pediatric allo-HCT patients. Given the high proportion of sites participating in multiple posoleucel Phase 3 studies and the intentional prioritization of the multi-virus prevention trial, both the vHC and AdV studies are expected to complete enrollment by year-end 2023, with topline data anticipated in 2024.

BKV Treatment in Kidney Transplant Patients

Topline final data from the Phase 2 study (NCT04605484) of posoleucel for the treatment of BK viremia in kidney transplant patients are expected in the first quarter of 2023. These data will inform next steps for this potential indication as well as our broader strategy in solid organ transplant patients.

Earlier Stage Pipeline

AlloVir's early clinical and preclinical VST therapy candidates provide portfolio expansion opportunities, with pipeline advancement led by AlloVir or a potential partner.

ALVR106

A Phase 1b/2 proof-of-concept clinical study (NCT04933968) of ALVR106 for the treatment of respiratory syncytial virus (RSV), human metapneumovirus, parainfluenza, and influenza, is enrolling auto- and allo-HCT patients in the U.S. into the dose escalation part of this two-part study.

ALVR107

Preclinical and IND-enabling studies of ALVR107 for chronic HBV have been completed and continue to support the potential for ALVR107 to achieve functional HBV cure. The company expects to initiate clinical development of ALVR107 upon completion of the posoleucel Phase 3 registrational studies.

ALVR109

The company continues to make ALVR109 available to physicians in response to appropriate compassionate use requests. Positive reports of ALVR109 compassionate use in immune-compromised patients have been published and presented at the 2022 American Transplant Congress, providing important insight into the potential utility of a virus-specific T cell approach to treating respiratory viruses in immunocompromised patients.

Financial Guidance

As of December 31, 2022, the company's cash balance was $234 million. For fiscal year 2023, AlloVir expects operating expenses to be in the range of $150 million to $170 million, excluding non-cash stock compensation expenses. The cash balance amount is preliminary and subject to revisions until the company reports its full financial results for fiscal year 2022.

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 safety, efficacy and regulatory and clinical progress of our product candidates, including posoleucel, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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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