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): November 30, 2021

Allakos Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38582**	**45-4798831**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

975 Island Drive, Suite 201 Redwood City, California	**94065**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 650 597-5002

(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:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001	ALLK	The 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. ☐

Item 8.01 Other Events.

On November 30, 2021, Allakos Inc. (the "Company") issued a press release announcing that a multicentered, randomized, double-blind, placebo-controlled Phase 2 clinical trial of subcutaneous (SC) lirentelimab in adult patients with moderate-to-severe atopic dermatitis has been initiated. The Company also announced its plans to initiate a multicentered, randomized, double-blind, placebo-controlled Phase 2/3 clinical trial of SC lirentelimab in patients with chronic spontaneous urticaria in the middle of 2022, as well as a multicentered, randomized, double-blind, placebo-controlled Phase 2 trial of SC lirentelimab in moderate-to-severe, uncontrolled asthma patients with or without an eosinophilic phenotype in Q4 2022, and clinical trials in additional indications are planned in 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press release dated November 30, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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 thereunto duly authorized.

Allakos Inc.

Date: November 30, 2021

By: /s/ H. Baird Radford, III
H. Baird Radford, III
Chief Financial Officer

Exhibit 99.1

Allakos Announces Expansion of Lirentelimab Development into Atopic Dermatitis, Chronic Spontaneous Urticaria and Asthma

– Phase 2 Atopic Dermatitis trial of subcutaneous lirentelimab initiated –
– Phase 2/3 Chronic Spontaneous Urticaria trial of subcutaneous lirentelimab to begin in mid 2022 –
– Phase 2 Asthma trial of subcutaneous lirentelimab to begin in Q4 2022 –
– Additional indications planned in 2023 –

REDWOOD CITY, Calif., November 30, 2021 (GLOBE NEWSWIRE) -- Allakos Inc. (the "Company" or "Allakos") (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) for the treatment of eosinophil and mast cell-related diseases, today announced it has initiated a randomized, double-blind, placebo-controlled Phase 2 clinical trial of subcutaneous (SC) lirentelimab in adult patients with moderate-to-severe atopic dermatitis. The company also announced plans to initiate two randomized, double-blind, placebo-controlled trials of SC lirentelimab in patients with chronic spontaneous urticaria (middle of 2022) and in moderate-to-severe, uncontrolled asthma patients with and without an eosinophilic phenotype (Q4 2022). Atopic dermatitis, chronic spontaneous urticaria and asthma are complex, chronic inflammatory diseases believed to be driven by activated eosinophils and mast cells.

"Lirentelimab's novel mechanism of action targeting Siglec-8 has the potential to help patients with eosinophil and mast cell driven diseases," said Craig Paterson, M.D., chief medical officer of Allakos. "Advancing these programs is an important next step in pursuing the broader potential of lirentelimab beyond eosinophilic gastrointestinal indications and could highlight the ability of lirentelimab to treat a variety of diseases."

Subcutaneous Lirentelimab in Atopic Dermatitis

Atopic dermatitis is a chronic pruritic inflammatory condition that is characterized by dry, red, itchy patches of skin. Atopic dermatitis affects approximately 16.5 million (7.3%) adults in the United States (US), of which approximately 6.6 million (40%) have moderate-to-severe disease[1]. The Phase 2 study in atopic dermatitis is a 16-week, multicentered, randomized, double-blind, placebo-controlled trial that will enroll approximately 240 adult patients with moderate-to-severe disease who are inadequately controlled by topical treatments. Patients will be randomized 1:1:1 to receive four monthly subcutaneous doses of either: (a) lirentelimab 450 mg, (b) lirentelimab 150 mg, or (c) placebo. The primary endpoint will be the proportion of patients who achieve an Investigator Global Assessment (IGA) score of 0 or 1 with $\geq$2-point improvement at week 16.

Subcutaneous Lirentelimab in Chronic Spontaneous Urticaria

Chronic spontaneous urticaria is an often-debilitating skin condition characterized by frequent and unpredictable eruption of hives, severe itching and swelling. The disease affects up to 3.5 million patients in the U.S., of which half are refractory to standard-of-care antihistamines[2]. The planned Phase 2/3 study in chronic spontaneous urticaria will be a multicentered, randomized, double-blind, placebo-controlled study in patients who are naïve to omalizumab and refractory to antihistamines. The primary end point of the trial will be the reduction of itch-severity score (ISS7).

Subcutaneous Lirentelimab in Asthma

Asthma is a chronic inflammatory disease of the lungs that leads to narrowing and swelling of the airways, making it difficult to breath. Moderate-to-severe, uncontrolled asthma affects approximately 1 million adults in the U.S.[3,4], of which 50% have an eosinophilic phenotype and 50% patients have a non-eosinophilic phenotype[5]. The planned Phase 2 study in moderate-to-severe, uncontrolled asthma patients with and without an eosinophilic phenotype will be a multicentered, randomized, double-blind, placebo-controlled study. The primary end point of the trial will be the reduction of annualized asthma exacerbation rate.

About Allakos

Allakos is a clinical stage biotechnology company developing antibodies that target immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory, and proliferative diseases. The Company's lead antibody, lirentelimab (AK002), is an investigational medicine and is being evaluated in a Phase 3 study in eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD), a phase 2/3 study in eosinophilic esophagitis and a Phase 2 study in atopic dermatitis. The company plans to initiate a Phase 2/3 study in chronic spontaneous urticaria and a Phase 2 study in asthma in the middle of 2022 and Q4 2022, respectively. Lirentelimab targets Siglec-8, an inhibitory receptor selectively expressed on human eosinophils and mast cells. Inappropriately activated eosinophils and mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. For more information, please visit the Company's website at www.allakos.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include, but are not limited to, Allakos' progress and business plans, the expected timing of anticipated study results and plans relating to its future clinical trials. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs, including but not limited to: Allakos' stages of clinical drug development; Allakos' ability to timely complete clinical trials for, and if approved, commercialize lirentelimab (AK002), its lead compound; Allakos' ability to obtain required regulatory approvals for its product candidates; uncertainties related to the enrollment of patients in its clinical trials; Allakos' ability to demonstrate sufficient safety and efficacy of its product candidates in its clinical trials; uncertainties related to the success of later-stage clinical trials, regardless of the outcomes of preclinical testing and early-stage trials; market acceptance of Allakos' product candidates; uncertainties related to the projections of the size of patient populations suffering from the diseases Allakos is targeting; Allakos' ability to advance additional product candidates beyond lirentelimab; Allakos' ability to obtain additional capital to finance its operations; and other important risk factors set forth in Allakos' most recent Annual Report on Form 10-K filed with the SEC on March 1, 2021, Quarterly Report on Form 10-Q filed with the SEC on November 8, 2021, and future reports to be filed with the SEC. These documents contain and identify important factors that could cause the actual results for Allakos to differ materially from those contained in Allakos' forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and Allakos specifically disclaims any obligation to update any forward-looking statement, except as required by law. These forward-looking

statements should not be relied upon as representing Allakos' views as of any date subsequent to the date of this press release.

Source: Allakos Inc.

[1] Asthma and Allergy Foundation of America

[2] Maurer et al. Allergy. 2011 Mar;66(3):317-30

[3] Walford H., J Asthma Allergy. 2014; 7: 53–65

[4] CDC Morbidity and Mortality Weekly Report (MMWR) May 6, 2011 / 60(17); 547552

[5] J Allergy Clinical Immunology Volume 124, Number 3 September 2009

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