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)
February 19, 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. ☒

Item 8.01 Other Events.

On February 19, 2019, Allakos Inc. (the "Company") hosted an Investor Day in New York City. A copy of the investor 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	Investor Presentation dated February 19, 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: February 19, 2019

By: /s/ Robert Alexander

Robert Alexander
President and Chief Executive Officer

Exhibit 99.1

Allakos

Developing Therapeutic Antibodies Targeting Allergic, Inflammatory and Proliferative Diseases

R&D Analyst Day

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" or the "Company"); 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 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; 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.

Allakos

Allakos R&D Day Agenda

Robert Alexander, PhD ▪ Introductions ▪ AK002	12:00 – 12:45 PM
Henrik Rasmussen, MD PhD ▪ Review of Clinical Program	12:45 – 1:00 PM
Marcus Maurer, MD ▪ Indolent Systemic Mastocytosis Phase 1 ▪ Chronic Urticaria Phase 2a	1:00 – 1:40 PM
Q&A	1:40 – 2:00 PM

Allakos

Robert Alexander, PhD
CEO – Allakos, Inc.

AK002: Introduction

Allakos

Executive Summary

- AK002 has shown clinical activity in multiple mast cell diseases
  - 3 forms of chronic urticaria (CU)
  - Indolent systemic mastocytosis (ISM)
- AK002 depletes eosinophils
  - Previously shown and confirmed in all studies to date
- Strong mechanistic and clinical support for AK002 activity in EG, EGE & EoE

AK002 has the potential to be best-in-class in multiple mast cell and eosinophilic diseases

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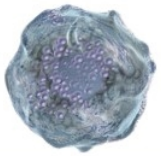
Mast Cells and Eosinophils: Effector Cells Central to Initiating and Maintaining Inflammatory Responses



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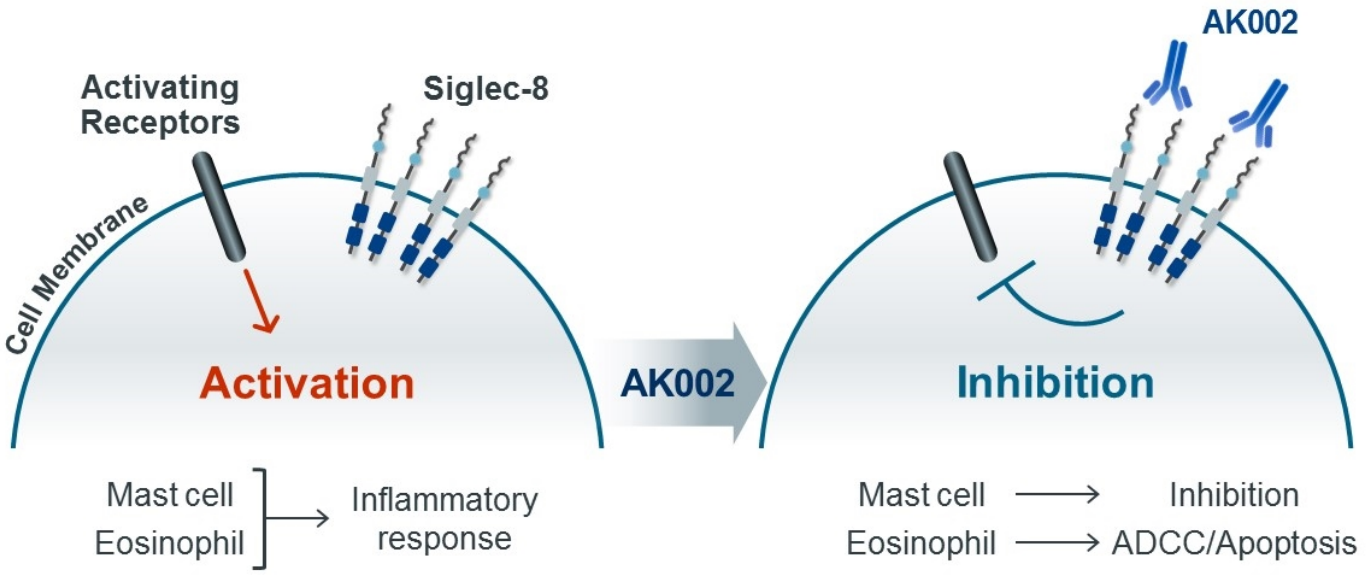
AK002 Developed to Target Siglec-8 on Mast Cells and Eosinophils



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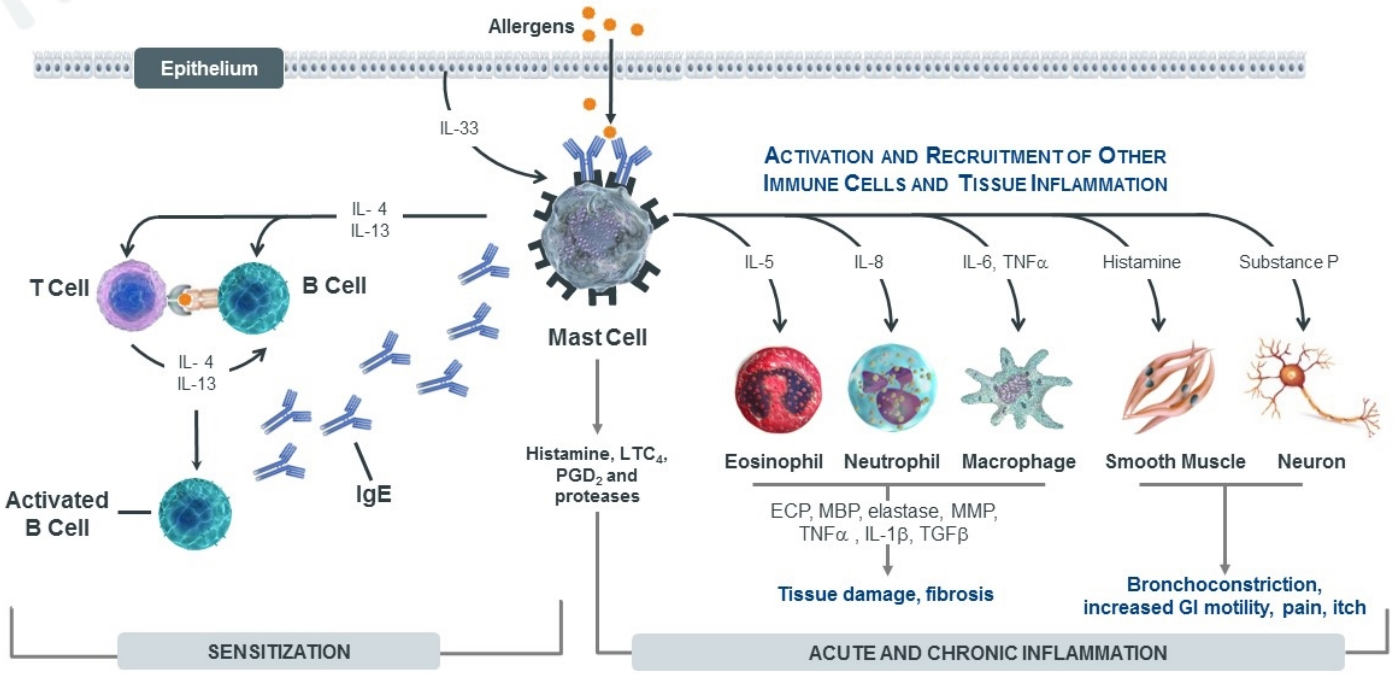
Mast Cells and Eosinophils are Key Drivers of Atopic & Inflammatory Disease



