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Developing Therapeutic Antibodies Targeting Allergic, Inflammatory and Proliferative Diseases

Phase 2 Eosinophil Gastritis and Gastroenteritis Study Results

Aug 5, 2019

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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**

Overview

Robert Alexander, PhD
CEO – Allakos

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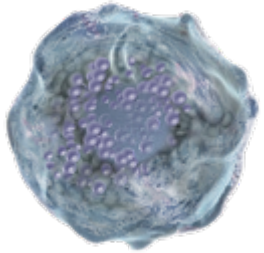
Mast Cells and Eosinophils: Effector Cells Central to Initiating and Maintaining Inflammatory Responses



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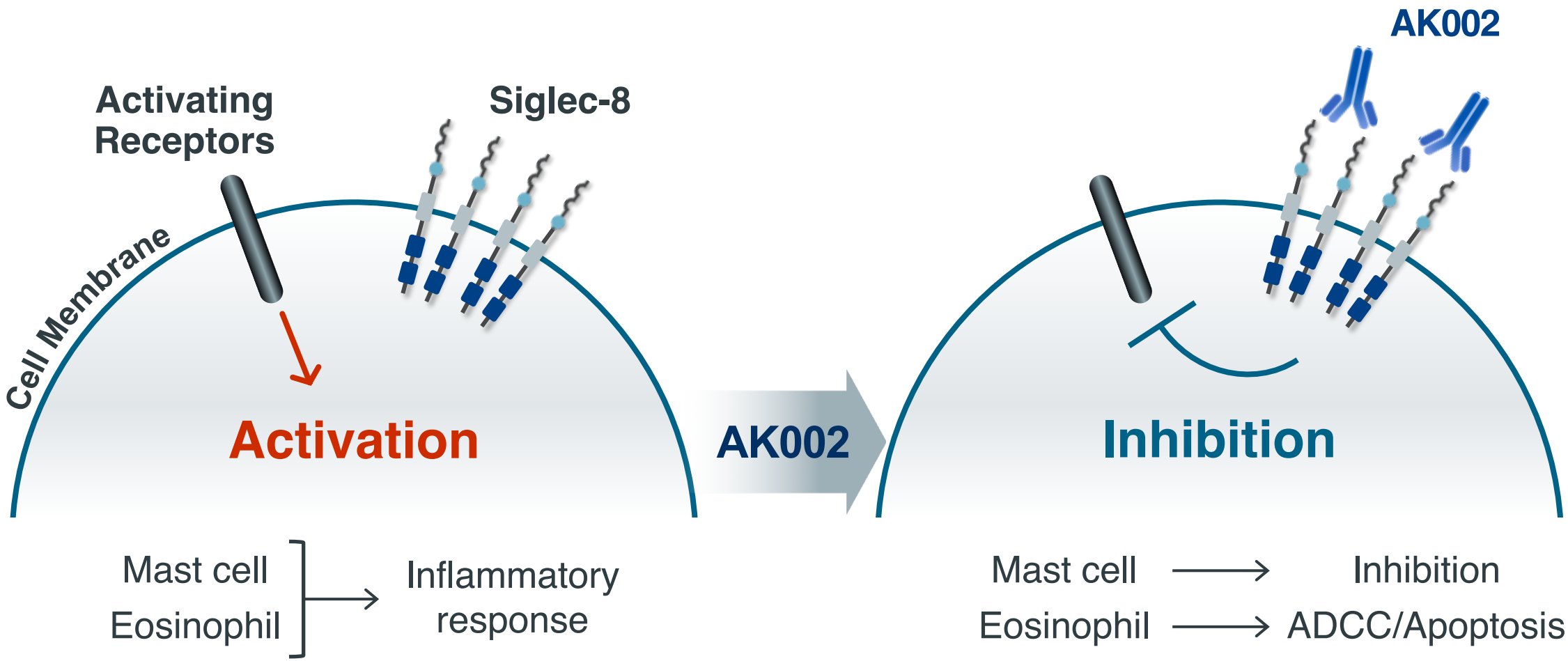
AK002 Developed to Target Siglec-8 on Mast Cells and Eosinophils



