#### **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 26, 2020** 

#### Allakos Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-38582

45-4798831 (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, inclu

Not Applicable (Former name or former address, if changed since last report)

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						
Check	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)								

Ш	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 chapter)	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).
Emergii	ng growth company □
	nerging 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 bange Act.

#### Item 8.01. Other Events

On October 26, 2020, Allakos Inc. (the "Company") hosted a conference call and webcast to present results from a prospective study examining the rates of elevated eosinophil and mast cell levels in patients with chronic unexplained gastrointestinal symptoms or functional gastrointestinal disorders. 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	Study Results Presentation dated October 26, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
	1

SIGNATURES

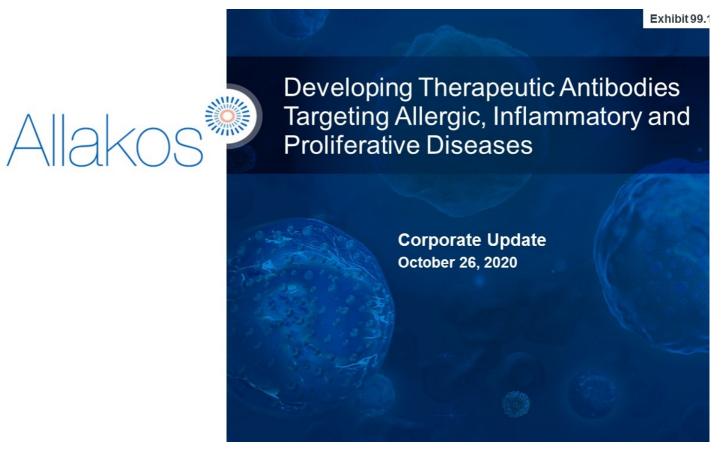
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Allakos Inc.

Date: October 26, 2020

By: /s/Robert Alexander

Robert Alexander, Ph.D.
Chief Executive Officer



#### 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, 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 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 in the diseases we are targeting; and our expectations with regard to our ability to acquire, discover and develop additional 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; the size of the acquired to candidates in the diseases the forward-looking statements. Product candidates in the clinical trains, country or country or continue, "country country country or count

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 <a href="https://www.sec.gov">www.sec.gov</a>.

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.





Robert Alexander, PhD  Overview	5:00 – 5:10 AM
Henrik Rasmussen, MD PhD  - Subcutaneous formulation study results	5:10 – 5:15 AM
Amol Kamboj, MD  EG/EoD prevalence study results	5:15 – 5:35 AM
Nicholas Talley, MD PhD & William Chey, MD  Clinical implications of prevalence study results	5:35 – 5:45 AM
Henrik Rasmussen, MD PhD  - Update on clinical program	5:45 – 6:00 AM
Q&A	



## Overview

Robert Alexander, PhD CEO – Allakos



## Today's Update

- Phase 1 lirentelimab (AK002) subcutaneous data
  - 63% bioavailability
  - Well-tolerated (no injection site reactions or injection reactions)
  - Sustained eosinophil suppression
- Results from prospective EGID prevalence study in patients with chronic functional GI symptoms
  - 45% (181/405) of symptomatic patients biopsied with chronic functional GI symptoms met the histologic criteria for eosinophilic gastritis and/or eosinophilic duodenitis (EG/EoD)



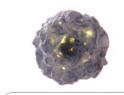
#### Lirentelimab Executive Summary

- Lirentelimab (AK002) has demonstrated activity in multiple inflammatory diseases
  - Eosinophilic gastrointestinal diseases: EG, EoD, EoE (GI)
  - Chronic urticaria (Skin)
  - Indolent systemic mastocytosis (Systemic)
  - Severe allergic conjunctivitis/atopic diseases (Eye)
- Phase 3 study initiated in eosinophilic gastritis and/or duodenitis (Results expected 2H21)
- Phase 2/3 study initiated in eosinophilic esophagitis (Results expected 2H21)
- Strong scientific rationale for development of lirentelimab (AK002) in additional indications
  - Asthma, ulcerative colitis, and other mast cell and/or eosinophil driven diseases

