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)
October 29, 2019

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, including zip code)

(650) 597-5002
(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 (see General Instruction A.2. below):

☐ 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))

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. ☒

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

Item 7.01 Regulation FD Disclosure

On October 29, 2019, Dr. Evan Dellon made a presentation at the American College of Gastroenterology 2019 Annual Scientific Meeting titled "Efficacy and Safety of AK002 in Adult Patients with Active Eosinophilic Gastritis and/or Eosinophilic Gastroenteritis: Primary Results from a Randomized, Double-Blind Placebo- Controlled Phase 2 Trial (ENIGMA Study)" (the "Presentation"). A copy of the Presentation made is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information contained in this Current Report on Form 8-K, including the attached Exhibit 99.1, is intended to be furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Forward-Looking Statements

This Form 8-K, including the Presentation, contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, the ability of AK002 to continue to demonstrate rapid and sustained benefit in patients with eosinophil gastrointestinal diseases, the timing of the Company's long-term extension study and the efficacy and safety results from such study, the timing and outcome of its end of the phase 2 meeting and Allakos' ability to conduct a phase 3 study in EG and/or EGE and a phase 2/3 study in EoE. 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' early stages of clinical drug development; Allakos' ability to timely complete clinical trials for, and if approved, commercialize 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 AK002; 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 14, 2019, Quarterly Report on Form 10-Q filed with the SEC on August 5, 2019 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 Form 8-K, including the Presentation[s], speak only as of the date hereof, and Allakos specifically disclaims any obligation to update any forward-looking statement, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	American College Gastroenterology 2019 Annual Scientific Meeting Presentation dated October 29, 2019.

SIGNATURES

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

Allakos Inc.

Date: October 29, 2019

By: /s/ Robert Alexander

Robert Alexander
Chief Executive Officer

Exhibit 99.1

AK002 (Antolimab) in Adult Patients with Active Eosinophilic Gastritis and/or Eosinophilic Gastroenteritis: Primary Results from a Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial (ENIGMA Study; NCT03496571)

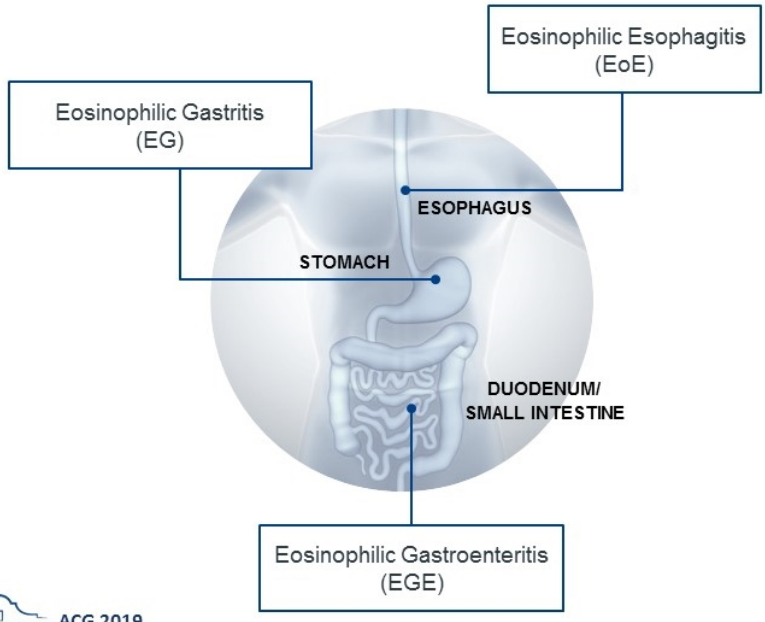
Evan S. Dellon[1], Kathryn A. Peterson[2], Joseph A. Murray[3], Gary W. Falk[4], Nirmala Gonsalves[5], Mirna Chehade[6], John Leung[7], Robert M. Genta[8], Marc E. Rothenberg[9], Paneez Khoury[10], Adam C. Bledsoe[3], Camilla Shaw[11], Henrik S. Rasmussen[11], Bhupinder Singh[11], Alan T. Chang[11], Amol P. Kamboj[11], Ikuo Hirano[5]

[1]University of North Carolina, Chapel Hill, NC; [2]University of Utah, Salt Lake City, UT; [3]Mayo Clinic Rochester, Rochester, MN; [4]University of Pennsylvania, Philadelphia, PA; [5]Northwestern University, Chicago, IL; [6]Icahn School of Medicine at Mount Sinai, New York, NY; [7]Tufts University, Boston, MA; [8]Baylor College of Medicine, Houston, TX; [9]Cincinnati Children's Hospital, Cincinnati, OH; [10]NIAID/NIH, Bethesda, MD; [11]Allakos, Inc., Redwood City, CA.