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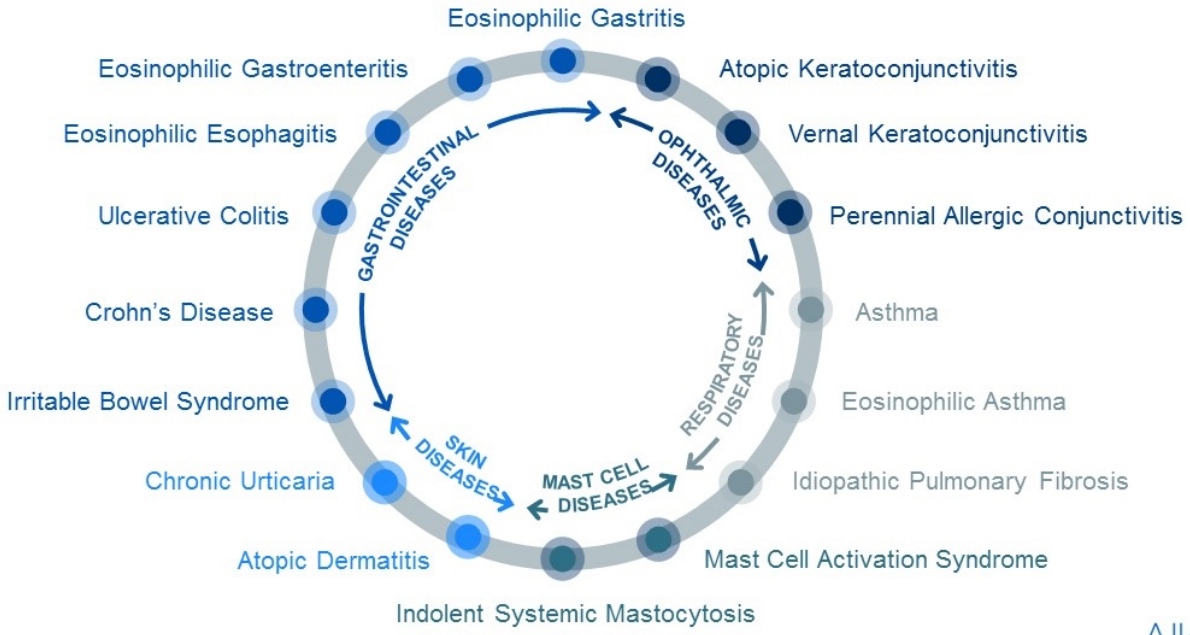
Eosinophils and Mast Cells Play a Significant Role in Many Diseases



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Current AK002 Development Status

AK002	Preclinical	Phase 1	Phase 2	Data Expected
Eosinophilic Gastritis				Mid 2019
Chronic Urticaria				Presented Today
Indolent Systemic Mastocytosis				Presented Today
Severe Allergic Conjunctivitis				Q1 / Early Q2 2019

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Development of AK002 for Eosinophilic Gastrointestinal Diseases

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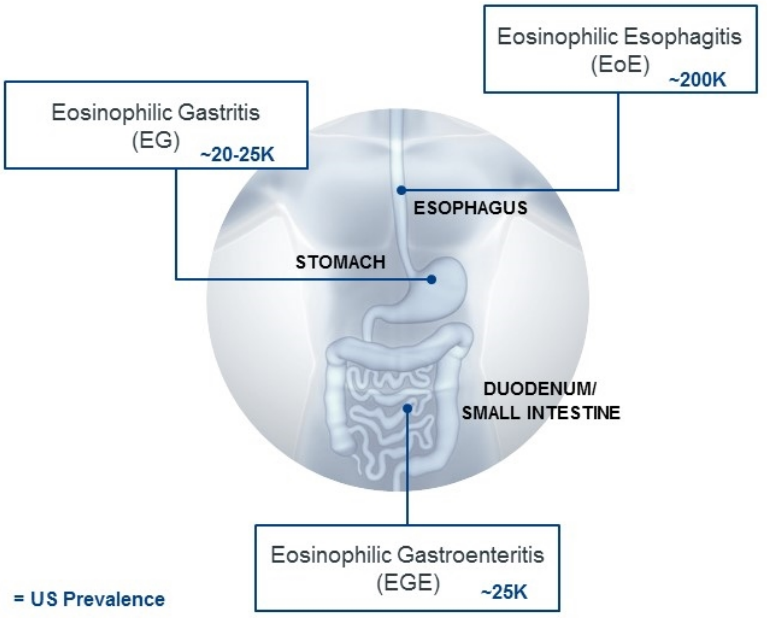
Eosinophilic Gastrointestinal Diseases (EGIDs)



EG, EGE, EoE

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

- Eosinophils and mast cells are important drivers of disease
- Severe symptoms: abdominal pain, nausea, vomiting, diarrhea, malnutrition, dysphagia
- No FDA-approved treatment for EG, EGE, or EOE
- Current standard of care: diet and/or steroids

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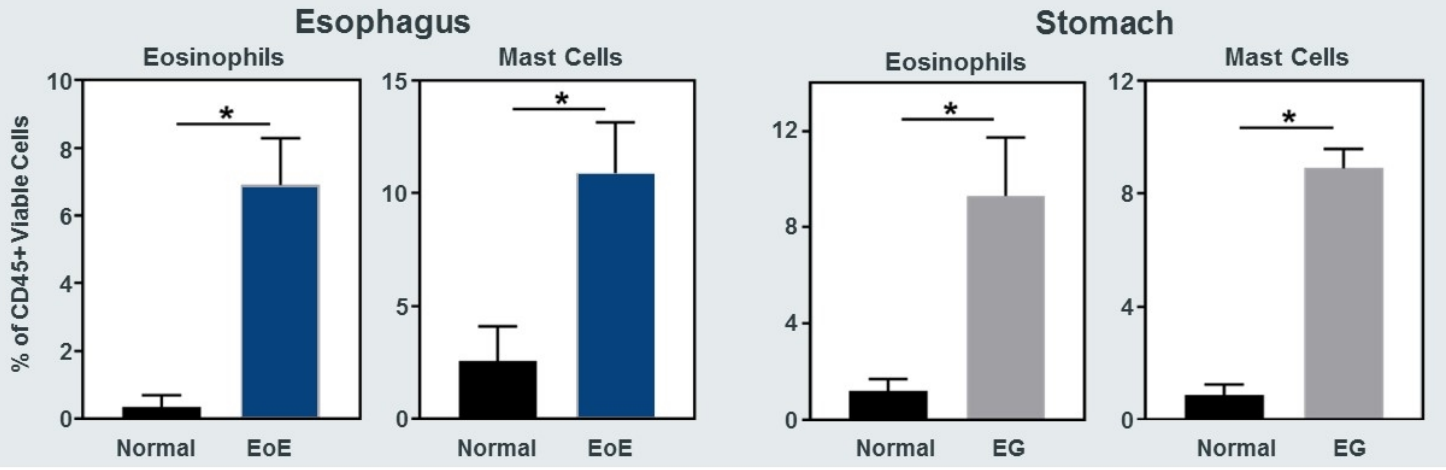
EoE and EG Biopsies Have Elevated Eosinophils & Mast Cells



Eosinophils and mast cells both appear to play a pathogenic role

* p<0.05

SOURCE: Youngblood B, et al. Gastroenterology. 2018; DDW Late Breaking Presentation.

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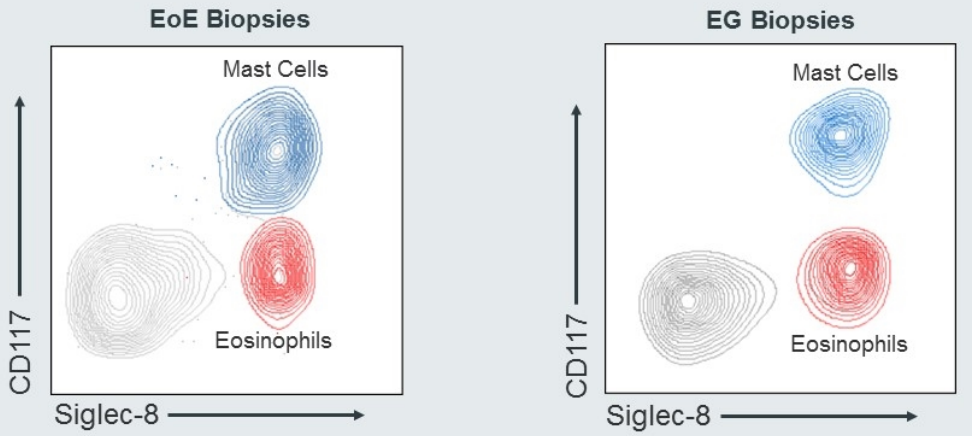
Siglec-8 is Expressed on Eosinophils and Mast Cells in EoE and EG



Siglec-8 is expressed in disease tissue

SOURCE: Youngblood B, et al. Gastroenterology. 2018; DDW Late Breaking Presentation.

