AlloVir Reports Full-Year 2022 Financial Results and 2023 Outlook

February 15, 2023

Completion of enrollment of all three posoleucel Phase 3 registrational trials for three distinct, first-to-market indications anticipated by end of 2023 and data readouts in 2024

Positive final results from randomized, double-blind, placebo-controlled Phase 2 study of posoleucel in kidney transplant recipients with BK viremia announced separately today; company to host investor webcast at 9:00 a.m. EST

Strong cash position, with $233.8 million as of year-end 2022

WALTHAM, Mass.--(BUSINESS WIRE)--Feb. 15, 2023-- AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today reported full-year 2022 financial results for the period ended December 31, 2022. The company also highlighted its progress and provided the outlook for 2023 and into 2024 across its allogeneic, off-the-shelf, virus-specific T cell (VST) programs, including its lead investigational therapy, posoleucel, for the treatment and prevention of life-threatening infections and diseases caused by six viruses that commonly impact patients following allogeneic hematopoietic cell transplant (allo-HCT).

“With the acceleration of the posoleucel multi-virus prevention study and continued enrollment in the viral hemorrhagic cystitis and adenovirus treatment Phase 3 studies in 2022, the posoleucel franchise is positioned for potentially significant value creation over the next 12-24 months,” said Diana Brainard, M.D., Chief Executive Officer, AlloVir. “During 2023, we plan to complete enrollment in our Phase 3 registrational studies, which would enable data readouts in 2024 and, with positive results, regulatory filings and acceleration of commercial preparations to follow.”

Dr. Brainard continued, “Today we also announced positive final Phase 2 results from our first study of posoleucel in the solid organ transplant setting, showing balanced safety across the posoleucel and placebo groups and clinically meaningful greater viral load declines with posoleucel versus placebo in kidney transplant patients with BKV. These results are important proof of concept for the use of posoleucel in the solid organ transplant setting. We look forward to working with regulatory authorities and transplant specialists on our future clinical development plans for this patient population with high unmet medical need."

Recent Highlights

- In an oral presentation at the American Society of Hematology (ASH) Annual Meeting and Exposition in December 2022, final data were presented from the Phase 2 study evaluating posoleucel for the prevention of clinically significant infections or diseases from adenovirus, BK virus, cytomegalovirus, Epstein-Barr virus, human herpesvirus-6 and JC virus in allo-HCT patients. The data demonstrated a substantial reduction in the expected rate of clinically significant viral infections in this high-risk patient population despite the expected high rates of viral reactivation observed. Biomarker data showed the persistence of posoleucel and association between expansion of functional VSTs and viral control.
- Final topline data from the posoleucel Phase 2 BKV treatment study in kidney transplant patients were reported earlier today. Posoleucel was generally well tolerated in the study and demonstrated clinically meaningful antiviral efficacy consistently across multiple BK viral load measures. The greatest effect was observed with biweekly posoleucel dosing in patients with screening viral load ≥10,000 copies/mL, who are at highest risk for BKV-associated graft loss.
- In January 2023, final data from the CHARMS Phase 2 study of posoleucel for the treatment of viral infections in treatment-refractory allo-HCT patients were published in *Clinical Cancer Research.* The data demonstrated that 95% of patients with one or more treatment-refractory infections achieved a clinical response with posoleucel.
- A compassionate use case report of posoleucel therapy for BKV nephropathy in a kidney transplant patient was presented in a poster at the annual meeting of the American Society of Nephrology in November 2022. Following posoleucel therapy, the patient experienced a significant reduction in BK viral load.
- In November 2022, a manuscript was published in *Haematologica* describing the development and first clinical use of ALVR109 for the treatment of COVID-19*.* The data underscore the company’s ability to rapidly develop VSTs for emerging viral threats and the potential application of these VSTs for the treatment of respiratory viruses.
- In the fourth quarter of 2022, the company established a scientific advisory board comprised of experts in cell therapies, stem cell and solid organ transplantation and infectious diseases. The standing group of advisors will provide insights and external perspective that will guide the advancement of the company’s science and pipeline.