ACG 2019
October 25-30
San Antonio, TX

ACG 2019
San Antonio, TX October 25th-30th 2019

Eosinophilic Gastrointestinal Diseases (EGIDs)

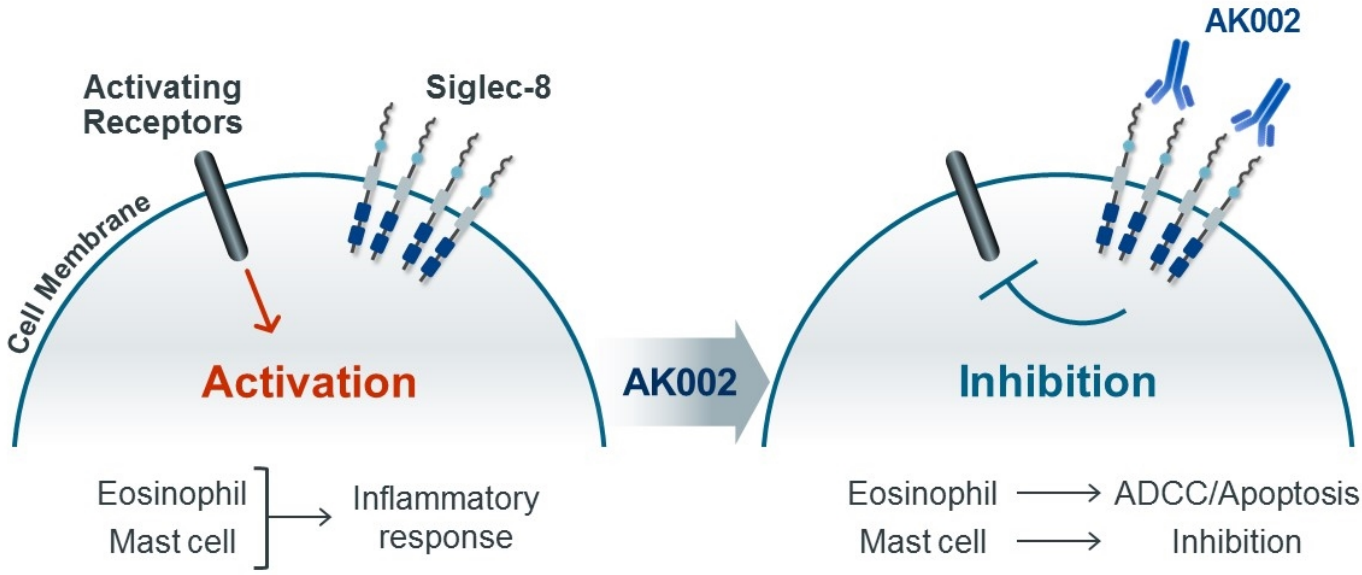


EG, EGE, EoE

Chronic Eosinophilic Inflammation of the Stomach, Small Intestine, or Esophagus

- Symptoms: abdominal pain, nausea, early satiety, loss of appetite, bloating, abdominal cramping, vomiting, diarrhea, and dysphagia
- Eosinophils and mast cells are important drivers of disease
- Current standard of care: steroids; diet
- No FDA-approved treatment for EG, EGE, or EoE