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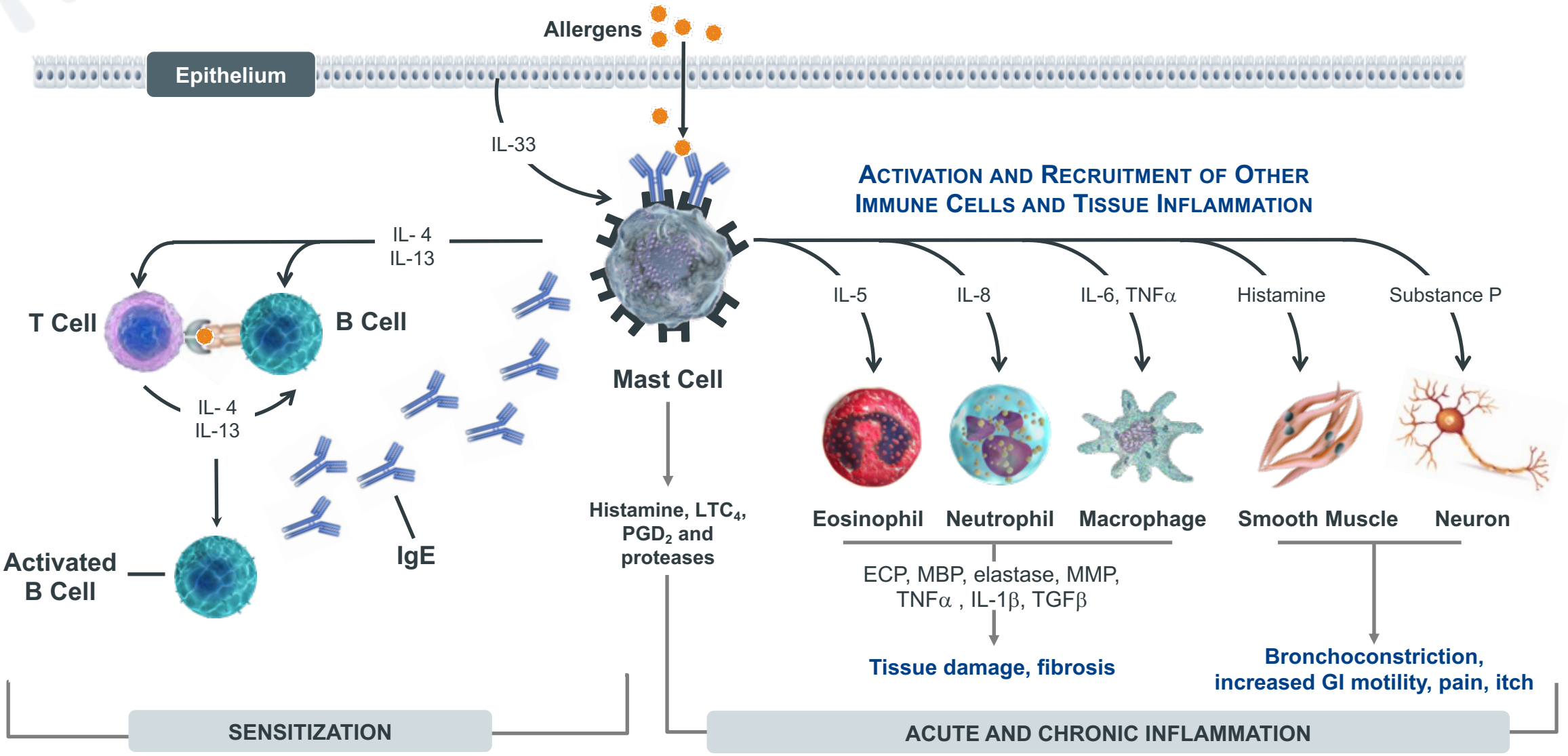
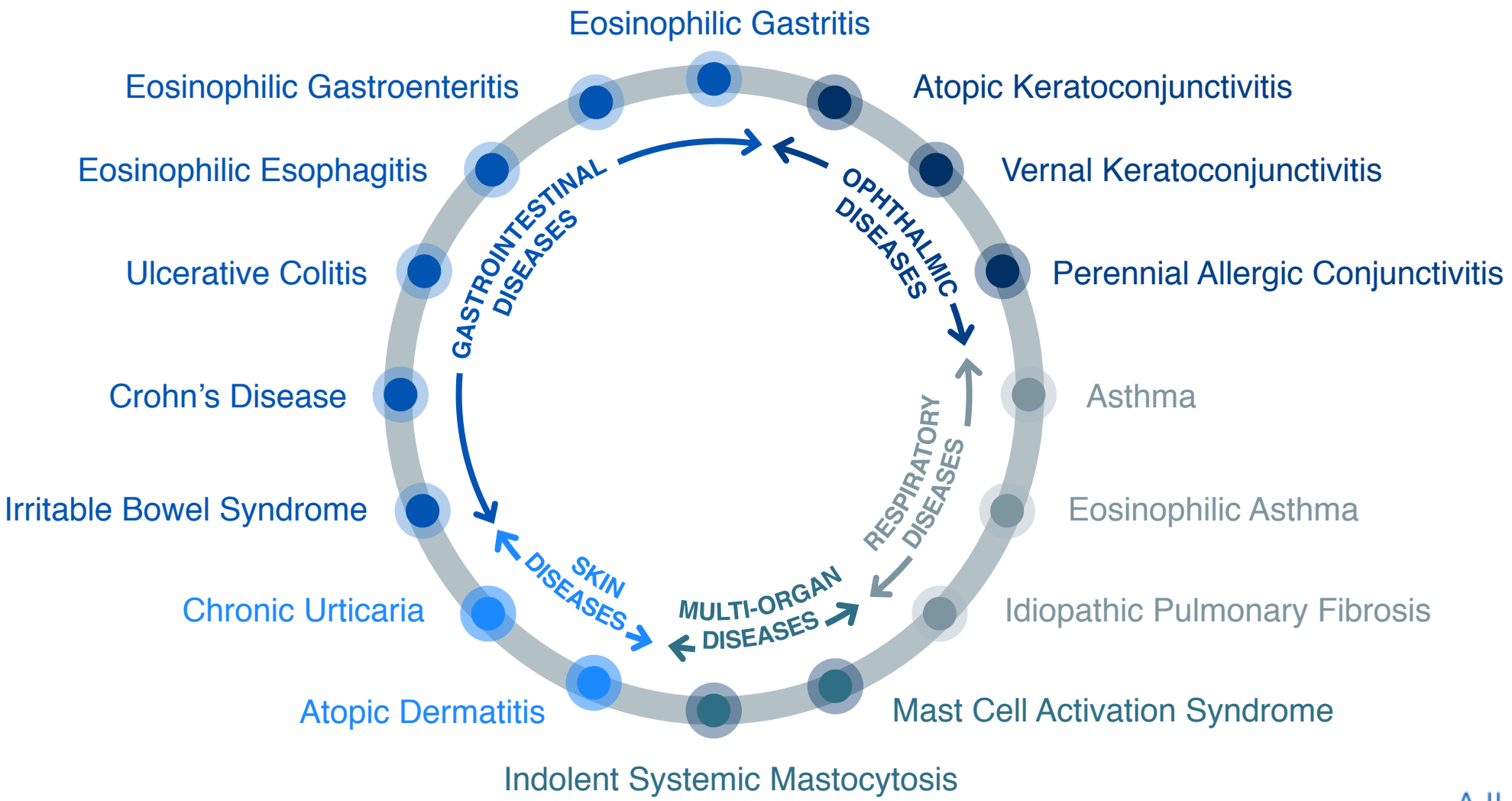
Mast Cells and Eosinophils are Key Drivers of Inflammatory Disease



