AlloVir Reports Second Quarter 2021 Financial Results

August 6, 2021

- Posoleucel (Viralym-M, ALVR105) proof-of-concept studies in multi-virus prevention in stem cell transplant patients and BK viremia in kidney transplant patients continue to progress with initial data expected 4Q21

- Posoleucel Phase 3 pivotal trial in virus-associated hemorrhagic cystitis continues to progress enrollment

- ALVR106 proof-of-concept study in respiratory syncytial virus, influenza, human metapneumovirus, and parainfluenza expected to initiate in 2H21

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 6, 2021-- AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, today reported financial results for the second quarter ended June 30, 2021.

“We believe virus-specific T-cell therapies can have a meaningful impact in treating as well as preventing multiple devastating viral infections. This approach is groundbreaking in the field of stem cell transplantation – and has the potential to transform care for patients and health care providers,” said Dr. Diana Brainard, Chief Executive Officer of AlloVir. “We are pleased with the progress of our first-of-its-kind posoleucel (Viralym-M, ALVR105) multi-virus prevention clinical trial in allogeneic hematopoietic stem cell transplant recipients and look forward to sharing initial results from that study later this year. In addition, enrollment continues to progress in our posoleucel BK viremia in kidney transplant proof-of-concept study, as well as our registrational study in virus-associated hemorrhagic cystitis.”

Business Updates and Upcoming Milestones

Second Quarter Business and Scientific Milestones

- Dr. Diana Brainard officially commenced her role as Chief Executive Officer as of May 17 this year. Dr. Brainard is a physician-scientist specializing in infectious diseases, with more than 20 years of experience in the biopharmaceutical industry and academic medicine, most recently serving as Senior Vice President and Head of the Virology Therapeutic Area at Gilead Sciences.
- Real-world data demonstrating the economic and clinical burden associated with virus-associated hemorrhagic cystitis following allogeneic hematopoietic stem cell transplant (allo-HSCT) was published in the journal *Transplantation and Cellular Therapy*.

2021 Near-Term Priorities Across Programs

- Initial data from the Phase 2 open-label phase of the multi-virus prevention, proof-of-concept (POC) clinical trial to assess the safety and efficacy of posoleucel in pediatric and adult patients following allo-HSCT are expected in the fourth quarter of 2021. The clinical trial, targeting the prevention of clinically significant BK virus (BKV), cytomegalovirus (CMV), adenovirus (AdV), Epstein-Barr virus (EBV), human herpesvirus 6 (HHV-6), and JC virus (JCV) infections, is ongoing and continues to enroll patients. AlloVir embarked on this study since approximately 90% of all allo-HSCT patients experience at least one infection associated with BKV, CMV, AdV, EBV, or HHV-6, and over 60% of such patients experience infections caused by two or more of these five viruses within 100 days post allo-HSCT.
- The Phase 3 multicenter, double-blind, placebo-controlled clinical trial to assess the efficacy and safety of posoleucel for the treatment of virus-associated hemorrhagic cystitis (HC) in pediatric and adult patients following allo-HSCT, is ongoing and continues to enroll patients. Virus-associated HC, a well-described complication after HSCT, is a devastating inflammatory disease of the bladder with no approved or effective treatment options. Newly published data demonstrate that patients with virus-associated-HC had a 70% higher risk of mortality, and the viral disease was associated with significantly prolonged hospitalization including increased intensive care unit (ICU) stay and hospital readmission rates.
- The Phase 2 POC clinical trial with posoleucel for the preemptive treatment of BK viremia in adult kidney transplant recipients is ongoing, with initial data anticipated in the fourth quarter of 2021. BK viremia, which is detected in up to 20% of kidney transplant patients, can be a devastating complication leading to decreased kidney survival and return to end-stage renal disease and dialysis.
- A POC clinical trial of ALVR106, an allogeneic, off-the-shelf, multi-respiratory virus-specific T-cell therapy designed to target infections and diseases caused by respiratory syncytial virus (RSV), influenza, parainfluenza virus (PIV), and human metapneumovirus (hMPV), in allogeneic and autologous HSCT recipients is expected to be initiated in the second half of 2021 to coincide with the anticipated upcoming flu/respiratory virus season.
- The Phase 1 POC clinical trial for ALVR109, an allogeneic, off-the-shelf virus-specific T-cell therapy candidate designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19, is ongoing. However,

with the efficacy of available vaccines and therapies to prevent serious disease, the company does not currently see a role for ALVR109 to treat a broad patient population. There may be a future role for ALVR109 to treat immunocompromised patients who are not adequately served by available vaccines and therapies. The company is monitoring the evolution of the SARS-CoV-2 virus and the COVID-19 pandemic to guide the next steps for this program.
- The company is on track to complete preclinical and IND-enabling studies for ALVR107 to treat hepatitis B virus (HBV) in the second half of 2021. Chronic HBV infection is associated with significant morbidity and mortality. Current treatment options for chronic HBV consist of life-long antiviral therapy to suppress virus replication, which can slow the progression of liver cirrhosis and reduce the incidence of liver cancer, but there are no curative therapies available.

Second Quarter 2021 Financial Highlights

- Research and development expenses were $25.7 million for the quarter ended June 30, 2021, compared to $8.9 million for the quarter ended June 30, 2020. The increase year-over-year is attributable to costs related to the development of the company's product candidates, increased activity in outsourcing of manufacturing, and an increase in headcount and external consultants in support of research activities.
- The general and administrative expense was $12.0 million for the quarter ended June 30, 2021, compared to $3.3 million for the quarter ended June 30, 2020. The increase year-over-year was primarily attributable to increased headcount and professional fees for legal and accounting associated with operating as a public company.
- Stock-based compensation expense was $9.7 million and $0.5 million for the quarters ended June 30, 2021, and 2020, respectively.
- As of June 30, 2021, AlloVir had cash, cash equivalents, and marketable securities of $313.3 million, which compares to cash, cash equivalents, and marketable securities of $356.3 million as of December 31, 2020.
- For the quarter ended June 30, 2021, the net loss was $37.6 million or $0.60 per share compared to a net loss of $11.6 million or $4.43 per share for the quarter ended June 30, 2020.

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 targeting devastating viruses 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.

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. 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 313,337	$ 356,324

Other current assets	2,708	4,993
Total current assets	316,045	361,317
Other assets	11,466	9,504
Total assets	$ 327,511	$ 370,821
Liabilities and stockholders' equity		
Current liabilities	$ 20,708	$ 12,294
Long-term liabilities	4,334	5,463
Total liabilities	25,042	17,757
Total stockholders' equity	302,469	353,064
Total liabilities and stockholders' equity	$ 327,511	$ 370,821

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

	Three Months Ended June 30,	
	2021	**2020**
Operating expenses:		
Research and development	25,677	8,885
General and administrative	11,978	3,268
Total operating expenses	37,655	12,153
Loss from operations	(37,655)	(12,153)
Total other income (loss), net:		
Interest income	475	166
Other income (loss), net	(408)	355
Net loss	$ (37,588)	$ (11,632)
Net loss per share --- basic and diluted	$ (0.60)	$ (4.43)
Weighted-average common shares outstanding---basic and diluted	62,344,718	2,625,648

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