AlloVir Reports Second Quarter 2022 Financial Results

August 4, 2022

Three Phase 3 Posoleucel Registrational Trials Continue to Expand Globally, Enrolling Patients in the U.S., Europe and Asia

Company Is On Track to Release Final Results of Posoleucel Phase 2 Multi-Virus Prevention Study at Year-End and Topline Results of Phase 2 BKV Treatment Study in Kidney Transplant Patients in 1Q '23

$126.6 Million Registered Direct Offering in July 2022 Will Support the Completion of Three Phase 3 Registrational Trials of Posoleucel and Global Regulatory Submissions

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 4, 2022-- AlloVir, Inc. (Nasdaq: ALVR), a multiple Phase 3 clinical trial stage allogeneic T cell immunotherapy company, today reported financial results for the second quarter ended June 30, 2022. The Company also shared progress across its pipeline of multi-virus specific T cell (VST) therapies, including continued positive, preliminary Phase 2 data on posoleucel and the securing of additional capital to enable the completion of the three ongoing Phase 3 registrational trials of posoleucel and global regulatory submissions for three distinct indications – the treatment of virus-associated hemorrhagic cystitis (vHC), the treatment of adenovirus (AdV) infection, and the prevention of clinically significant infections from AdV, BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpes virus-6 (HHV-6) and JC virus (JCV), all in allogeneic hematopoietic cell transplant (allo-HCT) recipients.

"In the first half of 2022, AlloVir made great progress advancing our pipeline of off-the-shelf, multi-virus specific T cell therapies, especially with our lead candidate, posoleucel. The preliminary Phase 2 multi-virus prevention data have strengthened awareness of the transformational potential of posoleucel as preemptive or prophylactic therapy for viral infections post allo-HCT and have facilitated engagement in our Phase 3 program with leading international transplant centers," said Diana Brainard, M.D., Chief Executive Officer, AlloVir. "In addition, we are excited to have the strong support of our investors who recently provided additional capital to enable the completion, data readouts and global regulatory submissions for all three ongoing Phase 3 registrational trials of posoleucel. We believe their investment demonstrates a strong affirmation of our science and ability to execute our plans to deliver this potentially transformative therapy to immunocompromised patients in need."

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 globally in the second quarter of this year, with patients enrolling 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. Multi-virus prevention has the potential to transform the management of transplant patients, who currently have limited to no approved treatment options for these devastating infections that threaten patient survival.

- In July 2022, the Company received confirmation from the European Medicines Agency that the orphan medicinal product designation granted to posoleucel as a potential treatment of viral diseases and infections from AdV, BKV, CMV, EBV and HHV-6 in patients undergoing HCT also applies to the potential prevention of these multiple viruses in this patient population.

  This adds to the Regenerative Medicine Advanced Therapy (RMAT) designation for multi-virus prevention that the U.S. Food and Drug Administration granted to posoleucel in April 2022, and prior RMAT designations for the treatment of AdV infection and for the treatment of hemorrhagic cystitis caused by BK viremia 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.

- New health economic and outcomes research (HEOR) data describing the clinical and economic burden of multiple viral infections post allo-HCT were published in *Transplantation and Cellular Therapy* in June 2022. The data demonstrate that patients with multiple viral infections post allo-HCT had a higher risk of all-cause mortality and were associated with greater health resource utilization and higher healthcare costs, supporting the value proposition of a multi-virus prevention therapy.

- Two compassionate use case reports of posoleucel therapy for refractory disseminated AdV infection post allo-HCT were presented at the 2022 Tandem Meetings |Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR) in April 2022. Following posoleucel therapy, both patients experienced reductions in viral load below measurable

levels.

- In June 2022, the Company completed enrollment in the ongoing Phase 2 study evaluating the safety and tolerability of posoleucel for the treatment of BK viremia in adult kidney transplant recipients. Blinded preliminary data from the study were presented in an oral plenary presentation at the American Transplant Congress (ATC) in June (Abstract 387) and provided an early indication of the safety and tolerability profile of posoleucel for this potential indication. Final topline results are expected to be reported in the first quarter of 2023.