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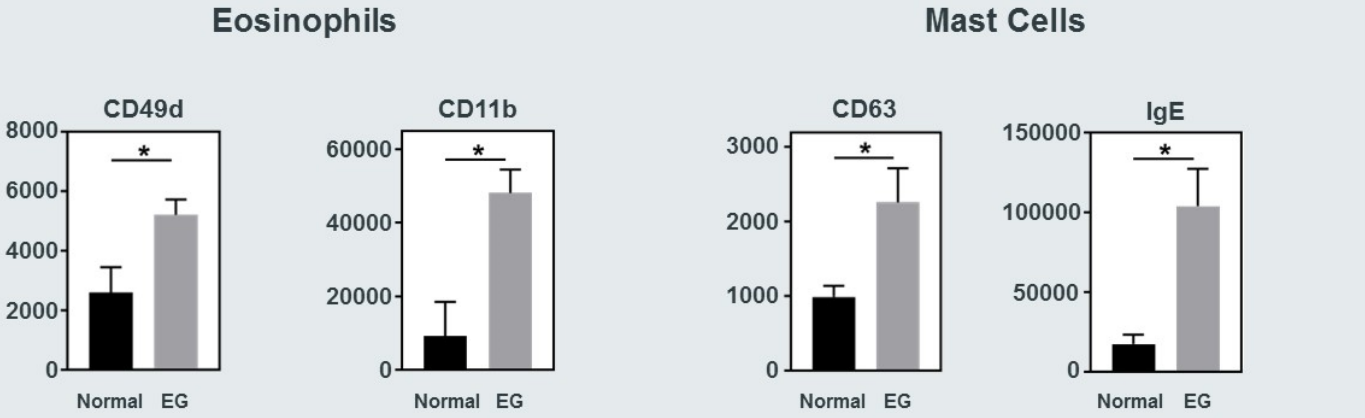
Eos and Mast Cells Are Activated in EG, EGE, and EoE Biopsies



*p<0.05

IgE appears to be a driver of mast cell activation

* p<0.05

SOURCE: Youngblood B, et al. Gastroenterology. 2018; DDW Late Breaking Presentation.

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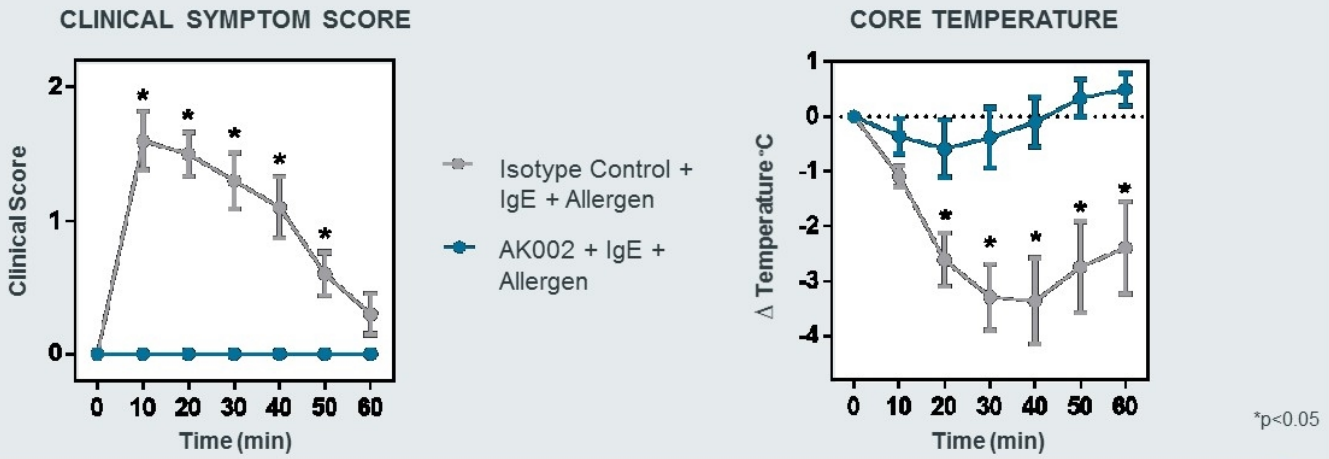
AK002 Inhibits Anaphylaxis in a Humanized Mouse Model



*p<0.05

AK002 inhibits IgE-mediated activation of human mast cells

SOURCE: Youngblood B, et al. Annals of Allergy, Asthma and Immunology. 2018; Distinguished Oral Presentation at ACAAI 2018.

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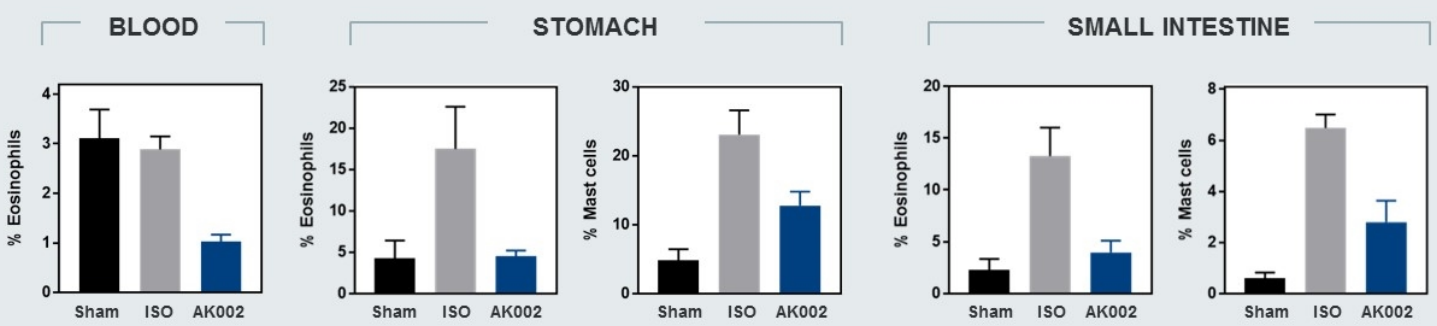
AK002 Reduces Eos & Mast Cell Infiltration in EG/EGE Mouse Model

EG + EGE Mouse Model: Eosinophil and Mast Cell Counts



SOURCE: Youngblood B, et al. Gastroenterology. 2018; DDW Late Breaking Presentation.

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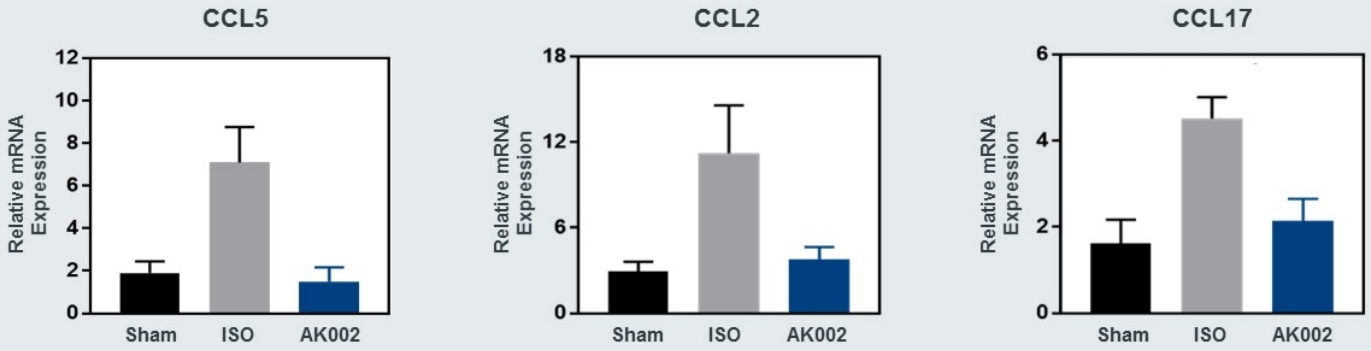
AK002 Reduces Chemokines in EG/EGE Mouse Model

EG + EGE Mouse Model: Chemokine Expression



SOURCE: Youngblood B, et al. Gastroenterology. 2018; DDW Late Breaking Presentation.

