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)
August 5, 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 8.01 Other Events.

On August 5, 2019, Allakos Inc. (the "Company") hosted a conference call and webcast to present detailed results from its Phase 2 trial in Patients with Eosinophilic Gastritis and/or Eosinophilic Gastroenteritis. A copy of the presentation is filed 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 Number	Description
99.1	Phase 2 EG Results Presentation dated August 5, 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: August 5, 2019

By: /s/ Robert Alexander

Robert Alexander
Chief Executive Officer

Exhibit 99.1

Allakos

Developing Therapeutic Antibodies Targeting Allergic, Inflammatory and Proliferative Diseases

Phase 2 Eosinophil Gastritis and Gastroenteritis Study Results

Aug 5, 2019

Disclaimer

This presentation contains forward-looking statements. All statements other than statements of historical fact contained in this presentation, including statements regarding the financial position of Allakos Inc. ("Allakos," the "Company," "we" or "our"); the generation of future value; business strategy; plans and objectives for future operations; our expectations regarding the potential benefits, activity, effectiveness and safety of our product candidates; our expectations with regard to the initiation, design, timing and results of our clinical studies, preclinical studies and research and development programs, including the timing and availability of data from such studies; our preclinical, clinical and regulatory development plans for our product candidates, including the timing or likelihood of regulatory filings and approvals for our product candidates; the size of the market opportunity for our product candidates in the diseases we are targeting; and our expectations with regard to our ability to acquire, discover and develop additional product candidates and advance such product candidates into, and successfully complete, clinical studies, are forward-looking statements. Allakos has based these forward-looking statements on its estimates and assumptions and its current expectations and projections about future events. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. The forward-looking statements included in this presentation speak only as of the date of this presentation and are subject to a number of risks, uncertainties, and assumptions, including, but not limited to: the Company's early stages of clinical drug development; the Company's ability to timely complete clinical trials for, and if approved, commercialize AK002, its lead compound; the Company's ability to obtain required regulatory approvals for its product candidates; uncertainties related to the enrollment of patients in its clinical trials; the Company's 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 the Company's product candidates; uncertainties related to the projections of the size of patient populations suffering from some of the diseases the Company is targeting; the Company's ability to advance additional product candidates beyond AK002; the Company's ability to obtain additional capital to finance its operations; and other risks described in the "Risk Factors" section included in our periodic filings that we have made and will make with the Securities and Exchange Commission ("SEC"). In addition, Allakos operates in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for Allakos's management to predict all risks, nor can Allakos assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements that Allakos may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this presentation are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Allakos does not undertake any obligation to update or revise any forward-looking statements, to conform these statements to actual results or to make changes in Allakos' expectations, except as required by law.

Accuracy of Data: This presentation contains statistical data based on independent industry publications or other publicly available information, as well as other information based on Allakos's internal sources. We have not independently verified the accuracy or completeness of the data contained in these industry publications and other publicly available information. Accordingly, Allakos makes no representations as to the accuracy or completeness of that data.

Additional Information:The Company has filed and will file Current Reports on Form 8-K, Quarterly Reports on Form 10-Q, and Annual Reports on Form 10-K, and other documents with the SEC. You should read these documents for more complete information about the Company. You may get these documents for free by visiting EDGAR on the SEC website at www.sec.gov.

This presentation concerns products that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. It is currently limited by federal law to investigational use, and no representation is made as to its safety or effectiveness for the purposes for which it is being investigated.

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Agenda

Robert Alexander, PhD ▪ Overview	**5:00 – 5:15 AM**
Henrik Rasmussen, MD PhD ▪ Results of the ENIGMA Phase 2 Study	**5:15 – 5:45 AM**
Evan Dellon, MD MPH ▪ Physician Perspective	**5:45 – 5:55 AM**
Q&A	**5:55 AM**

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Overview

Robert Alexander, PhD
CEO – Allakos

Executive Summary

- AK002 met all prespecified primary and secondary endpoints in EG/EGE
- Randomized, double-blind, placebo-controlled study results showed:
  - 95% reduction in tissue eosinophils vs. placebo +10% ($p < 0.0001$)
  - 69% treatment response rate vs. placebo 5% ($p = 0.0008$)
  - 53% decrease in symptom score vs. placebo 24% ($p = 0.0012$)
- Strong proof of concept in EoE
  - 13/14 (93%) of patients had eosinophils < 5 /hpf
  - 53% decrease in dysphagia vs. placebo 17%

Today's data builds on robust results in multiple other diseases

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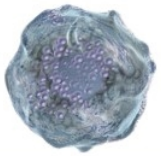
Mast Cells and Eosinophils: Effector Cells Central to Initiating and Maintaining Inflammatory Responses