Lirentelimab (AK002) has the potential to be best-in-disease treatment in multiple inflammatory conditions



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



MAST CELLS

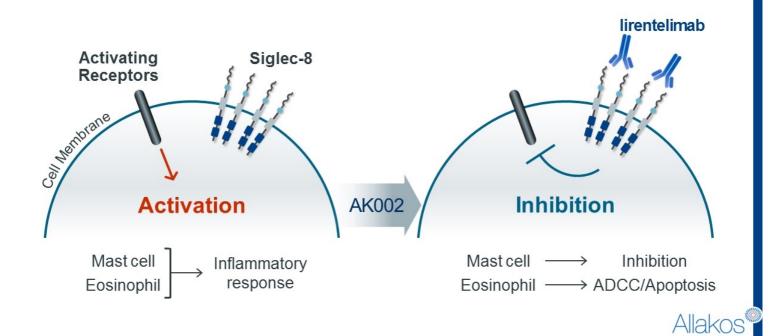


**EOSINOPHILS** 

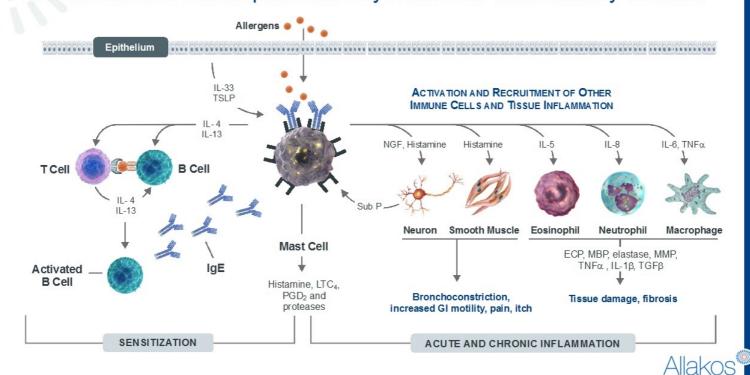
- · Found at the Internal/External Interface of the Body
  - In particular, in tissues and surrounding blood vessels and peripheral nerves
- Produce a Broad Range of Inflammatory Mediators
  - Vasoactive amines, lipid mediators, proteases, cytokines and chemokines
- Participate in Acute and Chronic Inflammation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



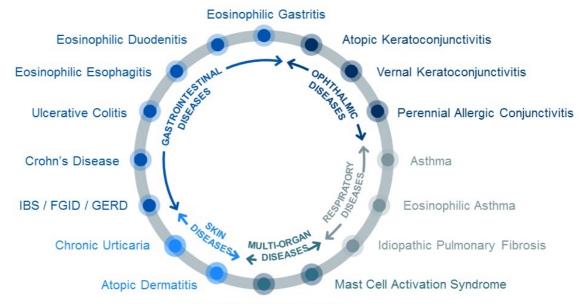
## Lirentelimab Targets Siglec-8 on Mast Cells and Eosinophils



### Mast Cells and Eosinophils Are Key Drivers of Inflammatory Disease



### Eosinophils and Mast Cells Play a Significant Role in Many Diseases



Indolent Systemic Mastocytosis



### Eosinophilic Gastritis (EG), Duodenitis (EoD), and Esophagitis (EoE)

- Chronic eosinophilic and mast cell inflammation of the stomach, duodenum, or esophagus
- Symptoms: abdominal pain, nausea, early satiety, loss of appetite, bloating, abdominal cramping, vomiting, diarrhea, and dysphagia
- No FDA-approved treatment for EG, EoD, or EoE
- · Current standard of care: diet and/or steroids



