Alakos

Developing Therapeutic Antibodies Targeting Allergic, Inflammatory and Proliferative Diseases

> Corporate Update March 2020

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Agenda

Robert Alexander, PhDOverview	5:00 – 5:20 PM
 Henrik Rasmussen, MD PhD Initiated clinical studies MGID Phase 1 study results 	5:20 – 5:50 PM
Q&A	5:50 – 6:00 PM



Overview

Robert Alexander, PhD CEO – Allakos



Executive Summary

- Recently initiated Phase 3 study in Eosinophilic Gastritis (EG) and/or Eosinophilic Duodenitis (EoD; previously referred to as EGE)
- Recently initiated Phase 2/3 study in Eosinophilic Esophagitis (EoE)
- First group of subjects dosed in Phase 1 subcutaneous healthy volunteer study
- Positive results from Phase 1 open-label study in Mast Cell GI Disease (MGID)
- EGID & MGID prevalence study in patients with chronic functional GI disease is underway



Impact of Coronavirus on Allakos Clinical Trials

- Phase 3 EG/EoD and Phase 2/3 EoE sites have been activated and potential patients have been identified
- To avoid study disruption, we have decided to delay enrollment in the Phase 3 EG/EoD and the Phase 2/3 EoE studies
 - Current estimated completion of H2 2021 but may be delayed
- Subcutaneous and Prevalence studies currently continue to enroll
 - Current estimated completion of H2 2020 but may be delayed
- We will continue to carefully monitor the situation to minimize the impact on our development programs



Antolimab (AK002) 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



Eosinophilic Gastrointestinal Diseases (EGIDs)



EG, EoD, EoE

Chronic Eosinophilic Inflammation of the Stomach, Duodenum, 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, EoD, or EoE
- Current standard of care: diet and/or steroids
- Large market opportunity



EGID Biopsies Have Elevated Eosinophils & Mast Cells





Source: Youngblood B, et al. JCI Insights. 2019

Eos and Mast Cells Are Activated in EGID Biopsies



Eosinophils and mast cells both appear to play a pathogenic role

Source: Youngblood B, et al. JCI Insights. 2019

End of Phase 2 (ENIGMA) Meeting Summary



Key Takeaways

Histologic Co-Primary Endpoint

- Consistent with EoE guidance, FDA recommended using a responder analysis
- Histologic response thresholds set at ≤4 eos/hpf in the stomach and/or ≤15 eos/hpf in the duodenum

Symptom Co-Primary Endpoint

- The same PRO questionnaire will be used in Phase 3 as was used in ENIGMA
- FDA recommended using a Total Symptom Score consisting of the 6 most frequent and severe symptoms (TSS-6): abdominal pain, nausea, bloating, early satiety, abdominal cramping, loss of appetite; vomiting and diarrhea are measured but excluded from the co-primary endpoint

Duration of study

- Consistent with EoE guidance, FDA recommended a 6-month study
- Change in nomenclature
 - Eosinophilic Gastroenteritis is now referred to as Eosinophilic Duodenitis



Phase 3 Eosinophilic Gastritis and/or Eosinophilic Duodenitis (formally referred to as EGE) Study Design Henrik S. Rasmussen, MD PhD Chief Medical Officer – Allakos



Phase 3 Eosinophilic Gastritis (EG) and/or Duodenitis (EoD) Study

Study Design

- Multi-center, randomized, double-blind, placebo-controlled study in EG/EoD
- Adult patients with active moderate to severe symptoms
- Biopsy confirmed EG/EoD
 - Stomach: ≥30 eos/high powered field (hpf) in 5 hpfs, and/or
 - Duodenum: ≥30 eos/hpf in 3 hpfs
- 160 Patients 2 arms
 - 80 patients 1.0, 3.0, 3.0, 3.0, 3.0, 3.0 mg/kg antolimab
 - 80 patients placebo
- 6 monthly doses

Same patient population as Phase 2 ENIGMA study



Symptoms Assessed With the Same PRO Questionnaire Used in ENIGMA

EG/EoD Questionnaire[©]

- Developed in accordance with FDA guidance on PRO development
- Captures the symptoms of EG/EoD patients on a daily basis
- Measures symptoms each on a scale of 0-10
- Co-primary symptomatic endpoint will consist of the TSS-6 (in bold):
 - Abdominal pain
 - Nausea
 - Early satiety
 - Vomiting

- Loss of appetite
- Abdominal cramping
- Bloating
- Diarrhea

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Phase 3 EG/EoD Endpoints

Histologic Co-Primary Endpoint

- Proportion of responders:
 - Stomach: ≤4 eos/hpf in 5 hpfs, and/or
 - Duodenum: ≤15 eos/hpf in 3 hpfs

Symptom Co-Primary Endpoint

• Absolute change in patient reported TSS-6

Key Secondary Endpoints

- Percent change in tissue eosinophils
- Treatment responders: patients who achieve tissue eosinophil thresholds AND >30% improvement in TSS-6

Phase 3 study has >90% power



Phase 2 ENIGMA Results Analyzed Against Phase 3 Endpoints (ITT)