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Summary

Mast cells and eosinophils are key drivers of atopic & inflammatory diseases

Siglec-8 is constitutively expressed on mast cells and eosinophils

AK002, an anti-Siglec-8 monoclonal antibody, depletes eosinophils and inhibits mast cells

Strong mechanistic, histologic, and clinical support for AK002 activity in EG, EGE, and EoE

Allakos R&D Day Agenda

Robert Alexander, PhD ▪ Introductions ▪ AK002	12:00 – 12:45 PM
Henrik Rasmussen, MD PhD ▪ Review of Clinical Program	**12:45 – 1:00 PM**
Marcus Maurer, MD ▪ Indolent Systemic Mastocytosis Phase 1 ▪ Chronic Urticaria Phase 2a	1:00 – 1:40 PM
Q&A	1:40 – 2:00 PM

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AK002 Clinical Development Overview

Henrik Rasmussen, MD PhD

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Current AK002 Development Status

AK002	Preclinical	Phase 1	Phase 2	Data Expected
Eosinophilic Gastritis				Mid 2019
Chronic Urticaria				Presented Today
Indolent Systemic Mastocytosis				Presented Today
Severe Allergic Conjunctivitis				Q1 / Early Q2 2019

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AK002 Showed Sustained Depletion of Eosinophils in Healthy Volunteers in Phase 1 Study

P1 Study

- Randomized, double-blind placebo-controlled
- 51 healthy volunteers

	Blood Eosinophils 10^3/mL				
	PLACEBO		AK002		AK002
Dose Cohort (mg/kg)	Pre-Dose	1hr Post-Dose	Pre-Dose	1hr Post-Dose	Minimal Duration Eos Depletion
0.001	NA*	NA*	70	0	1 day
0.003	120	70	160	0	2 days
0.01	210	150	160	0	4-7 days
0.03	150	150	160	0	7-14 days
0.1	100	80	250	0	14-28 days
0.3	180	140	180	0	28 days
1.0	60	40	120	0	56-84 days

All Doses: Complete depletion of blood eosinophils within 1 hour post drug administration

* No patients randomized to Placebo
**Blood eosinophils evaluated Day 1, 2, 4, 7, 14, 28, 56, 84, 112

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Eosinophilic Gastritis ± Gastroenteritis Phase 2 Study

Design	Key Endpoints		Status

• Randomized, DB, placebo-controlled study
• 60 Patients – 3 arms
  – 20 patients 0.3, 1.0,1.0, 1.0 mg/kg
  – 20 patients 0.3, 1.0, 3.0, 3.0 mg/kg
  – 20 patients placebo
• Multiple doses (x4)
• 9 month safety exposure trial
	Primary	• Change in eosinophils per high powered field from gastric and/or duodenal biopsies	• Top line data expected Mid 2019

	Secondary	• Change in symptoms from proprietary PRO questionnaire: – Abdominal pain, nausea, diarrhea, vomiting, fullness before finishing a meal, loss of appetite, abdominal cramping, bloating, and diarrhea • Assessment of comorbid EoE	

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Severe Allergic Conjunctival Disease Phase 1b Study

Design	Key Endpoints		Status

• Open-label, pilot study
• 30 patients – 3 cohorts
  – Atopic keratoconjunctivitis
  – Vernal keratoconjunctivitis
  – Perennial allergic conjunctivitis
• Dosed once monthly for 6 months
• 6 month follow up
• 0.3 mg/kg starting dose, followed by 1.0 mg/kg then either 1.0 mg/kg or 3.0 mg/kg, based on symptoms
	Primary	• Safety and tolerability	• 30 patients enrolled
			  – 13 AKC
			  – 16 PAC
			  – 1 VKC
			• Topline data 1Q / Early 2Q 2019

	Secondary	• Changes in symptoms from Allergic Conjunctivitis Symptom (ACS) PRO:
		  – Itching, photophobia, foreign body sensation, ocular pain, and lacrimation
		• Changes in signs and symptoms: Total Ocular Symptom Score (TOSS) Investigator assessment
		  – Itching, redness, tearing, and chemosis	

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ISM Phase 1 Multiple Dose Study

Design	Key Endpoints		Status
• Open-label, pilot study • 11 ISM patients • Three week screening period • 6 Monthly Doses: 1.0 mg/kg (cohort 9) and 1.0 then 1.0-10.0 mg/kg (cohort 10)	**Primary**	• Safety and tolerability	• Complete
	Secondary	• Patient reported outcomes: – MSQ (Allakos PRO): itching, hives, skin flushing, abdominal pain, diarrhea, headache, fatigue, difficulty concentrating, musculoskeletal pain – MAS^2 (Charite developed PRO) – MC-QOL Quality of Life	

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Chronic Urticaria Phase 2a Study

Design	Key Endpoints		Status

• Open-label, pilot study
• 47 patients – 4 cohorts
  – Xolair naïve CSU
  – Xolair refractory CSU
  – Cholinergic urticaria
  – Symptomatic Dermographism
• One month screening period
• Dosed once monthly for 6 months
• 8 weeks safety follow up
• 0.3 mg/kg starting dose; increase to 1.0 mg/kg (dose 2 and 3); if UCT <12, increase to 3.0 mg/kg (dose 4, 5, and 6)
	Primary	• Change in Urticaria Control Test (UCT) from Week 22 (2 weeks post last dose)
		  – Complete Response: UCT score ≥12 and ΔUCT ≥ 3
		  – Partial Response: ΔUCT ≥ 3
		  – No Response: ΔUCT < 3
			• Complete

	Secondary	• Safety and tolerability • Change in disease activity by UAS7	

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AK002 Safety Summary

PRECLINICAL

- No adverse findings in short- and long-term toxicity studies

CLINICAL

- Approximately 140 subjects exposed to drug in clinical studies
- Generally well-tolerated
- First infusion approximately 4 hours, subsequent infusions 2-3 hours
- Mild to moderate infusion reactions (flushing, feeling of warmth, headache, nausea, or dizziness) consistent with other mAbs with ADCC activity
  - ~22% IRR rate on first infusion
  - ~3% IRR rate on subsequent infusions
  - One SAE in healthy volunteer study; resolved completely with treatment

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Professor Marcus Maurer, MD

TITLE: Professor of Dermatology and Allergy
Director of Research - Allergie Centrum Charité
INSTITUTION: Charité Universitätsmedizin Berlin
SPECIALTY: Dermatology, Allergy and Immunology
FOCUS: Urticaria, Mastocytosis, Angioedema, Pruritus, Skin Infections, Allergic Diseases

- Organizing and Scientific Committee member: GA2LEN/ UCARE, multi-national urticaria Centers of Excellence
- Editorial Board: Advances in Dermatology and Allergology
- Author/Co-Author: >500 peer reviewed publications, 40 books and book chapters

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Allakos R&D Day Agenda

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Q&A	1:40 – 2:00 PM

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AK002 in Indolent Systemic Mastocytosis
Topline Data

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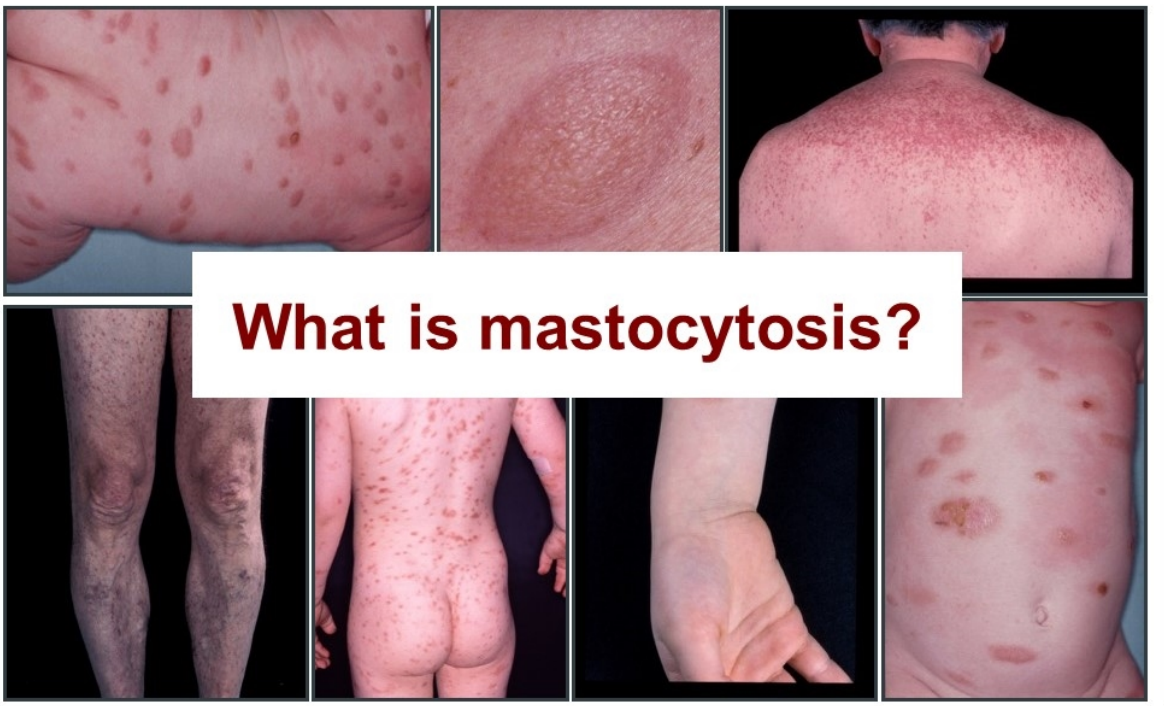
Indolent Systemic Mastocytosis (ISM)