  AlloVir’s scientific advisory board members are as follows:

- Michael Boeckh, M.D., Ph.D., Head of the Infectious Disease Sciences Program of the Vaccine and Infectious Disease Division at Fred Hutchinson Cancer Center

- Anil Chandraker, M.D., Director of Renal Transplant Medicine at Brigham and Women’s Hospital, and Associate Professor of Medicine at

Harvard Medical School

- Stella Davies, MBBS, Ph.D., MRCP, Director of the Division of Bone Marrow Transplantation and Immune Deficiency at Cincinnati Children's Hospital Medical Center

- John F. DiPersio, M.D., Ph.D., Director of the Center for Gene and Cellular Immunotherapy and a Professor of Medicine, Pathology & Immunology at Washington University School of Medicine

- John W. Mellors, M.D., Distinguished Professor of Medicine, Chief of Infectious Diseases, and Endowed Chair for Global Elimination of HIV and AIDS, at the University of Pittsburgh School of Medicine and UPMC Health System

- Gérard Socié, M.D., Ph.D., Head of Hematology-Transplantation at AP-HP Hospital Saint-Louis in Paris

Outlook – 2023 and Into 2024

Posoleucel: AlloVir's lead investigational therapy, posoleucel, offers a franchise opportunity, with three indications being evaluated in Phase 3 registrational trials.

- The posoleucel Phase 3 multi-virus prevention trial is enrolling adult and pediatric patients globally. Enrollment is expected to complete by year-end 2023, enabling topline data in mid-2024.
- Global enrollment is ongoing in Phase 3 studies of posoleucel for the treatment of virus-associated hemorrhagic cystitis and adenovirus infection, both in adult and pediatric allo-HCT patients. Both studies are expected to complete enrollment by year-end 2023, with topline data anticipated in 2024.
- The company plans to present comprehensive results from the BKV Phase 2 study at a scientific congress later this year, and will work with regulatory authorities and transplant specialists to inform next steps for this program and AlloVir's broader solid organ transplant strategy.

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.

- A Phase 1b/2 proof-of-concept clinical study of ALVR106 for the treatment of respiratory syncytial virus, 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.
- 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 after completion of the posoleucel Phase 3 registrational studies.

2022 Financial Highlights

- Research and development expenses were $118.9 million for the year ended December 31, 2022, compared with $120.7 million for the year ended December 31, 2021. The decrease year-over-year is primarily attributable to a reduction in costs related to the outsourcing of manufacturing, offset by an increase in costs related to the development of clinical trials to advance product candidates.
- General and administrative expense was $52.3 million for the year ended December 31, 2022, compared with $49.1 million for the year ended December 31, 2021. Stock-based compensation expense was $41.3 million and $44.0 million for the years ended December 31, 2022 and 2021, respectively.
- As of December 31, 2022, AlloVir had cash, cash equivalents, and marketable securities of $233.8 million, compared with cash, cash equivalents, and marketable securities of $248.1 million as of December 31, 2021.
- For the year ended December 31, 2022, net loss was $168.7 million or $2.20 per share, compared with a net loss of $172.0 million or $2.74 per share for the year ended December 31, 2021.

2023 Financial Guidance

- For fiscal year 2023, AlloVir expects operating expenses to be in the range of $150 million to $170 million, excluding non-cash expenses.

Investor Webcast Details

The company will host an investor webcast today at 9:00 a.m. EST to discuss the BKV study findings and the potential clinical impact of using posoleucel to treat viral infections in the solid organ transplant setting. The webcast will feature remarks from AlloVir CEO Diana Brainard, M.D., and from renal transplant specialist Anil K. Chandraker, M.D., Brigham and Women's Hospital.

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 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, the financial outlook for the full-year 2023, including estimates of operating expenses, 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 Securities and Exchange Commission (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.

ALLOVIR, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$233,795	$248,120
Other current assets	9,257	5,228
Total current assets	243,052	253,348
Other assets	34,027	33,246
Total assets	$277,079	$286,594
Liabilities and stockholders' equity		
Current liabilities	$ 24,338	$ 37,853
Long-term liabilities	28,222	23,475
Total liabilities	52,560	61,328
Total stockholders' equity	224,519	225,266
Total liabilities and stockholders' equity	$277,079	$286,594

ALLOVIR, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except share and per share data)

	Years Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development	118,870	120,735
General and administrative	52,332	49,083
Total operating expenses	171,202	169,818
Loss from operations	(171,202)	(169,818)
Total other income (loss), net:		
Interest income	1,876	1,315
Other income (loss), net	351	(2,452)
Loss before income taxes	(168,975)	(170,955)
Income tax (benefit) expense	(265)	1,007
Net loss	$ (168,710)	$ (171,962)
Net loss per share --- basic and diluted	$ (2.20)	$ (2.74)

Weighted-average common shares outstanding---basic and diluted	76,654,856	62,782,126

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