Co-Primary I	Endpoints	Antolimab 3 mg/kg	Placebo	p – value
Histologic Endpoint ¹	Proportion of Responders	95%	0%	<0.0001
Symptom Endpoint ²	Mean Absolute Change in TSS-6	-16.6	-8.1	0.0162
	Mean Percent Change in TSS-6	-59%	-27%	0.0033

1 Responder: Patients who achieve \leq 4 eos/hpf in 5 hpfs in the stomach and/or \leq 15 eos/hpf in 3 hpfs in the duodenum 2 TSS-6: Total score of 6 symptoms (abdominal pain, nausea, bloating, early satiety, abdominal cramping, and loss of appetite)

Phase 2/3 Eosinophilic Esophagitis (EoE) Study Design



Phase 2/3 Eosinophilic Esophagitis (EoE) Study

Study Design

- Multi-center, randomized, double-blind, placebo-controlled study in Eosinophilic Esophagitis
- Patients (12 to 80 years old) with active moderate to severe symptoms
- Biopsy confirmed EoE
 - Esophagus: ≥15 eos in 1 hpf
- 300 Patients 3 arms
 - 100 patients 1.0, 3.0, 3.0, 3.0, 3.0, 3.0 mg/kg antolimab
 - 100 patients 1.0, 1.0, 1.0, 1.0, 1.0, 1.0 mg/kg antolimab
 - 100 patients placebo
- 6 monthly doses



Phase 2/3 Eosinophilic Esophagitis Endpoints

Histologic Co-Primary Endpoint

• Proportion of responders: ≤6 eos/hpf in 1 hpf in the esophagus

Symptom Co-Primary Endpoint

• Absolute change in patient reported Dysphagia Symptom Questionnaire (DSQ)

Key Secondary Endpoints

- Percent change in esophageal tissue eosinophil count
- Percent change in DSQ score

Follows 2019 FDA EoE Guidance



Phase 1 Subcutaneous Healthy Volunteer Study



Study Design

- Phase 1 single-dose, placebo-controlled study
- 50 healthy volunteers
- Doses assessed:
 - SC: Antolimab 0.3, 1.0, 3.0, 5.0 mg/kg and placebo
 - IV: Antolimab 1.0, 3.0 mg/kg
- Data available: Q4 2020



Mast Cell Gastrointestinal Disease (MGID) Patients with Chronic GI Symptoms and Elevated Mast Cells



ENIGMA Screening Patient Distribution



16 of 88 symptomatic patients had elevated mast cells only



1 65 met all enrollment criteria for ENIGMA; 1 patient had elevated eos only

Phase 1 Mast Cell GI Disease (MGID) Study

Study Design

- Multi-center, open-label, multi-dose, Phase 1 study
- Active moderate to severe symptoms as measured by PRO used in ENIGMA
 - N=7 patients
- Biopsy confirmed elevated mast cells
 - Stomach: ≥30 mast cells/high powered field (hpf) in 5 hpfs, and/or
 - Duodenum: ≥30 mast cells/hpf in 3 hpfs
- 6 monthly doses
 - 0.3, 1.0, 3.0, 3.0, 3.0, 3.0 mg/kg antolimab



Baseline Gastrointestinal Eosinophils and Mast Cell Counts





EG/EoD and MGID Patients Have Similar Symptomatic Burden

EG/EoD patients (n=65) MGID Patients (n=7) **Reported Symptom Intensity During Screening (0-10)** Symptom Mean 5.4 Early Satiety 4.3 5.1 Bloating 3.7 4.8 Abdominal Pain 4.1 4.6 Abdominal Cramping 3.4 4.5 Loss of Appetite 4.1 4.0 Nausea 4.3 2.8 Diarrhea 1.9 8.0 Vomiting 1.3



64% Improvement in Total Symptom Score







Improvement Across All Symptoms Measured

MGID: PRO Symptom Score Antolimab (n=7)





MGID: Histologic Results



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MGID: Safety Summary

- Generally well tolerated
- Most common AE was infusion related reactions (IRR), all of which were mild
- No drug-related SAEs



EGID & MGID Prevalence Study



EGID & MGID Prevalence Study

Study Design

- Multi-center study to assess prevalence of EGIDs and MGID in patients with chronic functional GI symptoms with or without diagnosis of Irritable Bowel Syndrome (IBS), Functional Dyspepsia (FD), or Chronic Gastritis
- Biopsies from >200 adult patients with active moderate to severe symptoms as assessed by PRO questionnaire used in ENIGMA and Phase 3 EG/EoD study
- Primary endpoint: Proportion of patients with EG, EoD, or MGID
- Study initiated late January, data expected H2 2020





Recently initiated Phase 3 EG/EoD and Phase 2/3 EoE studies

First group dosed in subcutaneous healthy volunteer study

Antolimab improves symptoms in patients with chronic GI symptoms and elevated mast cells (MGID)

EGID & MGID prevalence study in patients with chronic functional GI disease is well underway







Strong Balance Sheet and Significant IP Protection

Cash, Cash Equivalents and Investments in Marketable Securities as of Dec 31, 2019	\$495.9M
Q4 2019 Operating Expenses	\$26.9M



- Antolimab US patents first to expire 2035
- Lonza currently manufactures antolimab



Anticipated Near-term Milestones





Thank you

Q&A