	Indolent Systemic Mastocytosis
Disease	• Patients have increased numbers of mast cells throughout the body • Symptoms due to increased release of mast cell mediators
Symptoms	• Include itching, hives, flushing, diarrhea, headache, fatigue, difficulty concentrating, abdominal, musculoskeletal pain, and anaphylaxis
Prevalence	• Estimated to affect 30,000 people in the United States
Treatments	• No approved therapies • Standard of care: steroids, antihistamines, and mast cell stabilizers

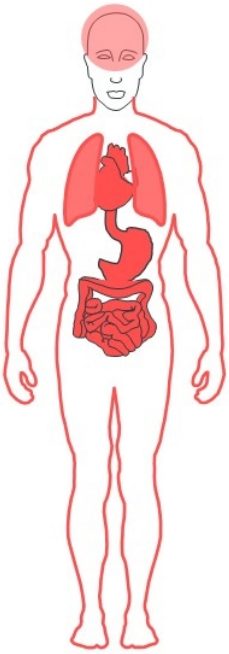


What is mastocytosis?

Indolent Systemic Mastocytosis - Symptoms

Pruritus (40%)
Flushing (36%)

Diarrhea, Vomiting (23%)
Weight loss (10%)
Peptic Ulcers (4-7%)



Fatigue, Fever (12%)
Headache (10%)

Tachycardia (18%)

Respiratory symptoms (< 5%)

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Phase 1 Multiple Dose Study in Patients with ISM

Design	Key Endpoints	
• Open-label • 11 ISM patients • 6 Monthly Doses: 1.0 mg/kg (cohort 9) and 1.0 then 1.0-10.0 mg/kg (cohort 10)	**Primary**	• Safety and tolerability
	Secondary	• Patient reported outcomes: - MSQ (Allakos ISM PRO) - MAS^2 (Charité ISM PRO) - MC-QOL (Charité ISM Quality of Life)

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ISM Study Key Inclusion/Exclusion Criteria

INCLUSION

- Adults (≥18 and ≤85 years old)
- Confirmed diagnosis of ISM based on World Health Organization (WHO) criteria
- Presence of at least 1 of the following ISM related symptoms:
  - Flushing (at least 1 episode per week)
  - Pruritus (minimum MAS score of 4)
  - Diarrhea (minimum MAS score of 4)
  - Anaphylaxis (at least 1 episode [grade 2 or higher] within the last 12 months)

EXCLUSION

- Presence of an associated hematologic non-mast cell lineage disorder or mast cell leukemia
- Use during the 30 days before screening of omalizumab (Xolair®), immunosuppressive drugs, or systemic corticosteroids with a daily dose >10 mg prednisone or equivalent

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ISM Study Baseline Patient Characteristics

	Multi-dose Patients (N=12)
Age, Median (Range)	47 (34-66)
Female	75%
Weight (kg), Median (Range)	71 (54-105)
BMI, Median (Range)	26 (20-39)
MSQ Total Symptom Score (0-90), Mean (Median)[1]	32.1 (33.3)
MAS[2] Total Symptom Score (0-36), Mean (Median)[2]	14.2 (15.7)
MC-QoL Total Score (0-108), Mean (Median)[2]	59.5 (64.8)

1 8 patients have recorded baseline MSQ
2 N=11

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Symptom Reduction by MSQ PRO

Measurement	Baseline (0-10)	Median %Δ Wk 21-22 to BL
MSQ Symptom Scores,		
Itching	3.7	-56%
Hives	4.2	-38%
Flushing (#)	4.1	-46%
Abdominal Pain	3.4	-60%
Diarrhea	2.9	-49%
Headache	3.7	-50%
Fatigue	5.1	-47%
Difficulty Concentrating	3.9	-59%
Muscle Pain	3.6	-27%
Joint Pain	3.4	-26%

MSQ PRO scores reported as intensity of symptoms on 0-10 scale
8 patients included in MSQ analysis. 3 patients from multi-dose cohort enrolled before MSQ PRO was available

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Symptom Reduction by MAS^2 PRO

Measurement	Baseline (0-4)	Median %Δ Wk 21-22 to BL
MAS^2 Symptom Scores,		
Itching	1.8	-53%
Hives	1.6	-59%
Flushing	1.7	-57%
Abdominal Pain	1.4	-84%
Diarrhea	1.0	-72%
Headache	1.5	-57%
Fatigue	2.2	-22%
Difficulty Concentrating	1.6	-30%
Bone-Joint-Muscle Pain	2.0	-22%

MAS^2 PRO scores reported as intensity of symptoms on 0-4 scale

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Improvement in Quality of Life MC-QoL

Measurement	Baseline (0-4)	Median %Δ Day 145 to BL
MC-QoL Scores (0-100),		
Symptoms	64	-39%
Social Life / Functioning	69	-42%
Emotions	48	-57%
Skin	51	-44%

MC-QoL Domains

- Symptoms: diarrhea, fatigue, headache, muscle or joint pain, difficulty concentrating; limited sleep, tired during the day due to not sleeping well; feeling less capable, lack of motivation
- Social Life/Functioning: limited in daily life in school/university/work, sexual activity, leisure time, relationships; change of food/drink, burdened by symptoms, choice of wear restricted; uncomfortable in public
- Emotions: afraid of allergic reaction, wrong treatment, worsening of mastocytosis; feeling alone with illness, concerned, sad
- Skin: itching, skin redness/swelling, flushing

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ISM Patient Case Study

Medical History

- 43 year old woman
- Diagnosed with ISM in 1993
- Suffered from severe ISM symptoms for over 20 years despite treatment
  - Tried ranitidine, fexofenadine, and steroids
- Her chief symptoms were gastrointestinal, headache and itchy skin

Response to AK002

- Patient reported significant resolution of her symptoms: GI, headache, and skin
- Would like to be back on AK002

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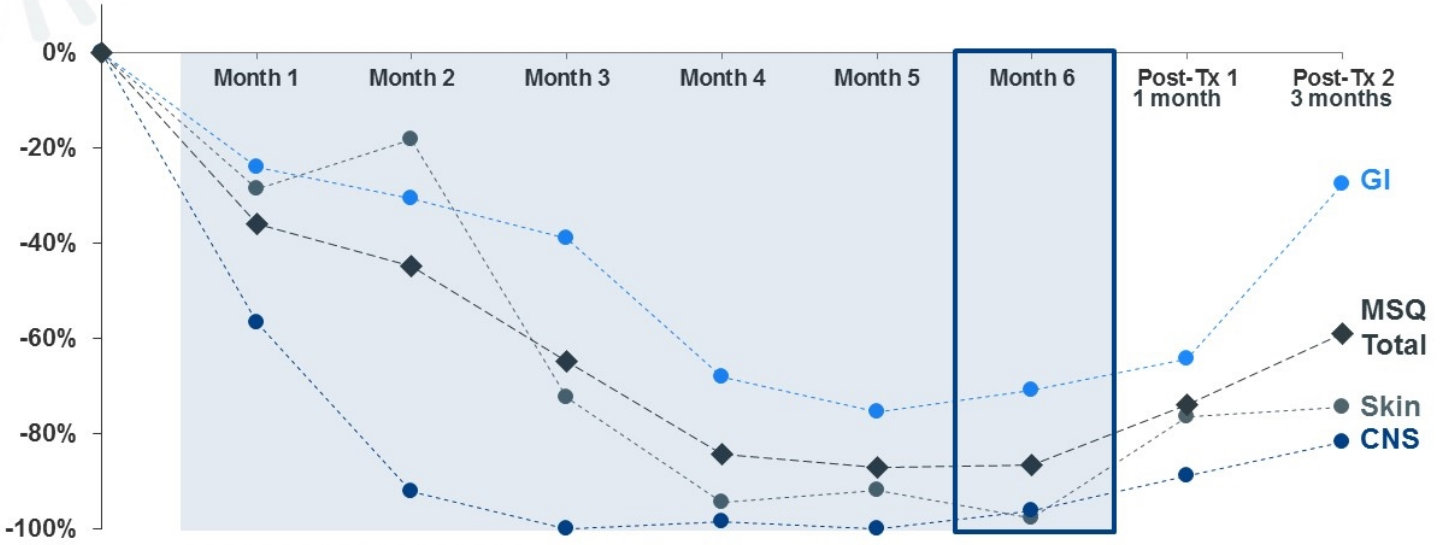
ISM Patient Case Study