MAST CELLS

EOSINOPHILS

- Found at the Internal/External Interface of the Body
  - In particular, in tissues and surrounding blood vessels and peripheral nerves
- Produce a Broad Range of Inflammatory Mediators
  - Vasoactive amines, lipid mediators, proteases, cytokines and chemokines
- Participate in Acute and Chronic Inflammation
  - Including both innate and adaptive immune responses
- Key Drivers in Many Serious Diseases
  - Including gastrointestinal, ophthalmic, dermatologic, respiratory, and proliferative diseases

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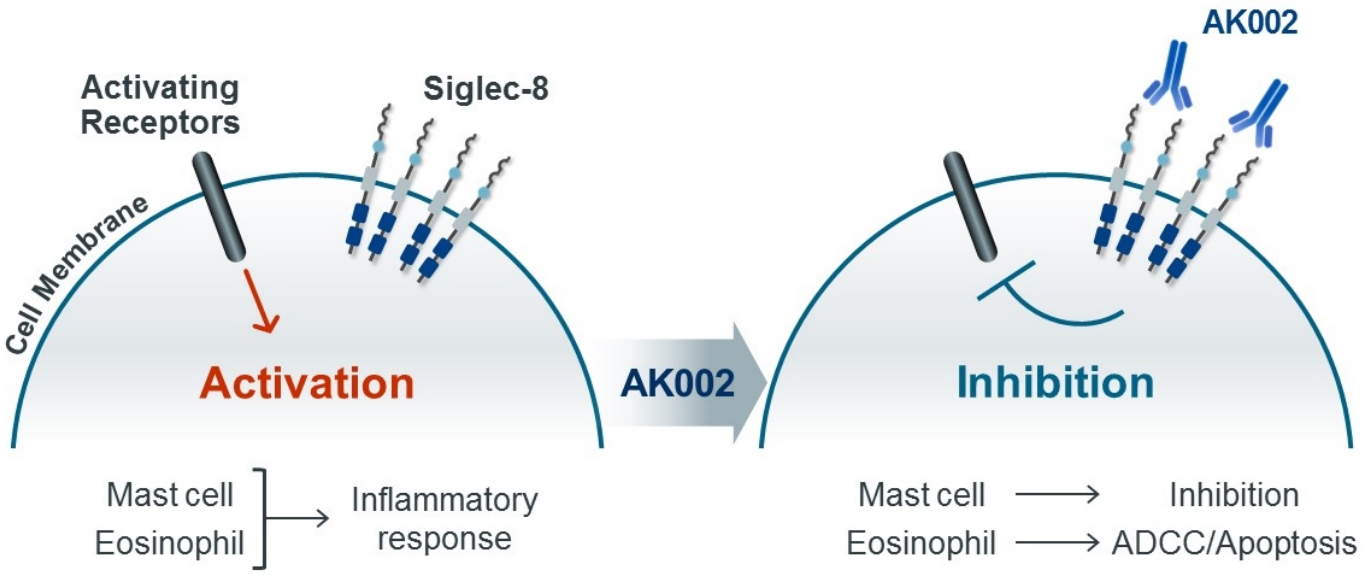
AK002 Developed to Target Siglec-8 on Mast Cells and Eosinophils