AK002 Targets Siglec-8 on Eosinophils and Mast Cells



ENIGMA Phase 2 Study Aim and Inclusion

Study Aim

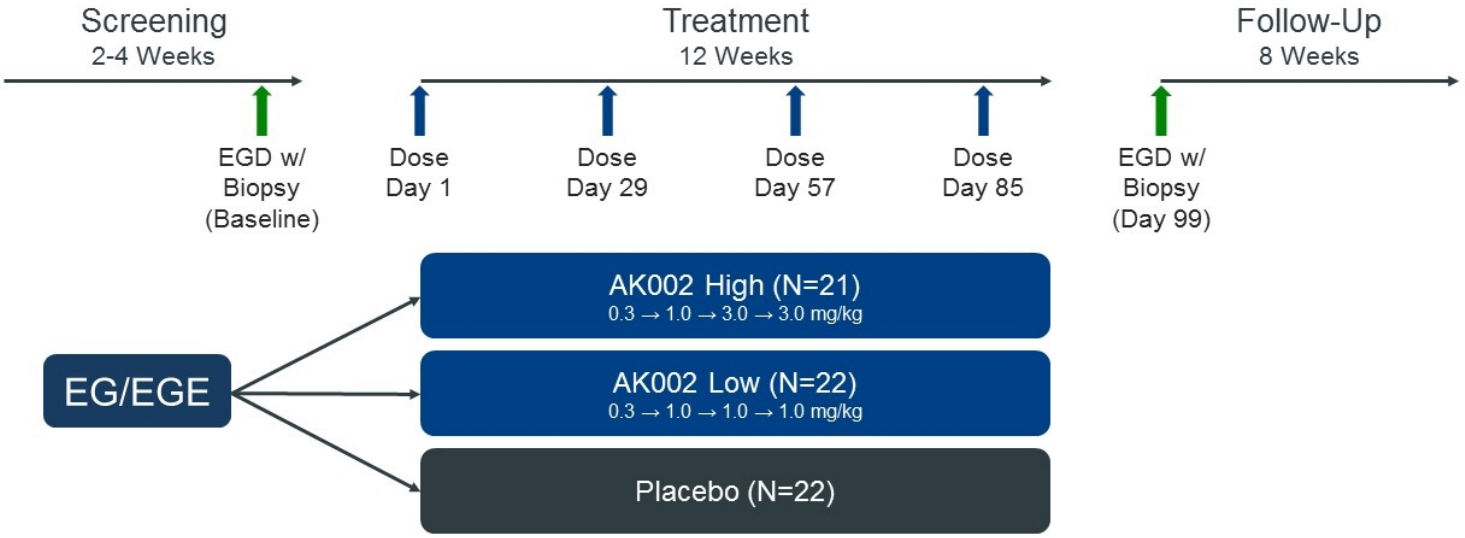
- Determine safety and efficacy of AK002 for treatment of EG and/or EGE

Key Inclusion Criteria

- Active moderate to severe symptoms[1] using the daily 8 symptom EG/EGE-SQ© Questionnaire
- Biopsy confirmed EG/EGE
  - Stomach: ≥30 eos/hpf in 5 hpfs
  - Duodenum: ≥30 eos/hpf in 3 hpfs

1 PRO entry criteria: average weekly score over ≥2 weeks of ≥3 for either abdominal pain, diarrhea and/or nausea

ENIGMA Phase 2 Study Design



Endpoints

Primary Endpoint

- Mean percent change in gastrointestinal eosinophil counts from baseline

Symptoms Secondary Endpoint

- Mean percent change in Total Symptom Score (TSS) from baseline

Responder Secondary Endpoint

- Proportion of patients who have:
  - >75% decrease in tissue eosinophils AND >30% benefit in TSS

Primary analysis with a pre-specified hierarchical per protocol approach

- Sensitivity analyses: ITT; subgroup with no steroid use

Baseline Characteristics

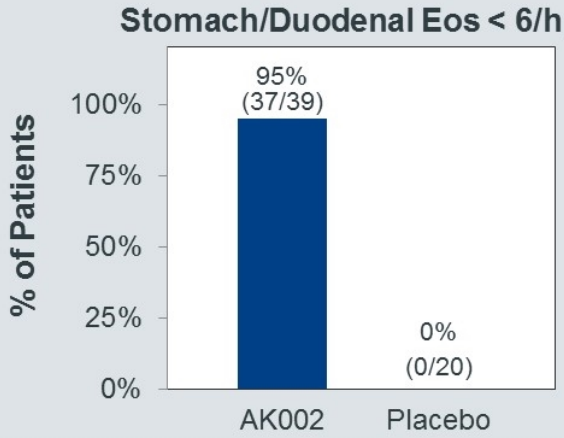
		AK002 Dose Groups				
		High 0.3-3.0 mg/kg (n=20)	**Low** 0.3-1.0 mg/kg (n=19)	**Combined** High/Low (n=39)	**Placebo** (n=20)	**Total** (N=59)
Age, Mean (Range)		42 (20-67)	43 (18-74)	42 (18-74)	40 (18-67)	41 (18-74)
Female		60%	84%	72%	50%	64%
White		85%	95%	90%	100%	93%
Mean Gastrointestinal[1] Eosinophils/hpf		76	80	78	75	77
Mean Gastrointestinal[1] Mast Cells/hpf		59	70	64	56	62
Mean Total Symptom Score (TSS) [0-80]		34.1	34.7	34.4	30.1	32.9
% of Patients (n) by AEC[2]/µL	<250	45% (9)	26% (5)	36% (14)	45% (9)	39% (23)
	250 to <500	35% (7)	42% (8)	38% (15)	15% (3)	31% (18)
	500 to <1500	20% (4)	21% (4)	21% (8)	35% (7)	25% (15)
	≥1500	0%	11% (2)	5% (2)	5% (1)	5% (3)