Eosinophils and Mast Cells Play a Significant Role in Many Diseases



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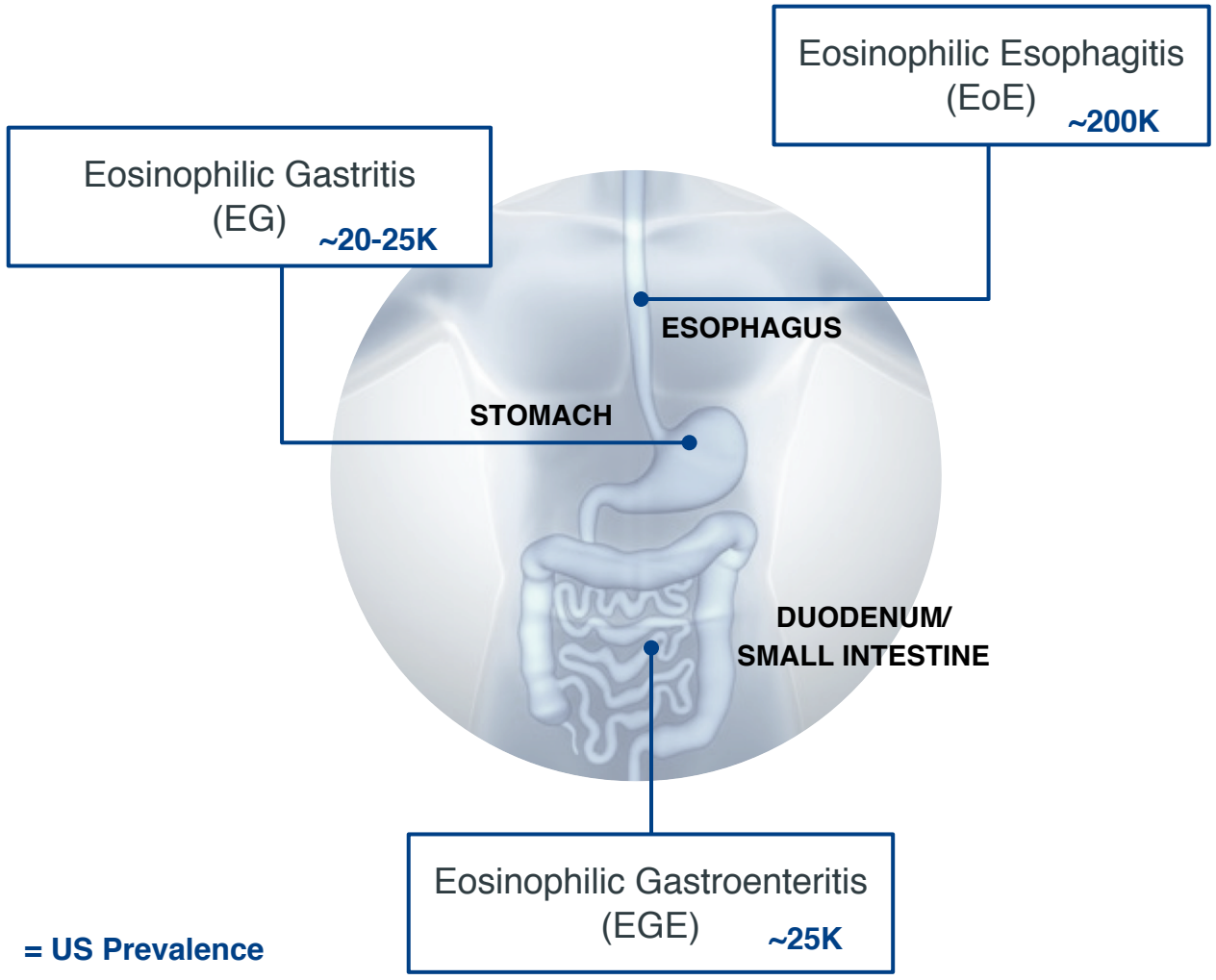
Eosinophilic Gastrointestinal Diseases (EGIDs)