## Phase 1 Subcutaneous Healthy Volunteer Study

Henrik Rasmussen, MD PhD CMO - Allakos



## Phase 1 Subcutaneous Healthy Volunteer Study

#### Study Design

- Phase 1 single-dose, randomized, double-blind, placebo-controlled study
- 58 adult healthy volunteers
- Dose groups:
  - SC: lirentelimab 0.3, 1.0, 3.0, 5.0 mg/kg, 300 mg fixed (single 2 mL injection), or placebo
  - IV: lirentelimab 1.0, 3.0 mg/kg



### Phase 1 Subcutaneous Healthy Volunteer Study

#### Results

- 63% bioavailability
- Prolonged peripheral blood eosinophil suppression on lirentelimab
- Lirentelimab was well tolerated
  - No injection site reactions or injection reactions
  - No treatment related adverse events
  - No serious adverse events
- Placebo
  - 1 mild (Grade 1) injection reaction occurred (flushing 2 hours post-injection)

Lirentelimab appears suitable for once monthly dosing

Allakos

# SC Lirentelimab Showed Sustained Depletion of Eosinophils in Healthy Volunteers in Phase 1 Study

			Median Blood Eosinophils 10 <sup>3</sup> /mL						
Route	Dose Cohort (mg/kg)	n	Baseline	1 hr	3 hr	Day 15	Day 35	Day 56	Day 85
	Placebo	10	100	100	200	200	100	200	100
	0.3	6	110	200	20	0	0	50	100
00	1.0	6	150	0	0	0	0	0	50
SC	3.0	6	150	0	0	0	0	0	0
	5.0	6	100	0	0	0	0	0	0
	300 mg	6	100	0	0	0	0	0	0
1) /	1.0	6	100	0	0	0	0	0	0
IV	3.0	12	100	0	0	0	0	0	0

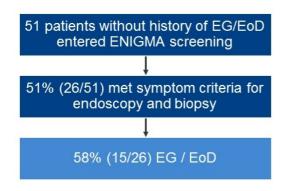


## EG/EoD Prevalence Study

Amol Kamboj, MD Senior Medical Director - Allakos



# ENIGMA: Unexpectedly High Diagnosis Rate of EG/EoD Among Previously Undiagnosed Patients



- 29% (15/51) received a de novo diagnosis of EG/EoD
- Majority of patients without a previous diagnosis of EG/EoD came from general GI practices
- These patients had a history of chronic nonspecific functional GI symptoms or diagnoses

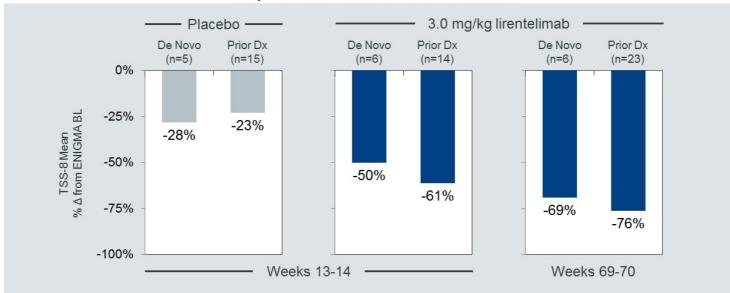
Suggests significant underdiagnosis of EG/EoD in GI patient population

Allakos

SOURCE: Peterson KA et al. AJG. 2020 (ACG 2020 presentation)

# De Novo EG/EoD Patients Had a Similar Response to Lirentelimab as Patients with a Prior History of EG/EoD

#### Improvement in TSS-8 From Baseline

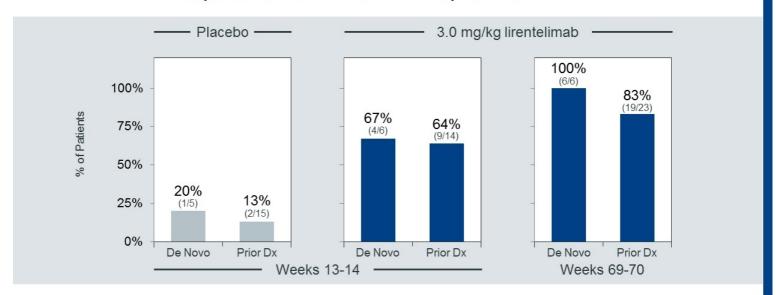


De novo: Newly diagnosed EG/EoD Prior Dx: Patients with diagnosis of EG/EoD prior to screening for ENIGMA OLE data as of 28SEP20