- **98% reduction in skin domain** (flushing, itching, and hives)
- **96% reduction in CNS domain** (headache, difficulty concentrating, fatigue)
- **71% reduction in GI domain** (abdominal pain and diarrhea)

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ISM Phase 1: Safety Summary

- Generally well-tolerated
- All drug-related adverse events (AEs) were mild to moderate
  - The most common AEs were mild-to-moderate infusion-related reactions (feeling hot, headache, erythema, fatigue, or dizziness)
- No drug related Serious Adverse Events

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Conclusions for AK002 in ISM

Significant and consistent symptom and QoL improvements on AK002

Generally well-tolerated

Results support further development in this indication

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AK002 in Patients with Chronic Urticaria (CU)
Topline Data

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Overview of Chronic Urticaria

- Disease caused by the inappropriate activation of mast cells in the skin
- Symptoms include hives, edema, and severe itching

Chronic Spontaneous Urticaria	Cholinergic Urticaria	Symptomatic Dermographism
• Trigger: unknown • 80% of urticarias	• Trigger: increase in body temp • 6% of urticarias	• Trigger: physical skin abrasion • ~8% of urticarias

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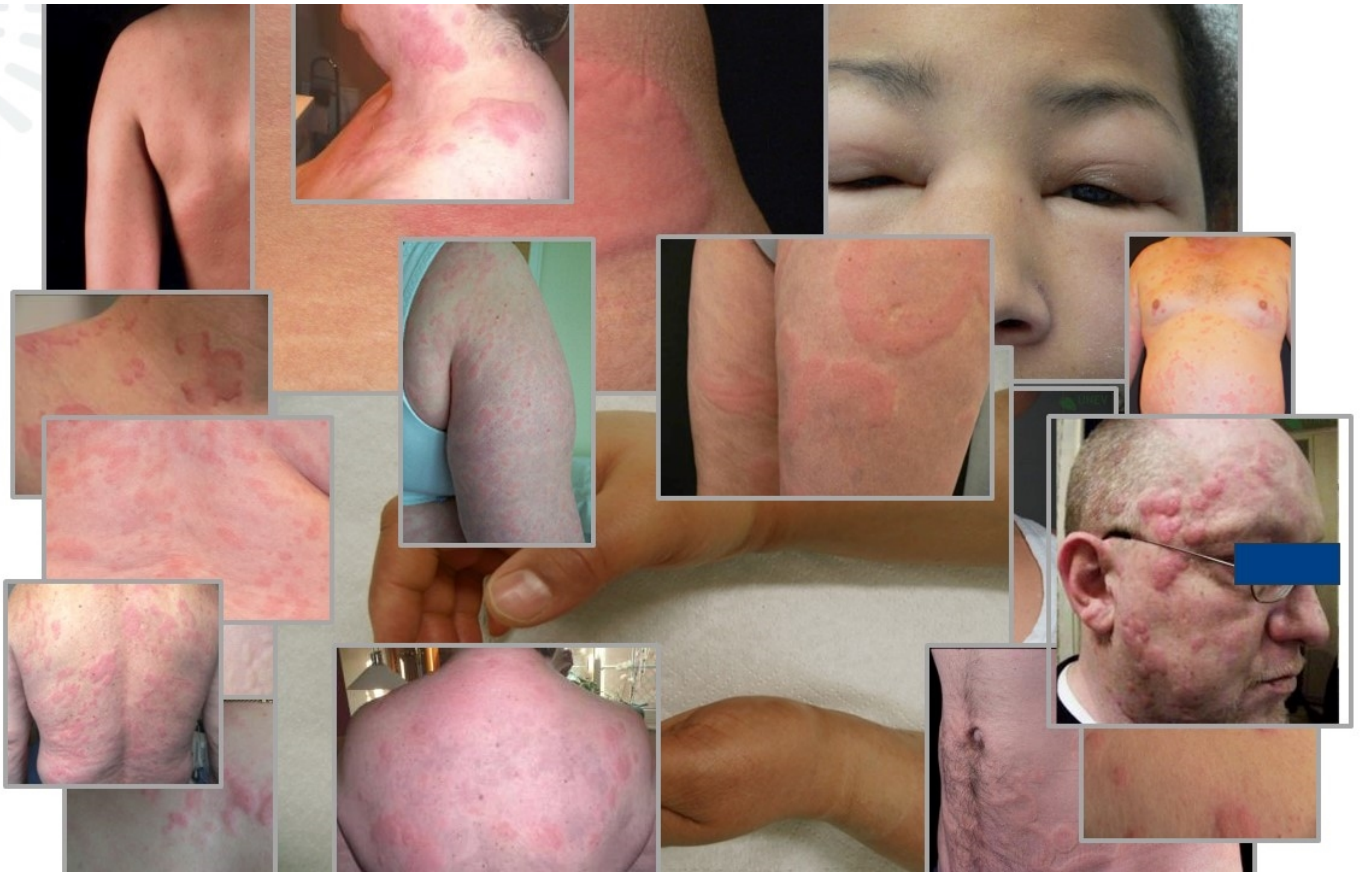
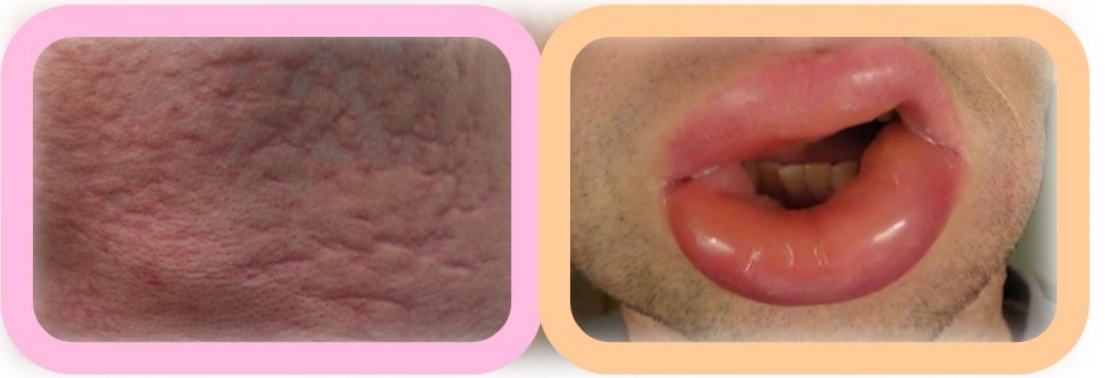
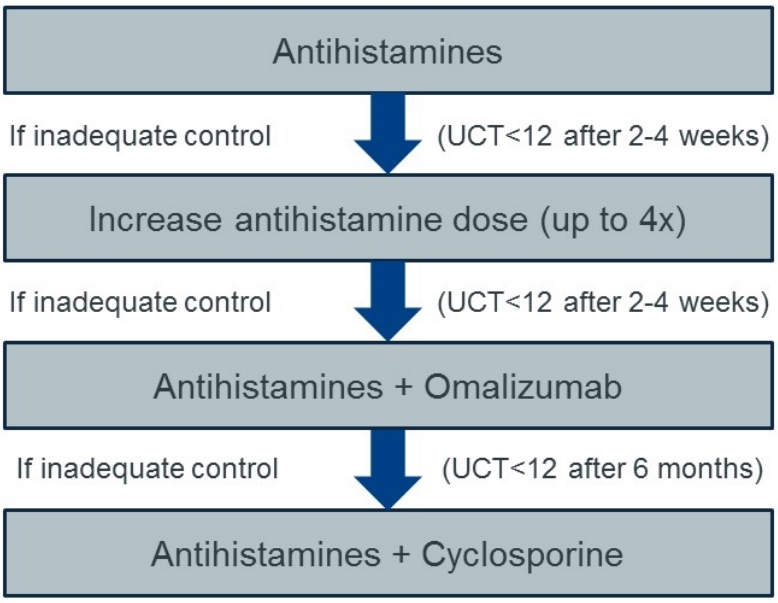


Chronic Urticaria



Itchy Wheals and/or Angioedema

EAACI CU Treatment Guidelines



SOURCE: Zuberbier et al. Allergy. 2018.