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

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

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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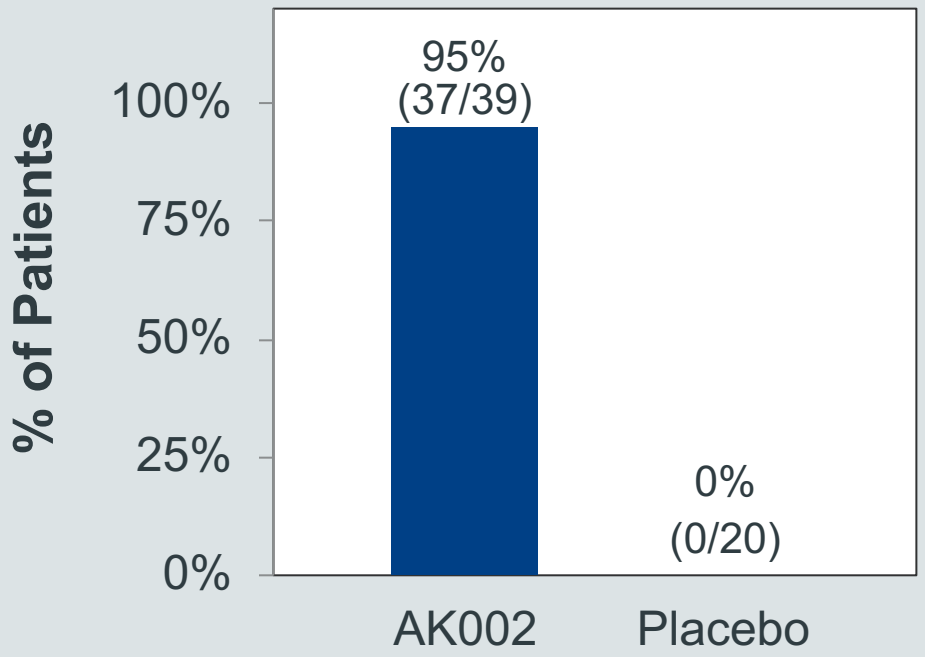
Primary Endpoint Met for All AK002 Groups