### Similar Response to Lirentelimab Regardless of History of EG/EoD

#### Proportion of Patients with ≥50% Improvement in TSS-8



De novo: Newly diagnosed EG/EoD Prior Dx: Patients with diagnosis of EG/EoD prior to screening for ENIGMA OLE data as of 28SEP20



### EG/EoD Prevalence Study

#### Study Design

- Prospective, multi-center study to assess the prevalence of EG/EoD in symptomatic patients with chronic functional GI symptoms
  - At least a 6-month history of abdominal pain, abdominal cramping, nausea, vomiting, diarrhea, bloating or early satiety without identifiable cause and unresponsive to pharmacologic or dietary intervention
  - Or a diagnosis of IBS or Functional Dyspepsia (FD) indicating a chronicity of symptoms
- Biopsies from 405 adult patients who met symptom criteria as assessed by the PRO questionnaire used in ENIGMA and ENIGMA 2 Phase 3 EG/EoD study
- 20 sites distributed across continental US
- Co-Primary endpoints:
  - Proportion of symptomatic patients that underwent biopsy and met the histologic criteria for EG and/or EoD
     (≥30 eos/hpf in 5 gastric or 3 duodenal hpf)
  - Proportion of symptomatic patients that underwent biopsy with ≥30 mast cells/hpf in 5 gastric hpfs and/or ≥30 mast cells/hpf in 3 duodenal hpfs and < 30 eos/hpf, referred to as MGID</li>



# Symptoms Assessed With the Same PRO Questionnaire Used in ENIGMA and Phase 3 ENIGMA 2

#### GI Symptom Questionnaire

- Developed in accordance with FDA guidance on PRO development
- · Captures the GI symptoms of patients on a daily basis
- Measures symptoms each on a scale of 0-10 for the following:

Abdominal pain

- Nausea

Early satiety

- Vomiting

- Loss of appetite

Abdominal cramping

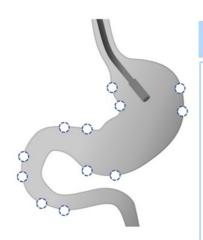
- Bloating

- Diarrhea

 Average weekly symptom score of ≥3 (on a scale from 0-10) and a Total Symptom Score ≥10



## Systematic Biopsy Protocol



#### **Biopsy Protocol**

#### Stomach

- GASTRIC ANTRUM: 4 biopsies (2-5 cm proximal to the pylorus)
- **GASTRIC CORPUS: 4 biopsies** (2 from the proximal lesser curvature and 2 from the greater curvature)

**Duodenum** • 4 biopsies from the duodenum, 2 each from the descending and horizontal parts



# High Prevalence of Chronic GI Patients Who Met Histologic Criteria for EG/EoD

Entered Screening n=556

73% Met Symptom Criteria & Biopsied n=405

45% Met Histologic Criteria for EG/EoD<sup>1</sup> n=181 50% Met Histologic Criteria for MGID<sup>2</sup> n=204 5% Did Not Meet Histologic Criteria for EG/EoD or MGID n=20

33% (181/556) of patients with chronic functional GI symptoms met histologic criteria for EG/EoD

1 Patients who met symptom criteria and ≥30 eos/hpf in 5 gastric hpfs and/or ≥30 eos/hpf in 3 duodenal hpfs; 7 patients did not meet MGID histologic criteria