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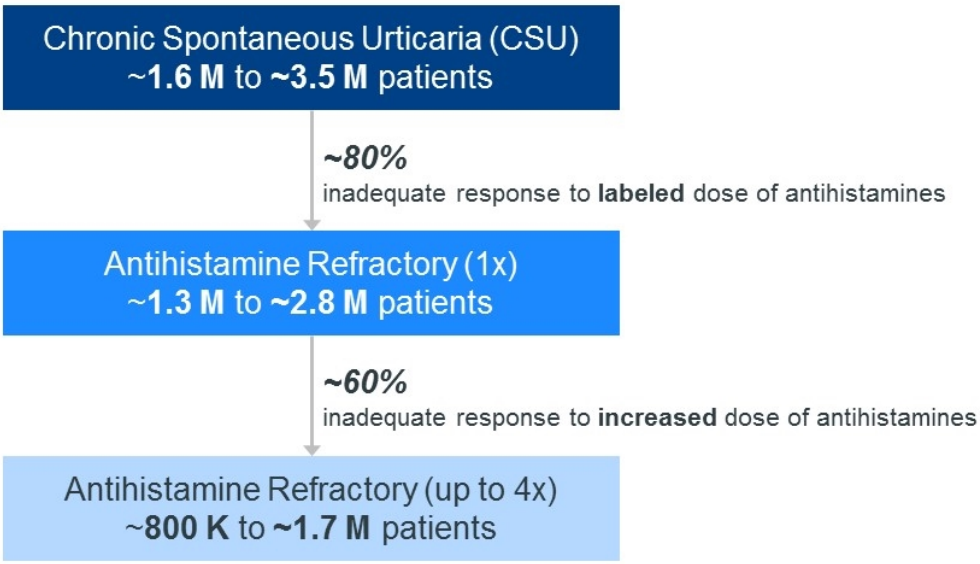
CSU Epidemiology Estimate: ~800K to 1.7M US Patients Refractory to High Dose Antihistamines



SOURCES: Maurer et al. *Allergy*. 2011 Mar;66(3):317-30; Staevska et al. *J Allergy Clin Immunol*. 2010 Mar;125(3):676-82; Van den Elzen et al. *Clin Transl Allergy* (2017) 7:4

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Many Patients Have Inadequate Response to Xolair®

	Omalizumab			Ligelizumab vs Omalizumab
	ASTERIA[1] I+II Phase III (n=322)	GLACIAL[1] Phase III (n=252)	Weller, Maurer et al.[2] (n=54)	Phase IIb[3], (n=85)
	12 Weeks	24 Weeks	8 Weeks	20 Weeks
UCT (CR)	-	-	• 63% (300 mg)	-
UAS7 %Δ from BL	• -53% (150 mg) • -70% (300 mg)	• -61% (300 mg)	-	• -61%* (oma 300 mg) • -69%* (lige 72 mg) • -69%* (lige 240 mg)
UAS7 ≤6	• 41% (150 mg) • 59% (300 mg)	• 52% (300 mg)	• 56% (300 mg)	-
UAS7 =0	• 19% (150 mg) • 40% (300 mg)	• 34% (300 mg)	• 32% (300 mg)	• 31% (oma 300 mg) • 39% (lige 72 mg) • 40% (lige 240 mg)
HSS7 =0	-	-	-	• 26% (oma 300 mg) • 51% (lige 72 mg) • 45% (lige 240 mg)

* Estimated from available data

SOURCE: 1 Saini S, et al J Invest Dermatol 2015 , Maurer M, et al NEJM 2013, Kaplan A et al JACI 2013; 2 Weller, Maurer M, et al. JACI 2019; 3 Maurer M, et al. EAACI. 2018

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Chronic Urticaria – Unmet Need

- Significant number of patients suffer from chronic urticaria
- Often high disease burden to those afflicted
- Current therapies do not always achieve disease control
- There is a need for new drugs with novel mechanisms

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Chronic Urticaria Phase 2a Study

Design	Key Endpoints	

• Open-label
• 47 patients – 4 cohorts
  - Xolair naïve CSU
  - Xolair refractory CSU
  - Cholinergic urticaria
  - Symptomatic Dermographism
• One month screening period
• Dosed once monthly for 6 months
• 8 weeks safety follow up
• 0.3mg/kg starting AK002 dose; if tolerated, increase to 1.0 mg/kg (dose 2 and 3); if UCT <12, increase to 3.9 mg/kg (dose 4, 5, and 6)
	Primary	• Change in Urticaria Control Test (UCT) Week 22 from BL
		  - Complete Response: UCT score ≥12 and ΔUCT ≥ 3
		  - Partial Response: ΔUCT ≥ 3
		  - No Response: ΔUCT < 3

	Secondary	• Safety and tolerability • Change in disease activity by UAS7

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CU Phase 2a: Key Inclusion/Exclusion Criteria

INCLUSION

- Adults (≥18 and ≤85 years old)
- Body weight <125 Kg
- Diagnosis of CU for at least three months, refractory to antihistamine treatment in single or 4-fold dosage
- Uncontrolled CU (UCT <12) at the time of enrollment

EXCLUSION

- Acute urticaria
- Concurrent/ongoing treatment with immunosuppressives or significant medical condition or illness rendering patient immunocompromised or otherwise unable to participate
- Use of omalizumab (Xolair®) within the last 2 months before screening

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Urticaria Disease Assessment Tools (1 of 2)

URTICARIA CONTROL TEST (UCT)

- Measures disease control (symptoms and quality of life)
- Used in clinical practice
- Can be used in both chronic spontaneous urticaria and chronic inducible urticarias (e.g. cholinergic and symptomatic dermographism

URTICARIA ACTIVITY SCORE (UAS)

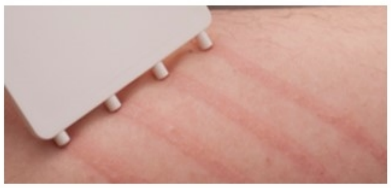
- Comprised of measures of itch & hives:
  - Itch Severity Score (ISS)
  - Hives Severity Score (HSS)
- UAS7 used as primary endpoint for regulatory approval in CSU
  - Xolair® used ISS change from BL
  - Ligelizumab Phase 3 is using UAS7 change from BL

UCT and UAS7 recommended by EAACI CU Guidelines to assess CSU disease

Urticaria Disease Assessment Tools (2 of 2)

SDerm: UCT & Fric Test®

- Instrument with 4 pins of increasing heights to trigger hives
- Presence of hives reported for each pin
- Itch reported with validated visual analog scale



Cholinergic: UCT & PCE

- Pulse Controlled Ergometry (PCE) Test utilizes a stationary bike or treadmill for the patient to trigger hives
- Positive response = hives appearing <10 mins post start of sweating
- Negative response (Responder) = no hives <10 mins post start of sweating

UCT & provocation tests are recommended by EAACI CU Guidelines to assess Chronic Inducible Urticarias

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CU Study Baseline Patient Characteristics

	XN (N=14)	XR (N=12)	CholU (N=11)	SDerm (N=10)	Total (N=47)
Age, Median (Range)	66 (30-75)	29 (22-60)	33 (18-62)	27 (19-56)	42 (18-75)
Female	93%	83%	55%	60%	75%
Weight, Median (Range)	90 (50-124)	82 (57-115)	83 (66-112)	91 (70-112)	85 (50-124)
BMI, Median (Range)	32 (20-44)	27 (20-42)	27 (23-39)	30 (22-36)	28 (20-44)
UCT, Mean[1]	3.2	3.7	5.4	5.7	-
UAS7, Mean[1]	18.5	28.7	n/a	n/a	-