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%	-

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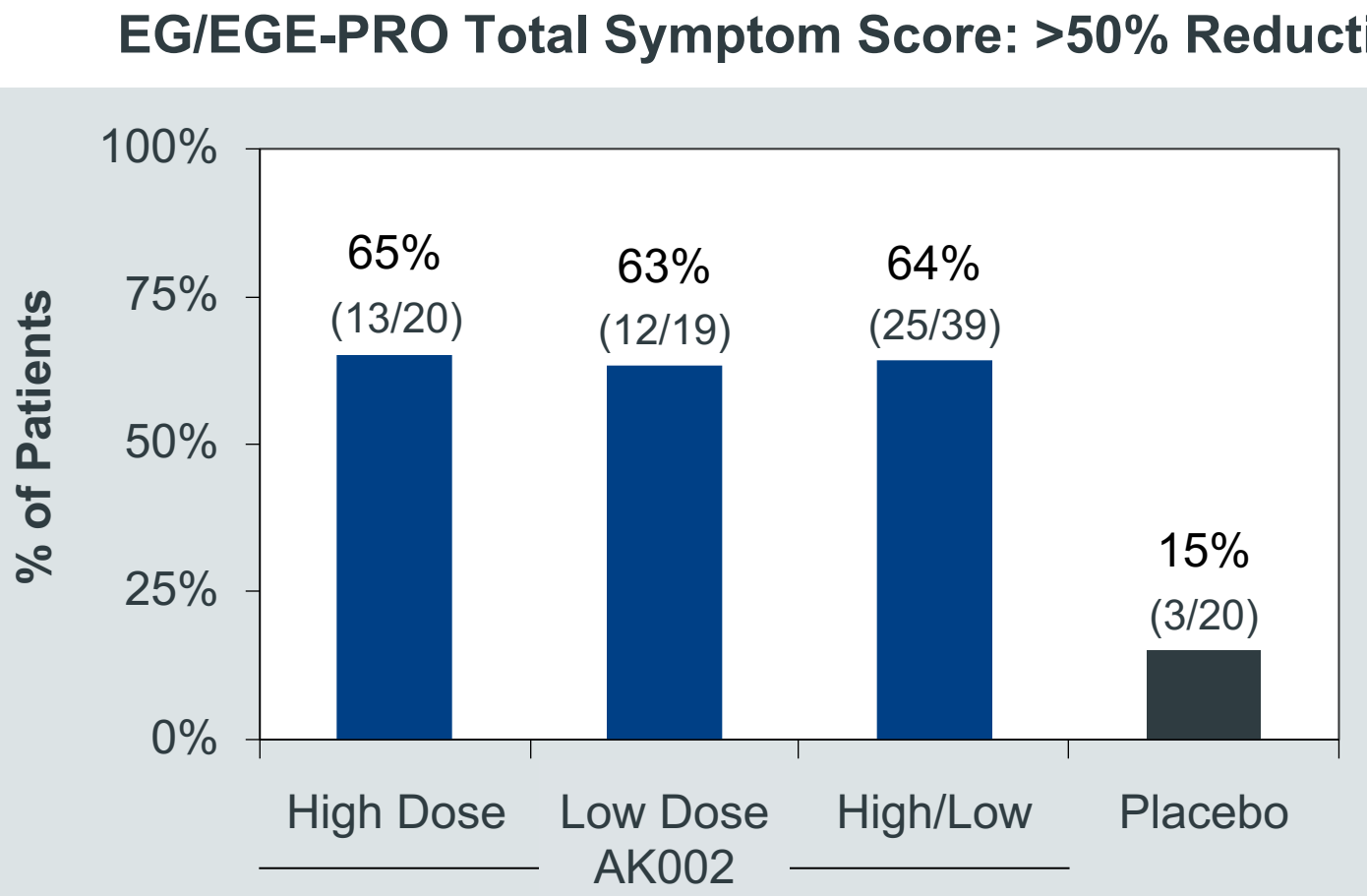
Higher Proportion of Patients with >50% Reduction in TSS on AK002 vs. Placebo