2 Patients who met symptom criteria and ≥30 mast cells/hpf in 5 gastric hpfs and/or ≥30 mast cells/hpf in 3 duodenal hpfs and < 30 eos/hpf



## Patients Were Screened from Multiple Sites Across the U.S.



Consistent discovery rate of EG/EoD across regions



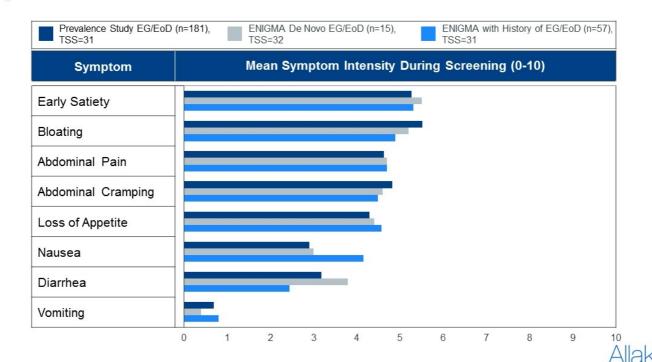
# Baseline Characteristics of Patients in Prevalence Study Compared to ENIGMA

Patient Characteristics	Screened n=556	EG/EoD n=181	MGID n=204	ENIGMA <sup>a</sup> n=72
Mean age, years (range)	45 (18–83)	45 (19–78)	44 (18–76)	42 (18-74)
Female sex	72%	73%	72%	60%
White	89%	85%	90%	92%
Weight, median, kg	82	83	82	82
Peripheral blood eos count, /µL, median (IQR)	130 (80–220)	170 (100–250)	110 (70–165)	325 (138–673)
TSS [0-80], mean	27.8	31.3	30.0	31.9
History of GI symptoms, mean years	11	11	9	9
Prior diagnosis, n (%)				
Gastroesophageal reflux	53%	65%	55%	33%
Irritable bowel syndrome	46%	55%	51%	4%
Functional dyspepsia	16%	15%	18%	1%
Chronic gastritis or duodenitis	12%	11%	18%	6%
Any of the above	81%	93%	88%	43%

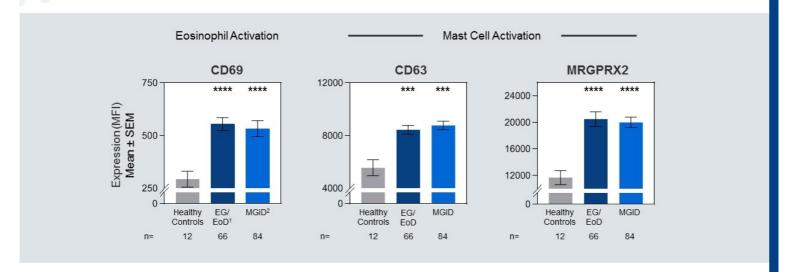
a 72 patients met histologic criteria for EG/EoD; 65 patients enrolled in ENIGMA



## Comparable Symptom Profile in Prevalence Study vs. ENIGMA



### Eosinophil and Mast Cells from Symptomatic Patients in the Prevalence Study Display an Activated Phenotype







<sup>1</sup> Patients who met symptom criteria and ≥30 eos/hpf in 5 gastric hpfs and/or ≥30 eos/hpf in 3 duodenal hpfs
2 Patients who met symptom criteria and ≥30 mast cells in 5 gastric hpfs and/or ≥30 mast cells/hpf in 3 duodenal hpfs and < 30 eos / hpf

### **Prevalence Study Summary**

45% (181/405) of symptomatic patients biopsied with chronic functional GI symptoms met the histologic criteria for EG/EoD

Many symptomatic patients had activated eosinophils and mast cells, likely contributing to disease despite not meeting histologic criteria for EG/EoD

Patients are not well managed by available therapies and there are no approved therapies targeting eosinophils and mast cells