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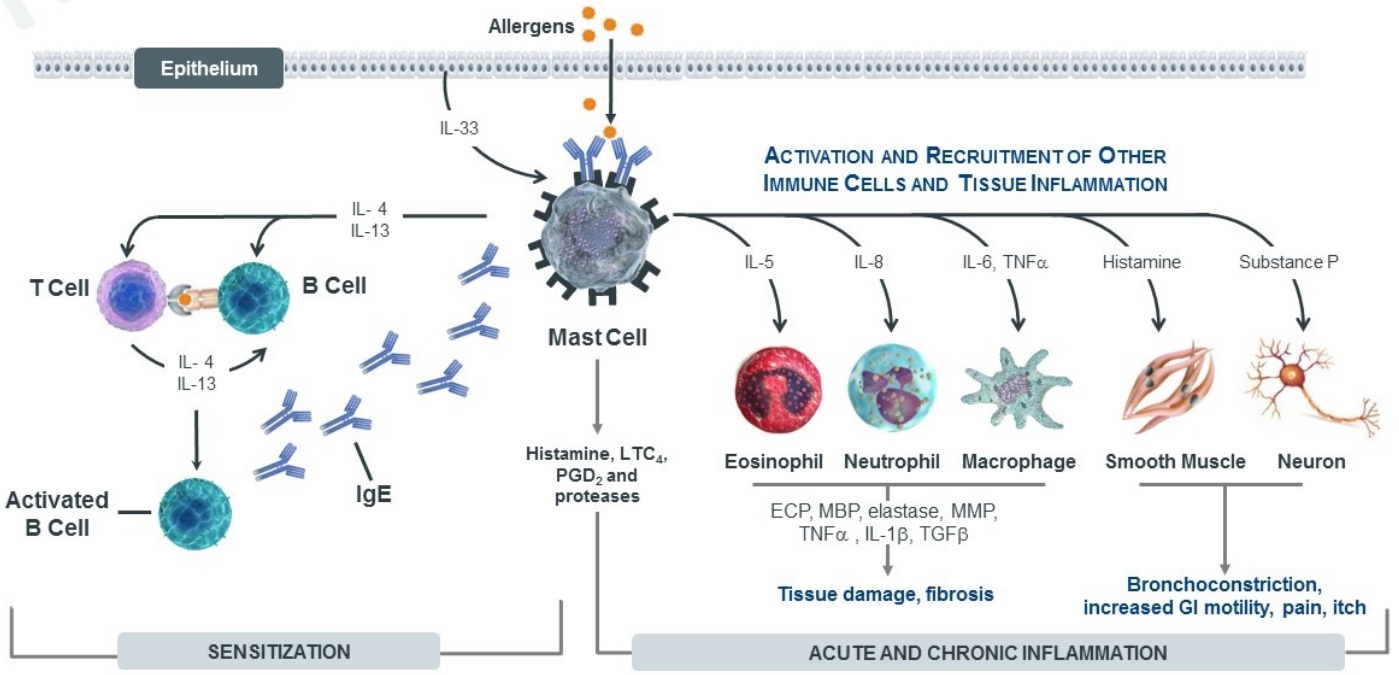
Mast Cells and Eosinophils are Key Drivers of Inflammatory Disease



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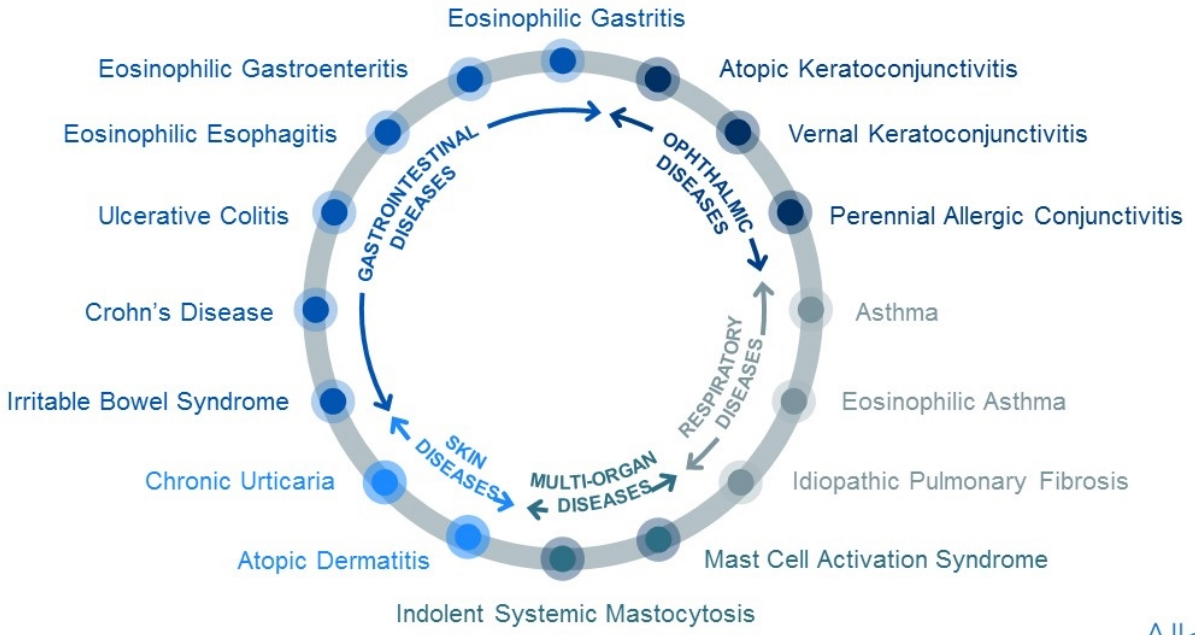
Eosinophils and Mast Cells Play a Significant Role in Many Diseases