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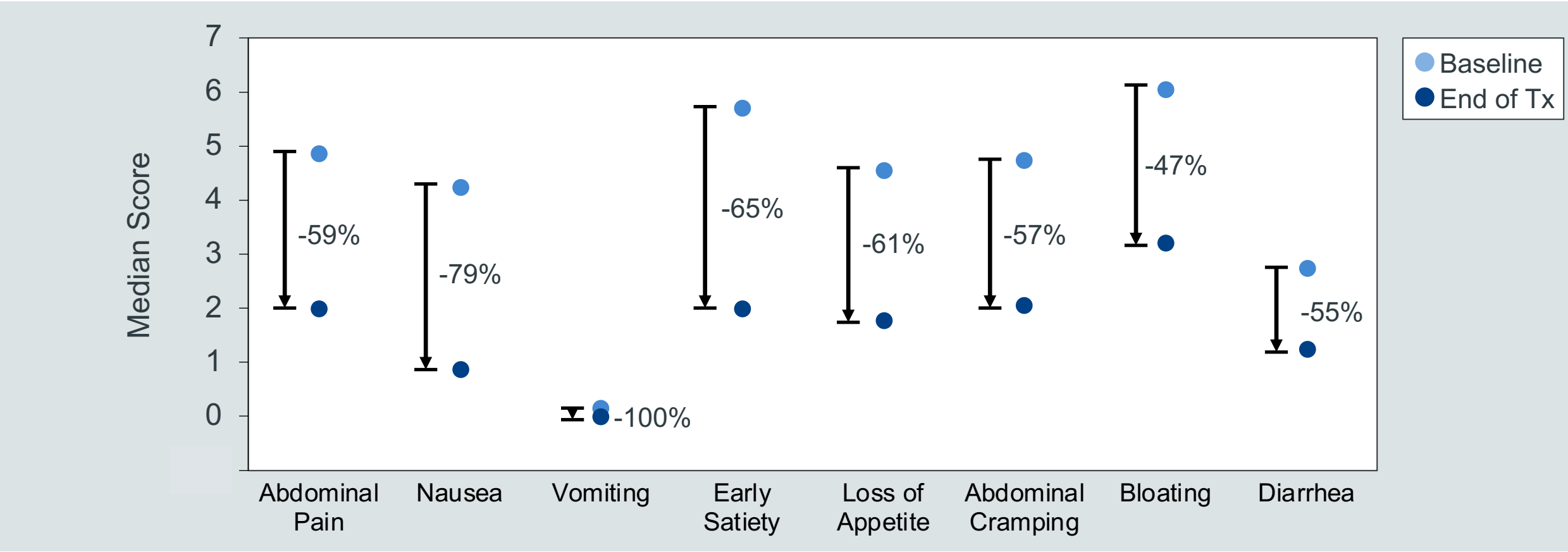
Improvement Across All Symptoms Measured on AK002



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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

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 High (n=20/16/21)	AK002 Dose Groups Low (n=19/12/22)	AK002 Dose Groups High/Low (n=39/28/43)	Placebo (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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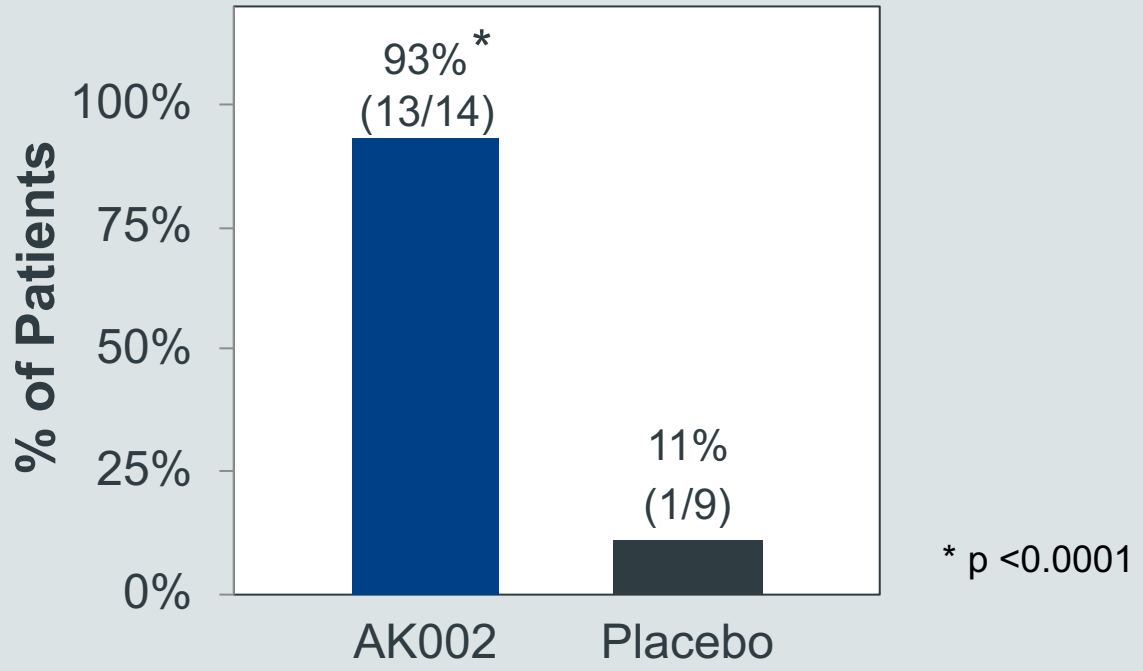
Eosinophilic Esophagitis Patients

