# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

# CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 5, 2020

# ALLOVIR, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-39409 (Commission File Number) 83-1971007 (I.R.S. Employer Identification No.)

AlloVir, Inc. 139 Main Street, Suite 500 Cambridge, Massachusetts 02142 (Address of principal executive offices, including zip code)

(617) 433-2605

(Registrant's telephone number, including area code)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

	Trade	Name of each exchange
Title of each class	Symbol(s)	on which registered
Common Stock, \$0.0001 par value per share	ALVR	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ⊠

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

#### Item 8.01 Other Events

On December 5, 2020, AlloVir, Inc. issued a press release titled "Preclinical Data Demonstrate Anti-Viral Activity of AlloVir's ALVR109, an Allogeneic, Off-the-Shelf SARS-CoV-2 Specific T Cell Therapy". A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.Description99.1Press release dated December 5, 2020

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# AlloVir, Inc.

By: /s/ David Hallal

David Hallal Chief Executive Officer

Date: December 7, 2020



# Preclinical Data Demonstrate Anti-Viral Activity of AlloVir's ALVR109, an Allogeneic, Off-the-Shelf SARS-CoV-2 Specific T Cell Therapy

- Data presented in an oral presentation at the 62nd American Society of Hematology Annual Meeting

- Proof-of-concept clinical trial underway for high-risk patients with COVID-19

**Cambridge, Mass.** – **December 5, 2020** – AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, today announced that preclinical data presented in an oral presentation at the 62nd American Society of Hematology (ASH) Annual Meeting, demonstrates selective antiviral activity of ALVR109 –the company's virus-specific T cell therapy designed to combat SARS-CoV-2, the virus responsible for COVID-19. The data presented found that the SARS-CoV-2 virus-specific T cell therapy, ALVR109, was able to produce effector molecules and selectively kill viral antigen-expressing targets, while leaving non-infected targets intact. These data suggest the potential for using these cells to treat COVID-19 in hospitalized high-risk patients in order to prevent the development of severe disease. These data were featured in the ASH Annual Meeting press program. A clinical trial evaluating ALVR109 has recently been initiated at the Center for Cell and Gene Therapy, Baylor College of Medicine (BCM), Texas Children's Hospital, and Houston Methodist Hospital. Researchers at BCM and AlloVir developed a bank of off-the-shelf, SARS-CoV-2 specific T cells that are ready to be administered to patients enrolled in the study.

"It's increasingly clear that T cell dysregulation is a critical factor in the development of severe COVID-19 and that the presence of healthy SARS-CoV-2-specific CD4+ and CD8+ T cells is important in helping patients fight off the virus," said Ann Leen, Ph.D., Chief Scientific Officer at AlloVir. "Given the unprecedented threat and impact of COVID-19 and the ongoing need for protective and therapeutic options, we rapidly immunologically profiled SARS-CoV-2 and developed ALVR109. The pre-clinical data presented at ASH shows that we can robustly generate T cells with the desired effector profile and AlloVir is sponsoring a proof-of-concept clinical trial being conducted in the Houston Methodist Hospital. The objectives of this trial are to assess the safety and efficacy of ALVR109 in preventing severe disease in hospitalized COVID-19 patients with high-risk features."

#### About these data:

To first identify immunogenic and protective SARS-CoV-2 antigens, researchers screened peripheral blood mononuclear cells (PBMCs) from convalescent individuals who had naturally controlled and cleared the virus using peptide libraries spanning structural, non-structural, and accessory SARS-CoV-2-derived proteins. Of the proteins screened, a subset was identified to advance to clinical virus-specific T cell manufacturing using AlloVir's proprietary and optimized manufacturing and cell culture process.

The data show ALVR109 is comprised almost exclusively of CD3+ T cells, with a mixture of cytotoxic (CD8+) and helper (CD4+) T cells. T cells fight viruses in two ways – helper CD4+ T cells spur B cells and other immune defenders into action and killer CD8+ T cells seek out and destroy the virus. In preclinical assessments ALVR109 was Th1-polarized, polyclonal, polyfunctional and selectively able to kill viral antigen-expressing targets indicative of both the selectivity of these cells and potential for safe clinical use.



Spyridoula Vasileiou, Ph.D., from the Center for Cell and Gene Therapy, Baylor College of Medicine, Texas Children's Hospital and presenting author said, "Our goal is to attack the virus at multiple points in its life cycle by targeting various virus-specific antigens to effectively and efficiently eliminate SARS-CoV-2 infected cells in patients with COVID-19. When we infuse these cells to patients, these virus-specific T cells have the capacity to expand and migrate to infected cells to selectively target the virus."

#### **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 patients with weakened immune systems. The company's innovative and proprietary technology platforms leverage off-the-shelf, allogeneic, 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 enables 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 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 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, and other risks identified in AlloVir's SEC filings. AlloVir cautions you not to place undue reliance on any forward-looking statements or kinements, 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 repres

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