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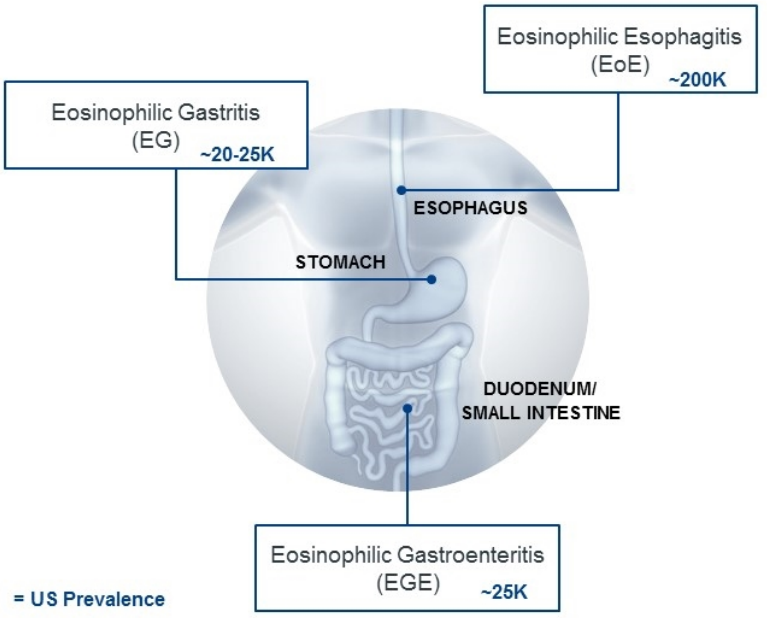
Eosinophilic Gastrointestinal Diseases (EGIDs)



EG, EGE, EoE

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

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

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Eosinophilic Gastritis and/or Eosinophilic Gastroenteritis Phase 2 Study

Henrik S. Rasmussen, MD PhD
Chief Medical Officer - Allakos

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ENIGMA Phase 2 Study

Study Design

- Randomized, double-blind, placebo-controlled study in EG/EGE
- Active moderate to severe symptoms
- Biopsy confirmed EG/EGE
  - Stomach: ≥30 eos/high powered field (hpf) in 5 hpfs
  - Duodenum: ≥30 eos/hpf in 3 hpfs
- 65 Patients – 3 arms
  - 22 patients 0.3, 1.0, 1.0, 1.0 mg/kg
  - 21 patients 0.3, 1.0, 3.0, 3.0 mg/kg
  - 22 patients placebo
- 4 monthly doses
- Endpoints assessed two weeks after last dose

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Symptoms Assessed Using Proprietary PRO

EG/EGE-SQ© Questionnaire

- Developed in accordance with FDA guidance on PRO development
- Captures the symptoms of EG/EGE patients on a daily basis
- Measures 8 symptoms each on a scale of 0-10 (Total Symptom Score 80 points):

- Abdominal pain	- Loss of appetite
- Nausea	- Abdominal cramping
- Vomiting	- Bloating
- Early satiety	- Diarrhea

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Prespecified Hierarchical Analysis Per Protocol

Primary Endpoint

- Mean percent change in gastrointestinal eosinophil counts from baseline

Responder Secondary Endpoint

- Proportion of patients who have:
  - >75% decrease in tissue eosinophils AND >30% benefit in Total Symptom Score (TSS)

Symptoms Secondary Endpoint

- Mean percent change in TSS from baseline

Endpoints designed to show (1) tissue eosinophil depletion, (2) symptom improvement, and (3) that these effects occur in the same individuals

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Baseline Characteristics

	AK002 (n=39)	Placebo (n=20)	Total (N=59)
Age, Median (Range)	43 (18-74)	40 (18-67)	42 (18-74)
Female	72%	50%	64%
EoE with Dysphagia	38% (15)	50% (10)	42% (25)
% of Patients with AEC[1] <500 eos/µL	74%	60%	69%
% of Patients with AEC[1] <1500 eos/µL	95%	95%	95%
Mean Baseline Gastrointestinal Eosinophils/hpf	78	75	77
Mean Baseline Gastrointestinal Mast Cells/hpf	64	56	62
Mean Baseline Total Symptom Score (TSS)	34	30	33

1 AEC: Blood Absolute Eosinophil Count

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Primary Endpoint Met for All AK002 Groups

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%	-

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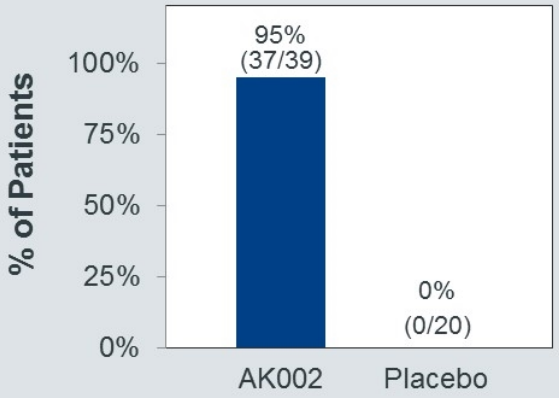
AK002 Demonstrates Potent Tissue Eosinophil Depletion