- In May 2022, HEOR data describing the economic and clinical burden associated with respiratory viral infections in allo-HCT patients were published in *Transplant Infectious Disease*. The study found that allo-HCT patients with respiratory viral infections were associated with significantly worse clinical outcomes, greater health resource utilization and higher reimbursed costs versus patients without these infections. A Phase 1b/2 proof-of-concept clinical study of ALVR106 for the treatment of human metapneumovirus, influenza, parainfluenza and respiratory syncytial virus in auto- and allo-HCT patients is ongoing.

- Compassionate use case reports of ALVR109 administered to six immunocompromised patients with protracted COVID-19 infection, including two lung transplant recipients, also were presented at ATC in June 2022 (Abstract 9011). The data add to the growing body of evidence supporting the potential for AlloVir's VST therapies in solid organ transplant patients.

- At the International Liver Congress in June 2022, AlloVir presented preclinical data on ALVR107, an investigational hepatitis B-targeted VST aimed at curing chronic disease. The *in vitro* data demonstrate that ALVR107 is polyclonal, polyfunctional and can kill HBV antigen-expressing targets with negligible auto- or allo-reactivity, indicating a selectivity and tolerability profile that supports clinical use.

- In July 2022, The European Patent Office granted to the 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 are expected to be presented at a medical conference later this year.

- 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.

Second Quarter Financial Highlights

- Research and development expenses were $31.4 million for the quarter ended June 30, 2022, compared with $25.7 million for the quarter ended June 30, 2021. The increase is primarily attributable to costs related to the development of the company's lead product candidate, posoleucel.

- General and administrative expenses were $13.2 million for the quarter ended June 30, 2022, compared with $12.0 million for the quarter ended June 30, 2021.

- Stock-based compensation expense was $11.0 million and $9.7 million for the quarter ended June 30, 2022 and 2021, respectively.

- As of June 30, 2022, AlloVir had cash, cash equivalents and marketable securities of $172.7 million, compared with $248.1 million as of December 31, 2021. These funds combined with aggregate net proceeds of $126.5 million from the registered direct offering announced on July 26, 2022, are expected to be sufficient to fund the three ongoing Phase 3 registrational trials of posoleucel and global regulatory submissions.

- For the quarter ended June 30, 2022, net loss was $44.6 million or $0.69 per share, compared with a net loss of $37.6 million or $0.60 per share for the quarter ended June 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-based compensation expense.

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)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 172,673	$ 248,120
Other current assets	3,844	5,228
Total current assets	176,517	253,348
Other assets	23,478	33,246
Total assets	$ 199,995	$ 286,594
Liabilities and stockholders' equity		
Current liabilities	$ 21,588	$ 37,853
Long-term liabilities	20,270	23,475
Total liabilities	41,858	61,328
Total stockholders' equity	158,137	225,266
Total liabilities and stockholders' equity	$ 199,995	$ 286,594

ALLOVIR, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	31,379	25,677	60,446	46,070
General and administrative	13,245	11,978	27,371	22,448
Total operating expenses	44,624	37,655	87,817	68,518
Loss from operations	(44,624)	(37,655)	(87,817)	(68,518)
Total other income (loss), net:				
Interest income	162	475	310	980
Other (loss) income, net	(27)	(408)	(845)	(973)
Loss before income taxes	(44,489)	(37,588)	(88,352)	(68,511)
Income tax expense	150	-	150	-
Net loss	$ (44,639)	$ (37,588)	$ (88,502)	$ (68,511)
Net loss per share --- basic and diluted	$ (0.69)	$ (0.60)	$ (1.38)	$ (1.10)
Weighted-average common shares outstanding---basic and diluted	64,467,483	62,344,718	64,231,579	62,399,034

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Source: AlloVir, Inc.