In ENIGMA de novo EG/EoD patients had a meaningful response to lirentelimab



## Implications of Prevalence Study Results

Nicholas J. Talley, MD William D. Chey, MD



## **Expert Panel**



Nicholas J. Talley, MD PhD

- Laureate Professor, Univ. of Newcastle
- Gastroenterologist & Epidemiologist
- Past Chairman of Medicine, Mayo Clinic
- APFED Medical Advisory Panel Member
- Past Co-editor-in-Chief of the American Journal of Gastroenterology



William D. Chey, MD

- Professor, Gastroenterology, Univ. of Michigan
- Board of Directors, Rome Foundation (IBS Guidelines)
- Board of Trustees of the American College of Gastroenterology
- Past Co-editor-in-Chief of the American Journal of Gastroenterology



### Strengths of Prevalence Study









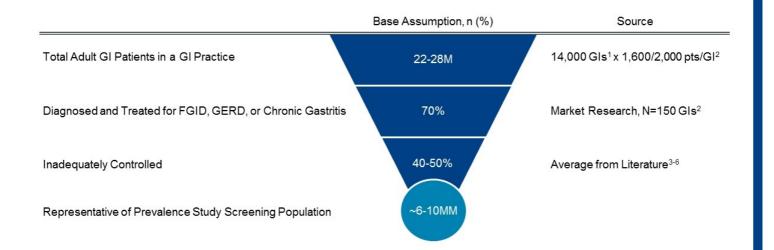


500+ patients screened and evaluated across 20 sites, with 400+ undergoing endoscopy PRO measured a broad constellation of symptoms and identified patients with moderate-to-severe symptoms Standardized endoscopy and biopsy protocol with predefined criteria for eosinophilia

- · First large prospective study looking at prevalence of EG/EoD
  - · Consistent findings across U.S. geographical locations
- · Study population highly representative of a typical community GI practice



# Projected 6-10 Million Adult Patients With Treatment Refractory Functional GI Disorders in the United States



SOURCE: 1. AAMC.org; 2. InCrowd market research survey of 150 adult gastroenterologists, fielded Aug 2020. 3. El-Serag, Becher A, and Jones J. AP&T. 2010.; 4. Pimentel M. Am J Manag Care. 2018.; 5. Buono JL, et al. J Med Econ. 2017; 6. Mönkemüller K, Malfertheiner P. World J Gastroenterol. 2006.



# Study Findings Substantiate the Pathogenic Role of Eosinophils and Mast Cells in Patients with Chronic GI Symptoms

Study 1: Functional Dyspepsia & Eos



Non-ulcer Dyspepsia and Duodenal Eosinophilia: An Adult Endoscopic Population-Based Case-Control Study

· Eos were significantly elevated in FD patients

Study 2: Functional Dyspepsia & Eos



Duodenal Eosinophilia Is Associated with Functional Dyspepsia and New Onset Gastro-oesophageal Reflux Disease

 Duodenal eosinophilia (D2) was associated with a 6-fold increased risk of new onset symptomatic GERD at 10-year follow-up in PDS (but not EPS)

Study 3: Activated Mast Cell & GI Symptoms



Mast Cell-nerve Interactions Correlate with Bloating and Abdominal Pain Severity in Patients with Non-celiac Gluten / Wheat Sensitivity

Proximity of mast cells to nerve endings correlates with GI symptoms

Study 4: Mast Cells & Eos Are Pathogenic in FGIDs



Functional Gastrointestinal Disorders: Advances in Understanding and Management

 Degranulation of mast cells and eosinophils can damage the intestinal barrier and stimulate and damage enteric nerve fibers...resulting in gastrointestinal symptoms

SOURCE: 1. Talley NJ, et al. Clin Gastroenterol Hepatol. 2007.; 2. Ronkainen J, et al. AP&T. 2019.; 3. Giancola F, et al. Neurogastroenterol Motil. 2020.; 4. Black CJ, et al. Lancet. 2020.