Stomach/Duodenal Eos < 5/HPF



37 of 39 patients had < 5 eos/hpf

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AK002 Met 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%	-

Statistically significant improvements in symptoms observed 1 day after first infusion and maintained throughout the study

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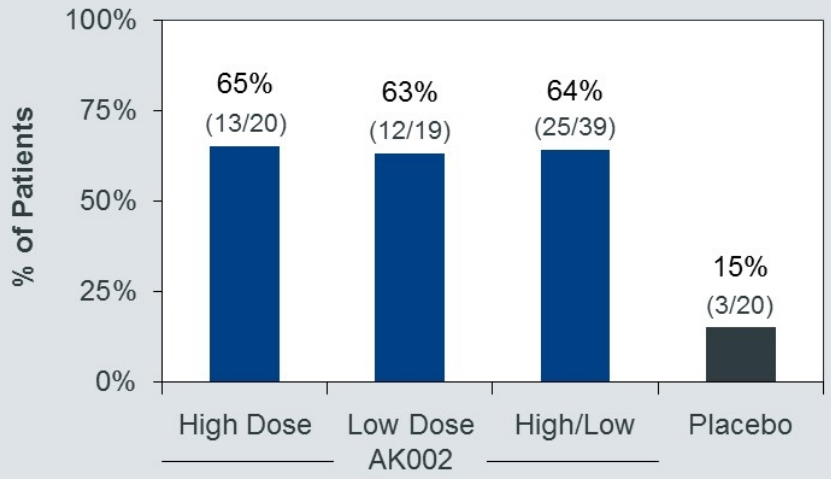
Higher Proportion of Patients with >50% Reduction in TSS on AK002 vs. Placebo

EG/EGE-PRO Total Symptom Score: >50% Reduction



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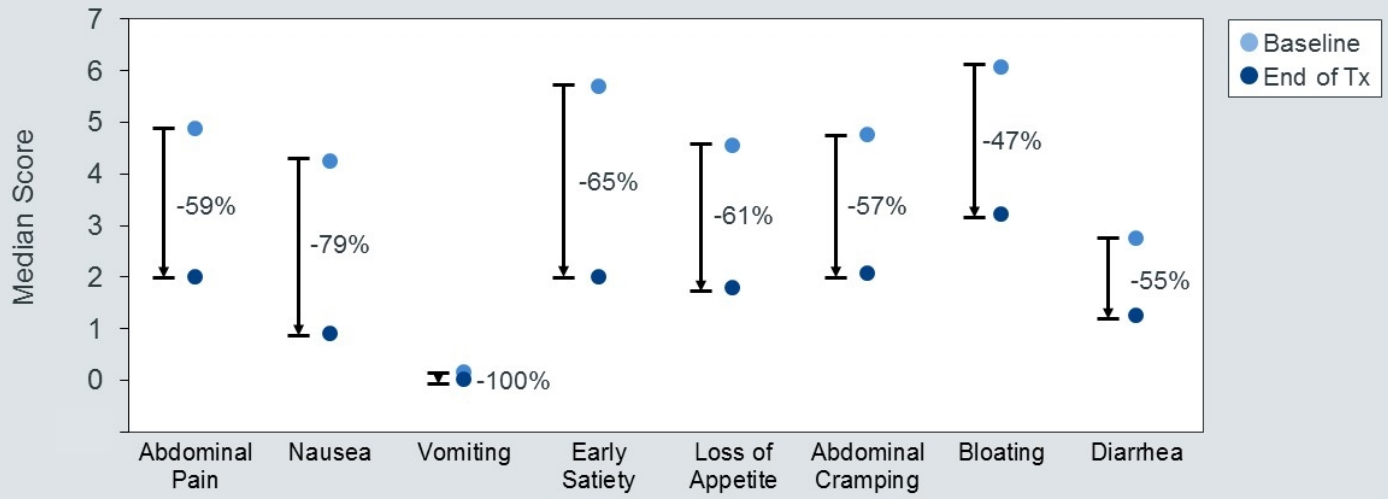
Improvement Across All Symptoms Measured on AK002

EG/EGE-PRO Symptom Score
AK002 (n=39)



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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)

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Additional Analyses

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Endpoint Sensitivity Analyses