1 Gastric or duodenum site with highest eosinophil or mast cell counts
2 AEC: Absolute Eosinophil Count

Primary Endpoint – Mean % Change in Eosinophil Count

Treatment Arm	Baseline Eosinophil Counts / hpf	Mean %Δ in Eosinophil Counts	*p* - value
High Dose AK002 (n=20)	76	-97%	**<0.0001**
Low Dose AK002 (n=19)	80	-92%	**<0.0001**
Combined AK002 (n=39)	78	-95%	**<0.0001**
Placebo (n=20)	75	+10%	-

Tissue Eosinophil Depletion

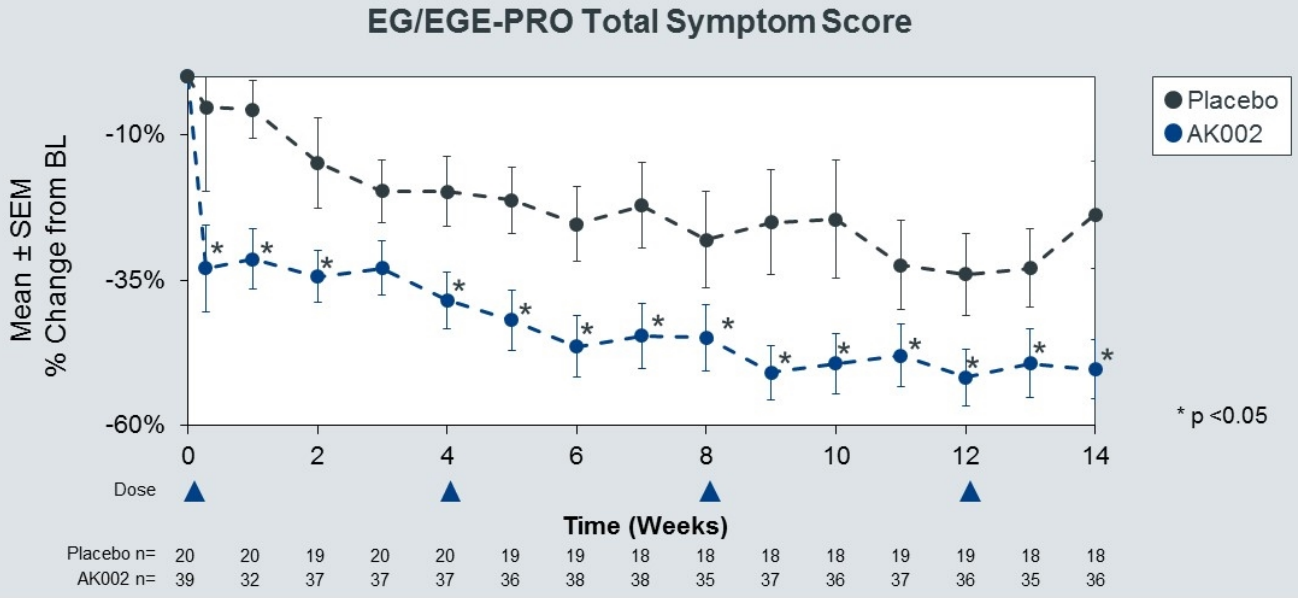


37 of 39 patients had < 6 eos/hpf; 31/39 had 0 eos/hpf

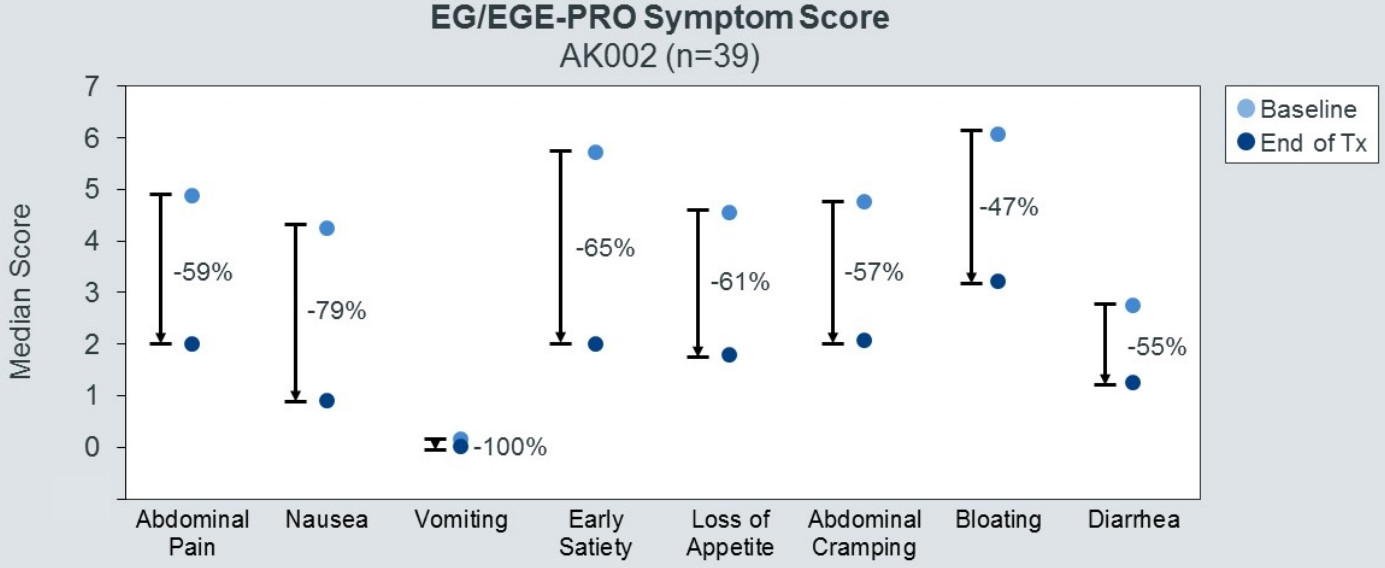
Patient Reported Symptoms Secondary Endpoint

Treatment Arm	Baseline TSS	Mean % Change in TSS	*p* - value
High Dose AK002 (n=20)	34	-58%	**0.0012**
Low Dose AK002 (n=19)	35	-49%	**0.0150**