	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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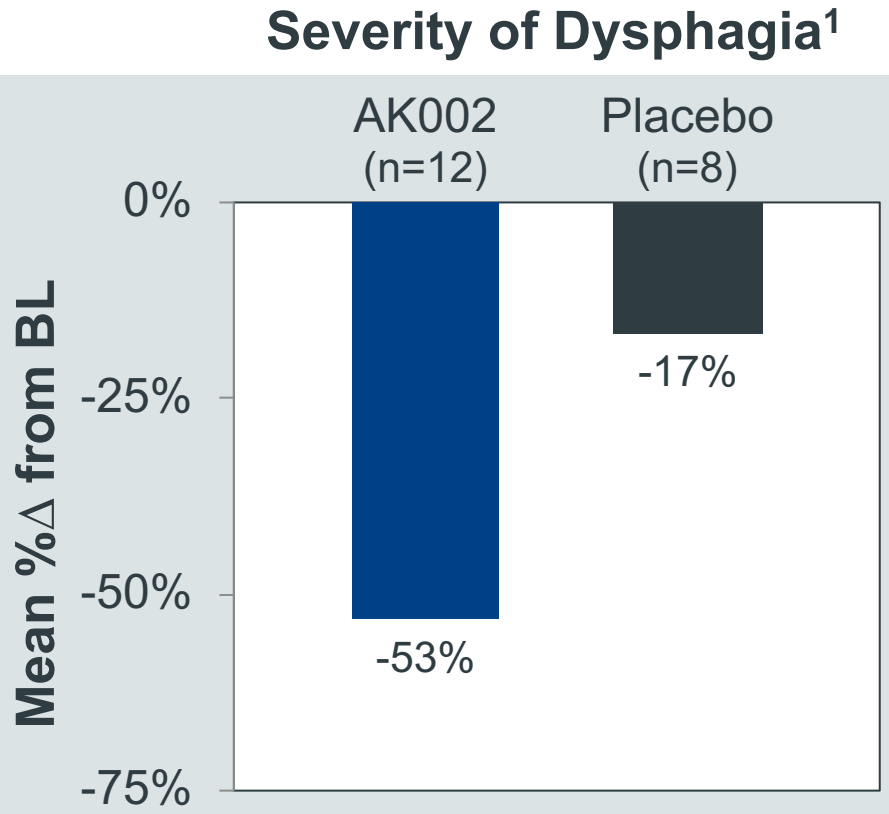
Substantial Improvement in Dysphagia



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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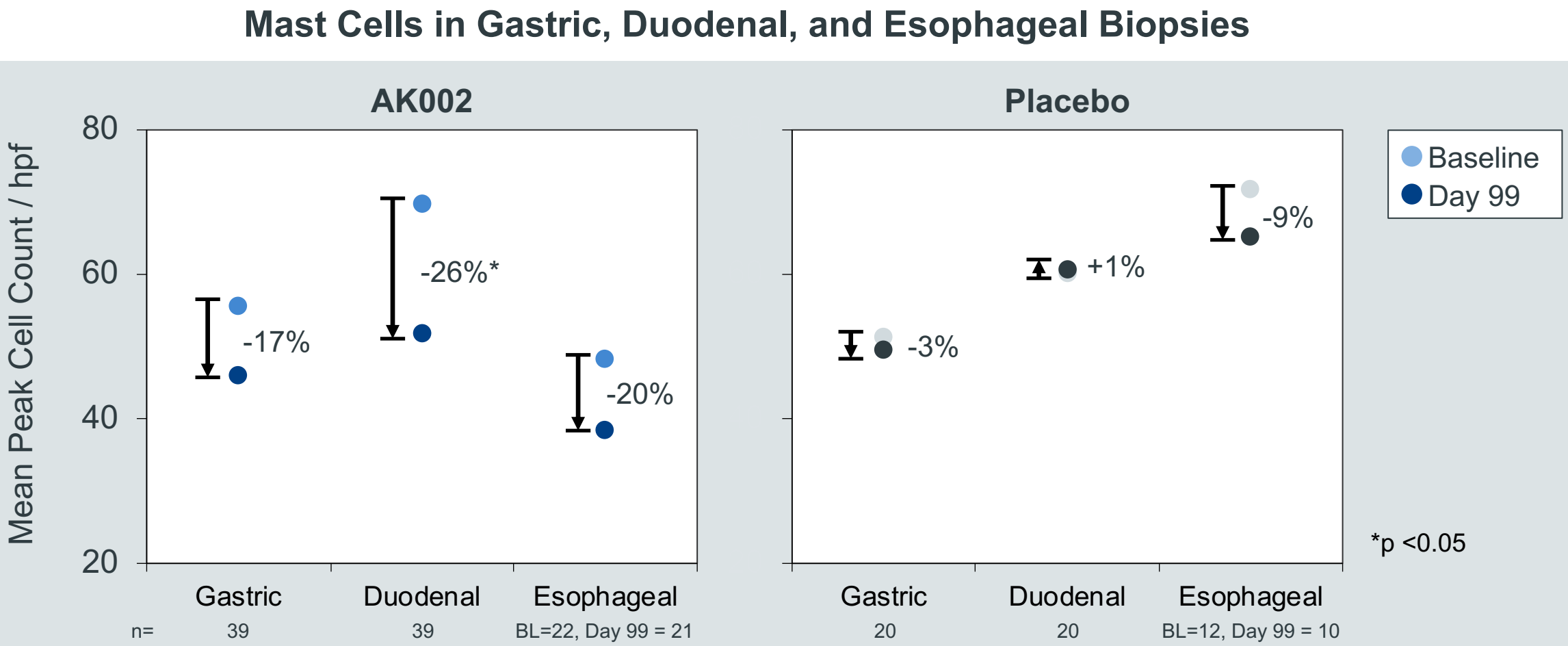
Mast Cell Counts Decrease on AK002