## This Prevalence Study Should Lead to a Change in Clinical Practice and Improved Detection of EG/EoD

#### **Current State Implications** 1 EGD should be performed for Guidelines do not call for EGDs patients with moderate-to-severe **EGD** unless alarm signs are present symptoms, refractory to SoC 2 Biopsies are generally limited to Systematic biopsies (8 in stomach and 4 areas of interest or where mucosa Biopsy in duodenum) should be taken appears macroscopically abnormal Counting of eosinophils should be Histological Eosinophils are not typically standardized in symptomatic counted/reported patients, with recognition of histologic Evaluation cutoff of ≥30 eos/hpf



#### Summary

- Historically, EGDs & biopsies have not been recommended in patients with chronic GI symptoms because it did not guide patient management
- Current treatments remain ineffective for many patients with chronic functional GI symptoms, likely because these interventions do not address underlying pathogenic drivers of disease
- Historical and emerging research highlight the pathogenic role of eosinophils and mast cells in patients with chronic GI symptoms
- The prevalence combined with the histologic and symptom improvements seen in newly identified EG/EoD patients in ENIGMA, offer promise to many patients with chronic GI symptoms



### ENIGMA Open-Label Extension Study Update

Henrik Rasmussen, MD PhD CMO – Allakos



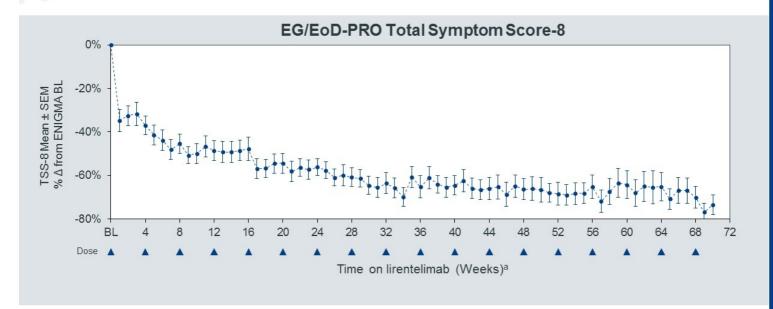
### **OLE Interim Analysis**

#### Patient Population

- 58 of 59 eligible patients entered the OLE study
- As of 9/28/2020,
  - 45 patients have completed ≥52 weeks of lirentelimab treatment (includes ENIGMA exposure)
    - Average ~78 weeks of lirentelimab treatment
  - 13 patients have discontinued with <52 weeks of lirentelimab treatment</li>
    - Average ~34 weeks of lirentelimab treatment



#### Substantial Symptom Improvement Over Time







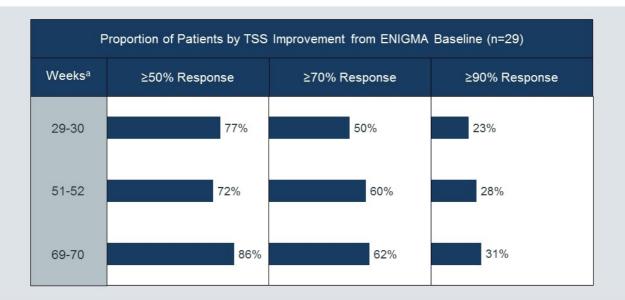
# Change in Symptoms Over Time in Patients with ≥70 Weeks of Lirentelimab Treatment

Total Lirentelimab Exposure (Weeks) <sup>a</sup>	TSS Mean Change from ENIGMA BL (n=29)			
	Baseline	Absolute	Percent	
29-30	34	-23	-68%	
51-52	34	-24	-70%	
69-70	35	-26	-75%	



a Total lirentelimab exposure, inclusive of lirentelimab exposure during the Phase 2 ENIGMA study Data as of 28SEP2020