Study Population

- **Intent to Treat (ITT):**
  - All patients randomized (n=65)
  - Includes Per Protocol (n=59) population plus:
    - 2 patients only received 1 dose of drug
    - 1 patient did not complete PRO
    - 3 patients had their daily steroid dose altered
- **Safety** evaluated on the ITT population

Acute Steroid Use

- **Protocol allowed steroid use:**
  - ≤ 10mg daily oral prednisone
    - Must be preexisting prior to screening start and stable throughout screening, baseline and study periods
  - Acute steroid use
    - Premedication before infusion
    - Therapeutically to manage IRR
- **Protocol violation:**
  - Increase or decrease in daily steroid amount
- **Acute steroid use across both groups:**
  - 28% AK002, 35% placebo

All Analyses Show Consistent Results

Primary and Secondary Endpoint p-values		AK002 Dose Groups			Placebo
		High (n=20/16/21)	Low (n=19/12/22)	High/Low (n=39/28/43)	(n=20/13/22)
1° - Tissue Eosinophils % Δ from BL to Day 99	Per Protocol	**<0.0001**	**<0.0001**	**<0.0001**	-
	No Steroids	**<0.0001**	**<0.0001**	**<0.0001**	-
	ITT	**<0.0001**	**<0.0001**	**<0.0001**	-
2° - Treatment Responders (Eos Δ >-75% & TSS Δ >-30%)	Per Protocol	**0.0009**	**0.0019**	**0.0008**	-
	No Steroids	**<0.0001**	**0.0001**	**<0.0001**	-
	ITT	**0.0008**	**0.0017**	**0.0007**	-
2° - Total Symptom Score % Δ from BL to End of Study	Per Protocol	**0.0012**	**0.0150**	**0.0012**	-
	No Steroids	**0.0016**	**0.0313**	**0.0027**	-
	ITT	**0.0260**	0.1556	**0.0359**	-

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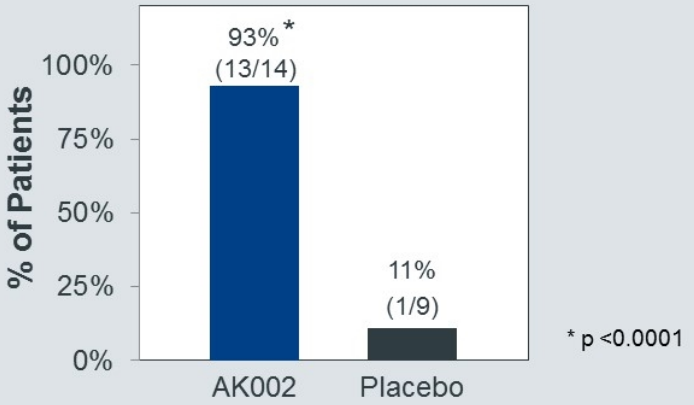
Eosinophilic Esophagitis Patients

	AK002 (n=15)	Placebo (n=10)	Total (N=25)
Age, Median (Range)	34 (18-68)	34 (21-53)	34 (18-68)
Female	67%	40%	56%
Mean Baseline Esophageal Eosinophils/hpf	43	79	56
Mean Baseline Esophageal Mast Cells/hpf	28	36	31
Mean Baseline Dysphagia Score	4.0	4.4	4.2

Significant Eosinophil Reductions in Patients With EoE

Esophageal Eos < 5/HPF[1]



13 of 14 patients had < 5 eos/hpf

1 Excludes patients with eos < 5/hpf at baseline

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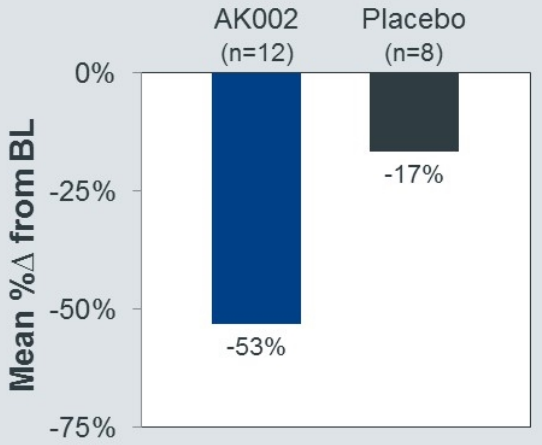
Substantial Improvement in Dysphagia

Severity of Dysphagia[1]