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

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

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

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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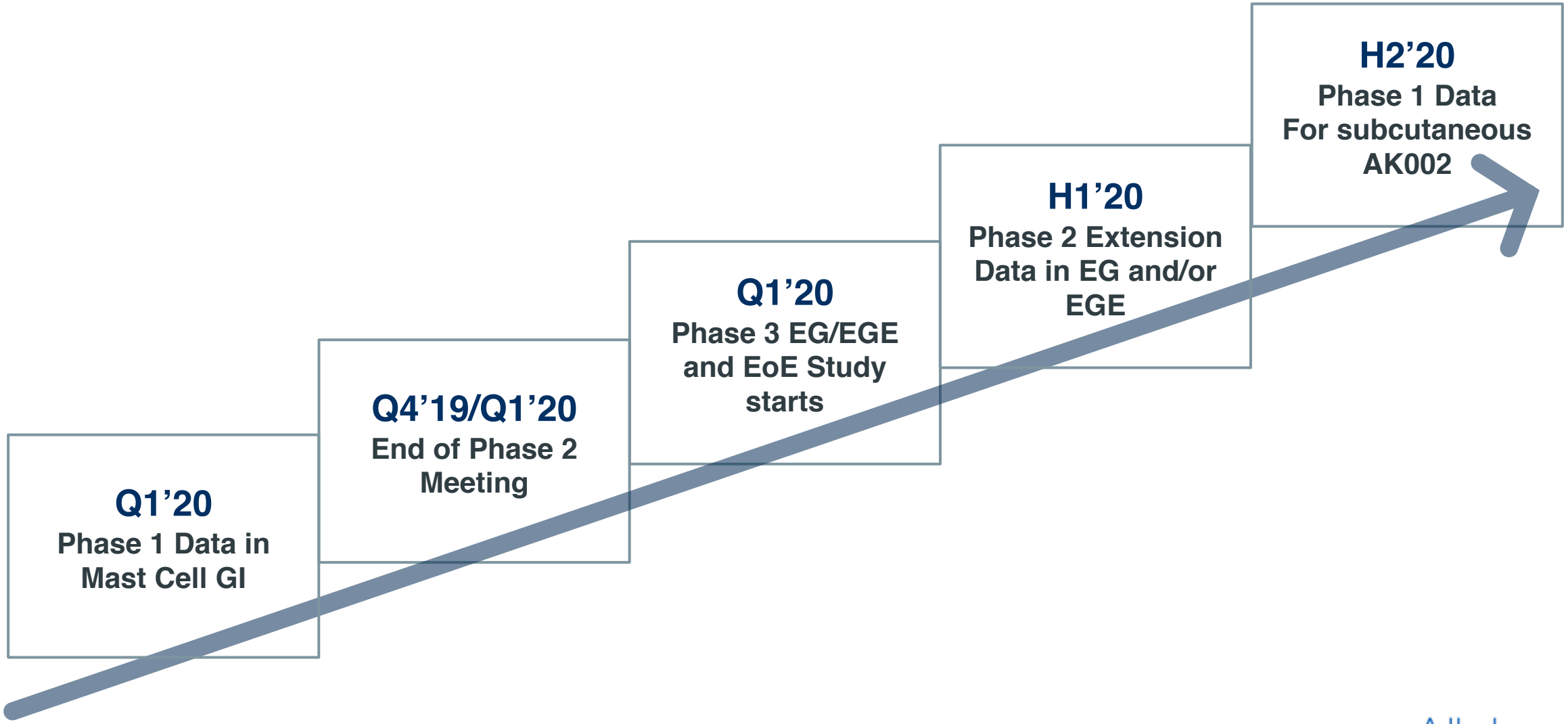
Anticipated Near-term Milestones



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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

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