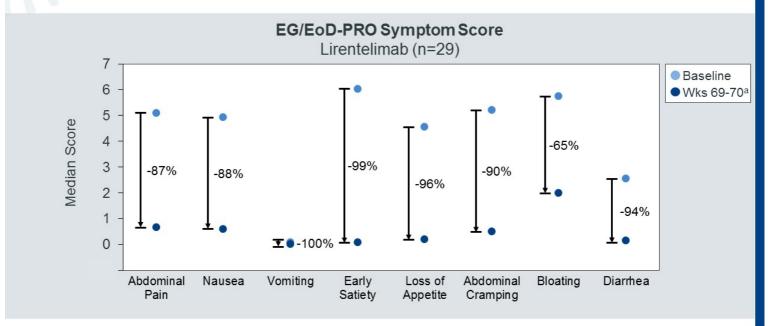
## Change in Symptom Response Rate in Patients with ≥70 Weeks of Lirentelimab Treatment



a Total lirentelimab exposure, inclusive of lirentelimab exposure during the Phase 2 ENIGMA study Data as of 28SEP2020



# Improvement Across All Symptoms in Patients with ≥70 Weeks of Lirentelimab Treatment



a Total lirentelimab exposure, inclusive of lirentelimab exposure during the Phase 2 ENIGMA study Data as of 28SEP2020



### Safety Summary

- · Generally well tolerated
- Most common adverse event (AE) was infusion-related reaction (IRR)
  - Most are mild to moderate (flushing, feeling of warmth, headache, nausea, dizziness)
  - Mostly on first infusion, greatly reduced or does not occur on subsequent infusions
  - No IRRs in 20 patients who received single-dose oral prednisone night before first infusion in OLE
- No drug-related serious AEs in OLE
- No other significant AEs



## Clinical Development Update



### Clinical Development Update

- Phase 3 study in EG/EoD (ENIGMA 2) is well underway
  - On track to have data in 2H21
- Phase 2/3 study in EoE (KRYPTOS) is well underway
  - On track to have data in 2H21



## Corporate Updates



### Strong Balance Sheet and Significant IP Protection

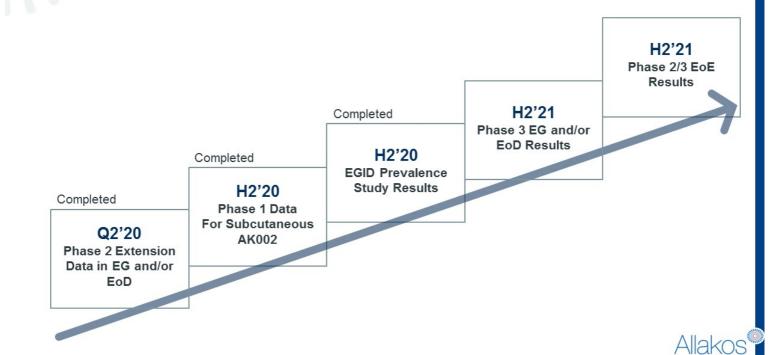
Cash, Cash Equivalents and Investments in Marketable Securities as of June 30, 2020	\$454.9M
H1 2020 Operating Expenses	\$70.3M
Q1 2020 Operating Expenses	\$29.9M
Q2 2020 Operating Expenses	\$40.4M



- AK002 US patents first to expire 2035
- Lonza currently manufactures AK002



### Completed and Near-term Milestones



### **Executive Summary**

- Registrational study enrollment is well underway
  - Phase 3 study in eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD)
  - Phase 2/3 study in eosinophilic esophagitis (EoE)
- Phase 1 lirentelimab subcutaneous data
  - 63% bioavailability
  - Well tolerated (no injection site reactions or injection reactions)
  - Sustained eosinophil suppression
- Results from EGID prevalence study
  - 45% (181/405) of symptomatic patients biopsied with chronic functional GI symptoms met the histologic criteria for eosinophilic gastritis and/or eosinophilic duodenitis