Histological and symptomatic improvement provides strong proof of concept in EoE

1 All EoE patients with end of treatment dysphagia scores

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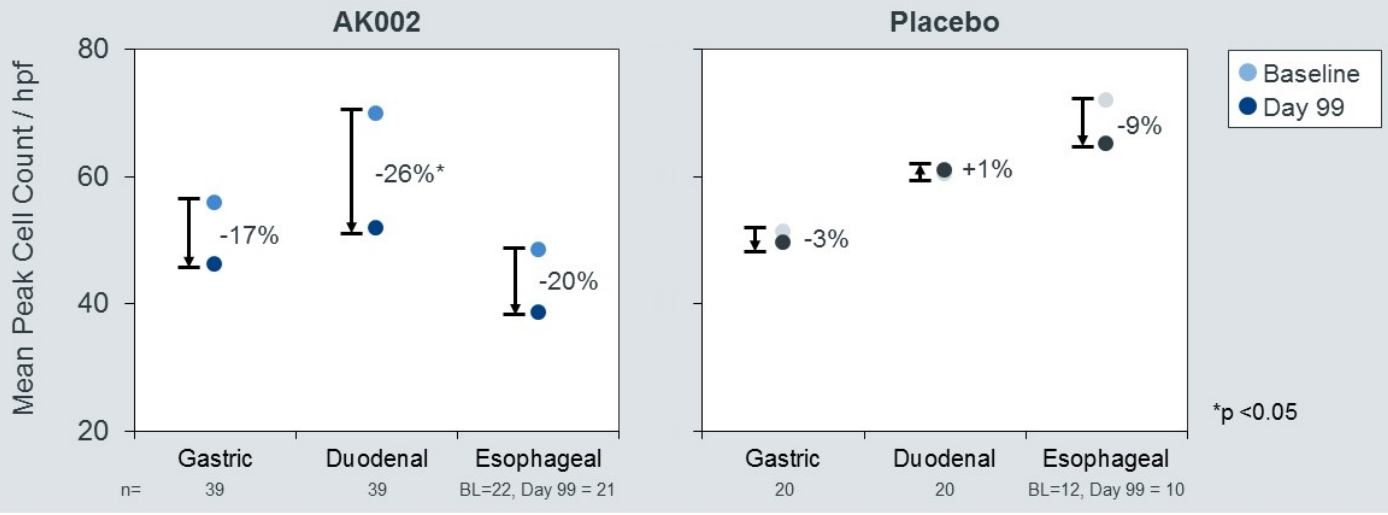
Mast Cell Counts Decrease on AK002

Mast Cells in Gastric, Duodenal, and Esophageal Biopsies



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Safety Summary

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Safety: 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)

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Safety Summary

- Generally well tolerated
- Most common AE was mild to moderate infusion related reactions (IRR)
  - 60% of AK002 patients vs 23% placebo
  - 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

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Open-Label Extension & Next Steps

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Extension Study Status

- 92% of patients elected to enter long-term extension study
  - Current median duration of treatment 3 months
  - Efficacy appears to improve with continued dosing
- Optimizing dose administration
  - Pre-dose with oral prednisone 1 day prior to first and second AK002 doses
  - No IRRs observed in patients using steroid pre-dose
  - Allows administration of 1mg/kg as first dose
  - Infusion time can be reduced to < 2 hours on second and subsequent doses

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EG/EGE and EoE Next Steps

- Q4 2019/Q1 2020 End of phase 2 meeting
- Q1 2020 Estimated phase 3 study start eosinophilic gastritis and/or eosinophilic gastroenteritis
- Q1 2020 Estimated phase 2/3 study start in eosinophilic esophagitis

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Evan S. Dellon, MD MPH

TITLE: Professor of Medicine, Gastroenterology & Epidemiology
Director, Center for Esophageal Diseases and Swallowing
Director, CGIBD Biostatistics and Clinical Research Core

INSTITUTION: University of North Carolina School of Medicine

SPECIALTY: Gastroenterology

FOCUS: Epidemiology, pathogenesis, diagnosis, treatment, and outcomes of Eosinophilic Gastrointestinal Disorders

- Investigator and member of NIH-funded Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR)
- Editorial Board: Clinical Gastroenterology and Hepatology
- Author/Co-Author: >200 peer reviewed publications
- Investigator for multiple EGID studies including EoE

Corporate Updates

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Strong Balance Sheet and Significant IP Protection

Cash, Cash Equivalents and Investments in Marketable Securities as of June 30, 2019	$153.1M
Q2 2019 Operating Expenses	$20.1M

