AlloVir Reports Third Quarter 2022 Financial Results

November 3, 2022

Posoleucel Continues to Advance in Three Ongoing Multi-National Phase 3 Registrational Trials

Final Data Presentation from Posoleucel Phase 2 Multi-Virus Prevention Study by Year-End

Company to Host Investor Webcast on December 14 with Clinical Trial Investigators on Posoleucel for Prevention of Viral Infections in Patients Following Allogeneic Stem Cell Transplant

Final Topline Data from Posoleucel Phase 2 Study for Treatment of BK Viremia in Kidney Transplant Patients on Track to be Released in Q1 2023

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 3, 2022-- AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today reported financial results for the third quarter ended September 30, 2022, and shared progress 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 from up to six viruses that commonly impact patients following allogeneic hematopoietic cell transplant (allo-HCT).

“We are focused on rapidly advancing the ongoing posoleucel Phase 3 registrational trials, with the goal of delivering a significant clinical advance for allo-HCT patients who currently have very limited therapeutic and preventive options for these common, yet devastating and potentially life-threatening, viral infections and diseases,” said Diana Brainard, M.D., Chief Executive Officer, AlloVir. “We are particularly excited to report final data before year-end from the Phase 2 multi-virus prevention study, where preliminary results supported the acceleration of our global Phase 3 study for this potential indication. Preventing clinically significant viral infections and diseases after allo-HCT represents the most transformative use of posoleucel.”

Investor Webcast

AlloVir plans to host an investor webcast on Wednesday, December 14 at 4:30 p.m. ET, 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 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.

Recent Highlights

- The Phase 3 study of posoleucel for the prevention of clinically significant infections and end-organ disease from posoleucel’s six target viruses in high-risk allo-HCT patients, continued to expand, with ongoing patient enrollment in the U.S., Europe and Asia.

  The multi-virus prevention study evaluates the use of posoleucel either as prophylactic therapy in patients without viremia or preemptive therapy for patients who have reactivated one or more of the target viruses: adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpes virus-6 (HHV-6) and JC virus (JCV). Multi-virus prevention has the potential to transform the management of allo-HCT patients, who currently have limited to no approved treatment or prevention options for these devastating infections that threaten patient survival.

- Enrollment in the posoleucel Phase 3 treatment trials also continues to progress, with virus-associated hemorrhagic cystitis trial sites at leading transplant centers in the U.S., Europe and Asia, and adenovirus trial sites at leading centers in the U.S. and Europe, with a focus on the pediatric patient population.

- Pediatric data from the CHARMS Phase 2 study of posoleucel for the treatment of severe, drug-refractory viral infections in pediatric allo-HCT patients were presented in a poster (Abstract 2161) at IDWeek in October 2022. The data continue to support the potential of posoleucel as a treatment for viral infections and diseases in this patient population.

- In July 2022, the European Medicines Agency confirmed that the orphan medicinal product designation granted to posoleucel to treat viral infections and diseases from AdV, BKV, CMV, EBV, and HHV-6 in allo-HCT patients also applies to the potential prevention of infections or disease by these multiple viruses in this patient population.

Posoleucel previously received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration for multi-virus prevention, the treatment of AdV infection and the treatment of virus-associated hemorrhagic cystitis in adults and children, all following allo-HCT. To the Company's knowledge, posoleucel is the only cell or gene therapy with three RMAT designations.

- In July 2022, The European Patent Office granted Baylor College of Medicine a patent licensed to AlloVir covering VST compositions including posoleucel and ALVR106, enhancing the company's intellectual property protections in Europe.

Upcoming Highlights/Activities

- Final data from the Phase 2 study of posoleucel for multi-virus prevention in high-risk allo-HCT patients will be presented at a medical conference before year-end.
- A compassionate use case report of posoleucel therapy for BKV nephropathy in a kidney transplant patient will be presented in a poster (Abstract SA-PO849) at Kidney Week 2022, the annual meeting of the American Society of Nephrology, on November 5. Following posoleucel therapy, the patient experienced a significant reduction in BK viral load.
- Final topline data from the Phase 2 study of posoleucel for the treatment of BK viremia in kidney transplant patients are expected to be reported in the first quarter of 2023. The study is the first to evaluate posoleucel in solid organ transplant patients, with the primary goal of understanding the safety of posoleucel therapy in this patient population with more sustained immunosuppression versus allo-HCT patients.

Third Quarter Financial Highlights

- Research and development expenses were $30.0 million for the quarter ended September 30, 2022, compared with $33.1 million for the quarter ended September 30, 2021. The decrease year-over-year is primarily attributable to a reduction in costs related to the outsourcing of manufacturing.
- General and administrative expenses were generally consistent year-over-year, with $12.9 million for the quarter ended September 30, 2022, compared with $12.4 million for the quarter ended September 30, 2021.
- Stock-based compensation expense was $10.9 million and $10.3 million for the quarter ended September 30, 2022, and 2021, respectively.
- As of September 30, 2022, AlloVir had cash, cash equivalents, and marketable securities of $264.1 million, compared with $248.1 million as of December 31, 2021. In July of 2022, AlloVir received aggregate net proceeds of $126.4 million from a registered direct offering.
- For the quarter ended September 30, 2022, net loss was $42.1 million or $0.50 per share, compared with a net loss of $45.5 million or $0.72 per share for the quarter ended September 30, 2021.

2022 Financial Guidance

- For fiscal year 2022, AlloVir continues to expect operating expenses to be in the range of $130 million to $145 million, excluding non-cash stock compensation expenses.

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 AlloVir's development and regulatory status of our 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.

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 264,107	$ 248,120
Other current assets	7,935	5,228
Total current assets	272,042	253,348
Other assets	21,656	33,246
Total assets	$ 293,698	$ 286,594
Liabilities and stockholders' equity		
Current liabilities	$ 20,719	$ 37,853
Long-term liabilities	19,753	23,475
Total liabilities	40,472	61,328
Total stockholders' equity	253,226	225,266
Total liabilities and stockholders' equity	$ 293,698	$ 286,594

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	30,004	33,062	90,450	79,132
General and administrative	12,946	12,442	40,318	34,890
Total operating expenses	42,950	45,504	130,768	114,022
Loss from operations	(42,950)	(45,504)	(130,768)	(114,022)

Total other income (loss), net:				
Interest income	668	253	978	1,233
Other income (loss), net	210	(259)	(634)	(1,232)
Loss before income taxes	(42,072)	(45,510)	(130,424)	(114,021)
Income tax expense	-	-	150	-
Net loss	$ (42,072)	$ (45,510)	$ (130,574)	$ (114,021)
Net loss per share --- basic and diluted	$ (0.50)	$ (0.72)	$ (1.83)	$ (1.82)
Weighted-average common shares outstanding---basic and diluted	84,948,837	62,962,434	71,213,219	62,588,898

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