Combined AK002 (n=39)	34	-53%	**0.0012**
Placebo (n=20)	30	-24%	-

Rapid & Sustained Improvement in Symptoms



Improvement Across All Symptoms



Improvements in TSS Were Not Driven by Any Single Symptom

Mean Reduction in TSS	Combined AK002 (N=39)	Placebo (N=20)	*p* - value
Total Score	**-53.5%**	**-24.3%**	**0.0012**
Minus Abdominal Pain	-53.1%	-22.5%	0.0010
Minus Nausea	-53.2%	-23.9%	0.0009
Minus Vomiting	-53.0%	-24.9%	0.0018
Minus Satiety	-51.8%	-25.4%	0.0019
Minus Loss of Appetite	-53.0%	-24.9%	0.0009
Minus Abdominal Cramping	-53.0%	-22.4%	0.0011
Minus Bloating	-55.9%	-26.9%	0.0029
Minus Diarrhea	-54.9%	-24.0%	0.0010

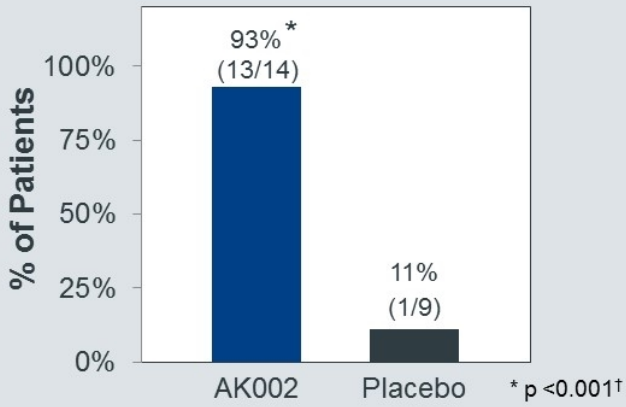
AK002 Met Treatment Responder Secondary Endpoint

