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 21, 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** **(Address of Principal Executive Offices)**	**94065** **(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.

Release of Study Results

On December 21, 2021, Allakos Inc. (the "Company") issued a press release announcing its topline Phase 3 data from the ENIGMA 2 study of lirentelimab in patients with eosinophilic gastritis and/or eosinophilic duodenitis and Phase 2/3 data from the KRYPTOS study of lirentelimab in patients with eosinophilic esophagitis met histologic co-primary endpoints, but did not achieve statistical significance on the patient reported symptomatic co-primary endpoints. 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 December 21, 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: December 21, 2021

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

Exhibit 99.1

Allakos Announces Topline Phase 3 Data from the ENIGMA 2 Study and Phase 2/3 Data from the KRYPTOS Study in Patients with Eosinophilic Gastrointestinal Diseases

– Lirentelimab met histologic co-primary endpoints but missed symptomatic co-primary endpoints in both ENIGMA and KRYPTOS studies –

REDWOOD CITY, Calif., Dec. 21, 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 reported data from ENIGMA 2, a 24-week Phase 3 randomized, double-blind, placebo-controlled study of lirentelimab in patients with biopsy confirmed eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD) and KRYPTOS, a 24-week Phase 2/3 randomized, double-blind, placebo-controlled study of lirentelimab in patients with biopsy-confirmed eosinophilic esophagitis (EoE). Both ENIGMA 2 and KRYPTOS studies met their histologic co-primary endpoints, but did not achieve statistical significance on the patient reported symptomatic co-primary endpoints.

"We are deeply disappointed that the studies did not achieve their symptomatic endpoints," said Robert Alexander, PhD, Chief Executive Officer of Allakos. "The company is grateful to the patients with eosinophilic gastrointestinal diseases (EGIDs) and to the investigators who participated in the ENIGMA and KRYPTOS trials."

Dr. Craig Paterson, MD, Chief Medical Officer of Allakos added, "Although the EGID results are surprising and disappointing, we will continue to analyze the data to understand the results and to determine the path forward for lirentelimab in EGIDs. At present we intend to continue our development efforts with subcutaneous lirentelimab in atopic dermatitis, chronic spontaneous urticaria, and asthma. The atopic dermatitis study is underway and we plan to initiate chronic spontaneous urticaria and asthma studies in 2022 and will continue to advance other programs in our preclinical pipeline."

ENIGMA 2 Phase 3 Topline Results

The co-primary endpoints for the Phase 3 study were (1) the proportion of patients achieving histologic resolution (defined as ≤4 eosinophils (eos) / high powered field (hpf) in 5 hpfs in the stomach and/or ≤15 eos/hpf in 3 hpfs in the duodenum) and (2) symptomatic improvement as measured by absolute change in the six symptom total symptom score (TSS).

Co-Primary Endpoints	Lirentelimab (n=91)	Placebo (n=89)
Histology Endpoint: Proportion of responders as determined by gastric or duodenal tissue eosinophil counts[1]	84.6% (p<0.0001)	4.5%
Symptom Endpoint: Absolute mean change in patient reported Total Symptom Score (TSS-6)[2]	Baseline TSS: 29.5	Baseline TSS: 27.7
	-10.0 (p=0.343)	-11.5

1 = A responder is a patient achieving the following peak eosinophil counts: eosinophil count ≤4 cells per hpf in 5 gastric hpf and/or eosinophil count ≤15 cells per hpf in 3 duodenal hpf. Endpoint assessed at end of Week 24.

2 = TSS-6 is daily patient reported symptom questionnaire assessing 6 symptoms (abdominal pain, nausea, bloating, early satiety, abdominal cramping, and loss of appetite) on a scale from 0 to 10. Endpoint assessed as mean change from baseline to Weeks 23-24.

The safety results of the trial were generally consistent with previously reported lirentelimab studies. No new safety signals were observed. Mild to moderate infusion-related reactions (including flushing, feeling of warmth, headache, nausea, and/or dizziness) occurred in 34% of lirentelimab-treated patients and 14% of placebo-treated patients.