- AK002 US patents run until 2035
- Lonza currently manufactures AK002

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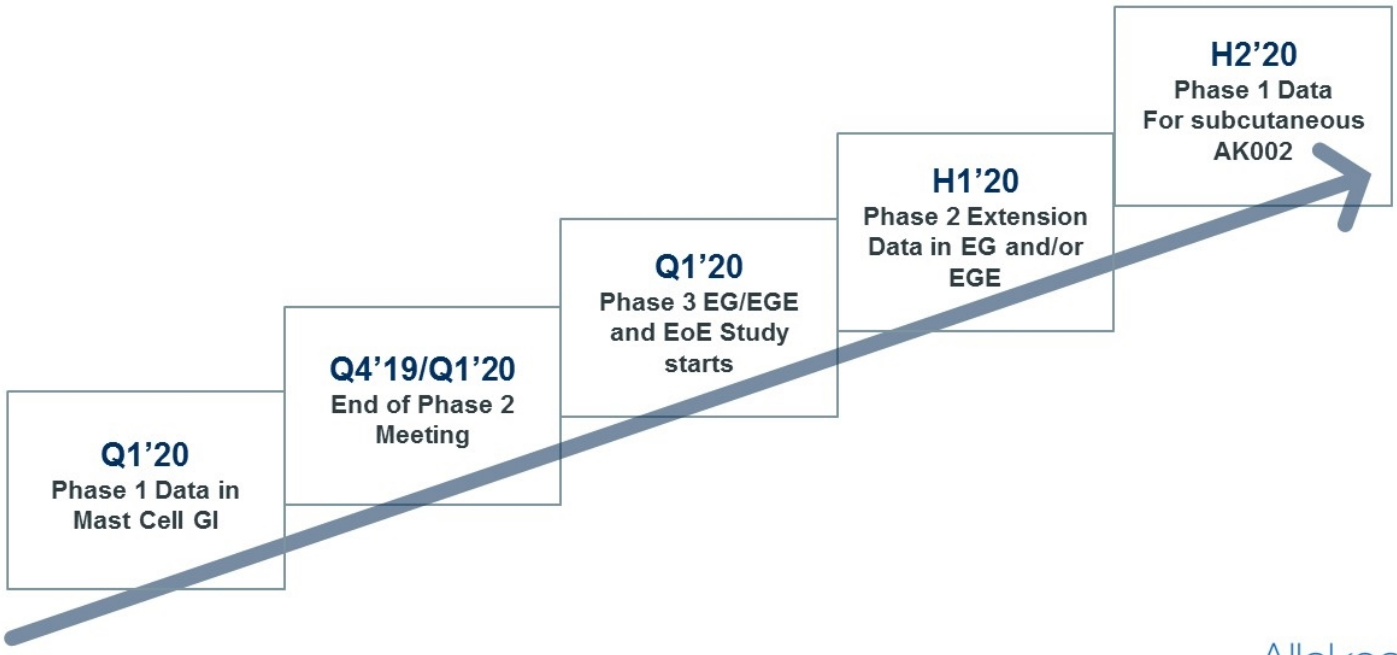
Anticipated Near-term Milestones



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Experienced Management Team

	Previous Experience
Robert Alexander, PhD Chief Executive Officer	• CEO, ZS Pharma • Director Alta Partners; Business Development, Genentech
Adam Tomasi, PhD President & COO	• CSO & Head of Corporate Development, ZS Pharma • Principal Alta Partners, Drug Discovery, Gilead, Cytokinetics
Henrik Rasmussen, MD, PhD Chief Medical Officer	• CMO, ZS Pharma • Head of Clinical Development, Medical and Regulatory Affairs, Novo Nordisk
Leo Redmond Chief Financial Officer	• President & CFO, Presidio Pharmaceuticals • Senior Director Finance; Genentech
Simon Greenwood, PhD Chief Business Officer	• Director Roche Venture Fund • Head Genenfund; Business Development and Research, Genentech
Tim Varacek Chief Commercial Officer	• SVP, Sales and Commercial Operations, ZS Pharma • VP, Sales, InterMune
Mark Asbury Chief Legal Officer	• Chief Legal Officer, ZS Pharma, Pharmacyclics • Associate General Council, Genentech
Ruby Casareno, PhD VP CMC	• Director, Manufacturing, Portola • Director of Process Development and Manufacturing, OncoMed
Sally Bolmer, PhD VP, Reg. Affairs and Drug Development	• Senior Vice President, Development and Regulatory Affairs, Human Genome Sciences • Executive Director, Regulatory Affairs, Centocor

Executive Summary

- AK002 met all prespecified primary and secondary endpoints in EG/EGE
- Randomized, double-blind, placebo-controlled study results showed:
  - 95% reduction in tissue eosinophils vs. placebo +10% ($p < 0.0001$)
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  - 53% decrease in symptom score vs. placebo 24% ($p = 0.0012$)
- Strong proof of concept in EoE
  - 13/14 (93%) of patients had eosinophils < 5 /hpf
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Today's data builds on robust results in multiple other diseases

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