Treatment Arm	Treatment Responders	*p* - value
High Dose AK002 (n=20)	70%	**0.0009**
Low Dose AK002 (n=19)	68%	**0.0019**
Combined AK002 (n=39)	69%	**0.0008**
Placebo (n=20)	5%	-

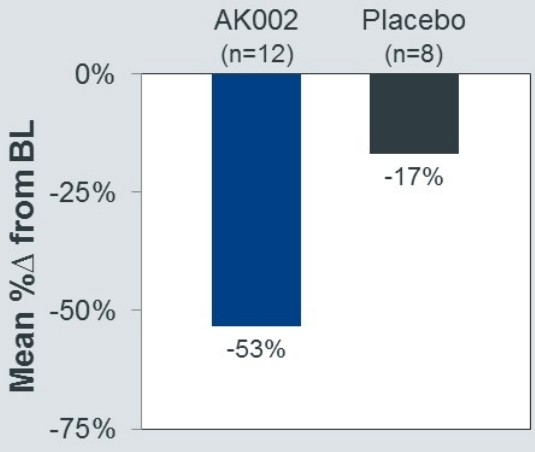
Treatment responder defined as: >75% reduction in tissue eosinophil counts AND >30% reduction in symptoms (TSS)

Response in Concomitant EoE[1]

Esophageal Eos ≤ 6/hpf[2]



Severity of Dysphagia[3]



1 25 patients with concomitant EoE (≥15 eos/hpf or history of EoE) and baseline dysphagia
2 Excludes patients with eos < 6/hpf at baseline. At end of treatment, 10/14 AK002 patients had 0 eos/hpf; 2/14 AK002 patients had 1 eos/hpf; 1/14 AK002 patients had 3 eos/hpf; 1/14 AK002 patients had 105 eos/hpf (biopsy occurred 6 weeks post last dose instead of 2 weeks per protocol); 1/9 placebo patients had 2 eos/hpf; 8/9 placebo patients had 19 – 200 eos/hpf
3 All EoE patients with end of treatment dysphagia scores
† p = 0.00015

Safety Summary

Treatment-Emergent AEs in ≥5% of Patients

% of Patients, (n)	AK002 (n=43)	Placebo (n=22)
Infusion related reaction	60% (26)	23% (5)
Headache	9% (4)	9% (2)
Upper respiratory tract infection	9% (4)	9% (2)
Urinary tract infection	9% (4)	5% (1)
Nausea	7% (3)	14% (3)
Fatigue	7% (3)	9% (2)
Diarrhea	5% (2)	9% (2)
Nasopharyngitis	5% (2)	9% (2)
Abdominal pain	2% (1)	9% (2)
Dehydration	2% (1)	9% (2)
Gastroenteritis viral	2% (1)	9% (2)
Pyrexia	2% (1)	9% (2)
Sinusitis	2% (1)	9% (2)
Cough	0% (0)	9% (2)
Influenza	0% (0)	9% (2)
White blood cell count increased	0% (0)	9% (2)

- Generally well tolerated
- Most common AE was mild to moderate infusion related reactions (IRR)
  - 93% mild to moderate (flushing, feeling of warmth, headache, nausea, dizziness)
  - Mostly on first infusion, greatly reduced or does not occur on subsequent infusions
  - 1 drug-related serious adverse event, an IRR which recovered within 24 hours with no further sequelae
- Treatment-emergent SAEs: 9% on AK002, 14% on Placebo
- No other significant AEs

ENIGMA Summary

- This was the first randomized study in EG/EGE
- Study met all primary and secondary endpoints, demonstrating significant histologic and symptom improvements in EG/EGE
- Strong histologic and symptom improvements in EoE
- Generally well-tolerated
- These results build on clinical activity of AK002 observed in other atopic and mast cell disorders (chronic urticaria, severe allergic conjunctivitis, asthma, atopic dermatitis, and indolent systemic mastocytosis)
- Further development of AK002 for EG/EGE is appropriate

We thank the patients who participated in this study, investigators, and study staff