KRYPTOS Phase 2/3 Topline Results

The co-primary endpoints for the Phase 2/3 study were (1) the proportion of patients achieving histologic resolution (defined as ≤6 eosinophils (eos) / high powered field (hpf) in the esophagus) and (2) symptomatic improvement as measured by absolute change in dysphagia symptom questionnaire (DSQ).

Co-Primary Endpoints	Lirentelimab High Dose (n=91)	Lirentelimab Low Dose (n=93)	Placebo (n=92)
Histologic Endpoint: Proportion of responders (eos ≤6 /hpf) as determined by esophageal tissue eosinophil counts [1]	87.9% (p<0.0001)	92.5% (p<0.0001)	10.9%
Symptom Primary Endpoint: Absolute mean change in patient reported Dysphagia Symptom Questionnaire (DSQ)[2]	DSQ Baseline: 34.2	DSQ Baseline: 36.4	DSQ Baseline: 35.2
	-17.4 (p=0.237)	-11.9 (p=0.247)	-14.6

1 = A responder is a patient achieving the following peak eosinophil counts: ≤6 eosinophils (eos) / high powered field (hpf) in 1 hpf in the esophagus. Endpoint assessed at end of Week 24.
2 = DSQ is a patient reported symptom questionnaire assessing difficulty swallowing. Endpoint assessed as absolute mean change from baseline to Weeks 23-24.

The safety results of the trial were generally consistent with previously reported lirentelimab studies. No new safety signals were observed. Mild to moderate infusion-related reactions (including flushing, feeling of warmth, headache, nausea, and/or dizziness) occurred in 39% of high dose lirentelimab- treated patients, 26% of low dose lirentelimab-treated patients and 12% of placebo-treated patients.

Phase 3 ENIGMA 2 Study Design

The randomized, double-blind, placebo-controlled Phase 3 trial of intravenous lirentelimab enrolled 180 patients with EG and/or EoD. Patients were required to be moderately to severely symptomatic based on a patient reported symptom questionnaire and have biopsy-confirmed eosinophilia of the stomach (≥30 eosinophils/hpf in 5 hpfs) and/or duodenum (≥30 eosinophils/hpf in 3 hpfs). Patients were randomized 1:1 to receive: 1.0 mg/kg of lirentelimab for the first month followed by five doses of 3.0 mg/kg given monthly or (b) a monthly placebo. Disease symptoms were measured daily using a patient reported symptom questionnaire that scored 6 symptoms (abdominal pain, nausea, bloating, early satiety, abdominal cramping, loss of appetite) each on a scale from 0 to 10 (TSS). Co-primary endpoints were (1) proportion of responders with ≤4 eos/hpf in 5 hpfs in the stomach and/or ≤15 eos/hpf in 3 hpfs in the duodenum at the end of week 24 and (2) absolute change from baseline in TSS at weeks 23-24.

Phase 2/3 KRYPTOS Study Design

The randomized, double-blind, placebo-controlled Phase 2/3 trial of intravenous lirentelimab enrolled 276 patients with EoE. Patients were required to be moderately to severely symptomatic based on the dysphagia symptom questionnaire (DSQ) and have biopsy-confirmed eosinophilia of the esophagus (≥15 eosinophils in 1 hpf). Patients were randomized 1:1:1 to receive: 1.0 mg/kg of lirentelimab for the first month followed by five doses of 3.0 mg/kg given monthly (b) monthly 1.0 mg/kg of lirentelimab (c) a monthly placebo. Disease symptoms were measured daily using a patient reported symptom questionnaire that assessed difficulty swallowing. Co-primary endpoints were (1) proportion of responders with ≤6 eosinophils in 1 hpf in the esophagus and (2) absolute change in dysphagia symptom questionnaire from baseline.

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 that is being evaluated in clinical studies, including in EGIDs 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.

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