1 Efficacy population: XN n=13; XR n=11; CholU n=11; SDerm n=10

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Chronic Spontaneous Urticaria (CSU)

Xolair® Naïve Cohort

Patients with inadequate response to antihistamines (up to 4x dose)

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High Levels of Response by UCT in CSU Xolair® Naïve Patients

Endpoint	Baseline	Week 22
UCT Complete Response	-	12/13 (92%)
UCT Partial Response	-	0/13 (0%)
UCT No Response	-	1/13 (8%)

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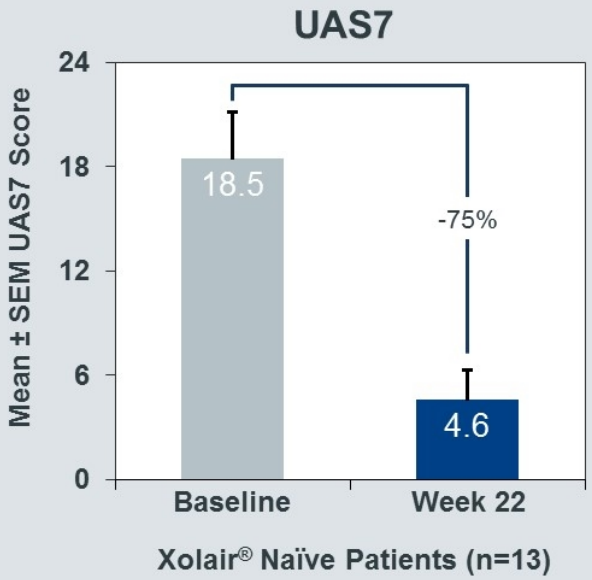
75% Improvement in Mean UAS7 in Xolair® Naïve Patients



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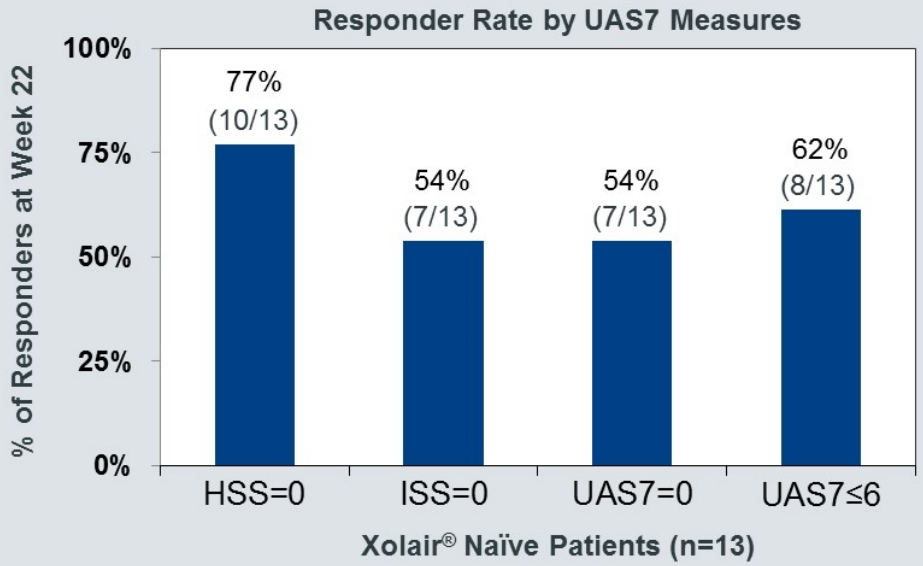
High Response Rates on AK002 by UAS7 Measures



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AK002 Xolair® Naïve Summary

Endpoint	Baseline	Week 22
UCT Complete Response	-	12/13 (92%)
UCT Partial Response	-	0/13 (0%)
UCT No Response	-	1/13 (8%)
Average UAS7 Score	18.5	4.6 (-75%)
Patients with UAS7 ≤ 6	0 (0%)	8/13 (62%)
Patients with UAS7 =0	0 (0%)	7/13 (54%)
Patients with ISS7 =0	0 (0%)	7/13 (54%)
Patients with HSS7 =0	0 (0%)	10/13 (77%)

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Chronic Spontaneous Urticaria (CSU)

Xolair® Refractory Cohort

Patients with inadequate response to Xolair and antihistamines (up to 4x dose)

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Xolair® Refractory Cohort – Medical History

CSU Patients Refractory to Xolair®

- Inadequate disease control despite extensive use of Xolair®

Prior Xolair® Treatment Experience

- **Average treatment duration:** ~10 months
- **Treatment regimen:**
  - Xolair: up to 600 mg
  - Antihistamine: up to 4x labeled dose
- **Average UCT score on Xolair:** 4.1

At Baseline for AK002 Study

- **Time since last Xolair® dose:** >2 months
- **Treatment regimen:**
  - Antihistamine: up to 4x labeled dose
- **Average UCT score at baseline:** 3.7

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Xolair® Refractory Patient Case

Medical History (2013 – 2017)

- Initially responded to Xolair®, but quickly became unresponsive within weeks
- Medications tried and failed: 4x antihistamines, Xolair® 300 mg, dapsone 50 mg for 1 month, steroids, hydroxychloroquine 200 mg for 3 months, montelukast, Xolair® 300 mg again
- Extremely severe symptoms with daily hives and itch despite these treatments
- Extreme low quality of life, very difficult to sleep with itchy hives: UCT ~ 1; UAS7 >30

AK002 Experience

- First improvement perceived after 2nd infusion (1.0 mg/kg) less hives and less itch
- By 4th dose, increased to 3.0 mg/kg with significant reduction of hives and itch and no flares
- By 5th dose, patient experienced full response: "***I can sleep. It feels like I have my life back***"
- 4 weeks post last infusion, urticaria symptoms returned and increasing in severity with flare-ups
- Patient desperately wishes to be back on AK002

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Significant Disease Control in Xolair® Refractory Pts on AK002

Endpoint	Baseline	Week 22
UCT Complete Response	-	4/11 (36%)
UCT Partial Response	-	2/11 (18%)
UCT No Response	-	5/11 (45%)

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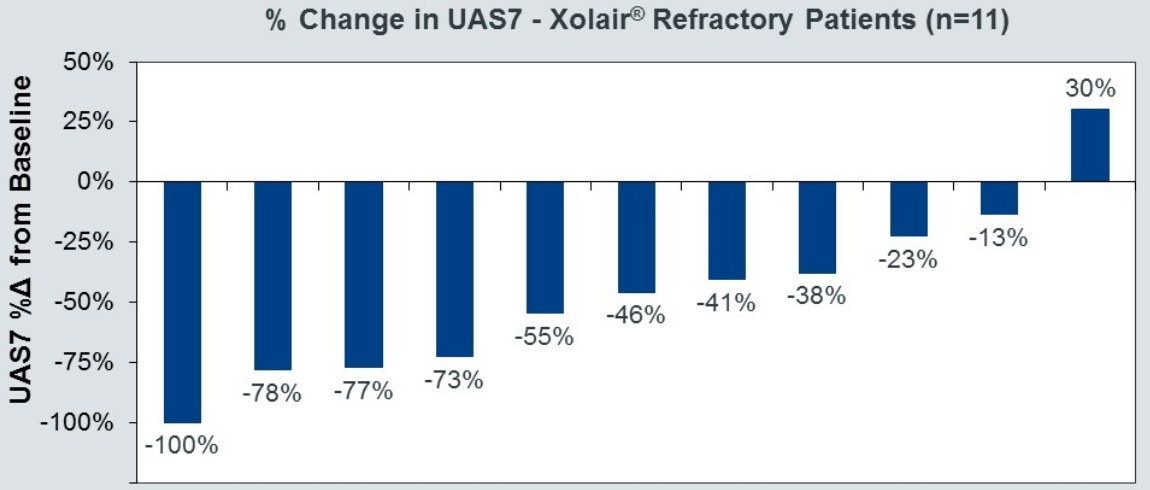
49% Improvement in UAS7 in Xolair® Refractory Patients



BL=	28	24	36	29	35	26	35	28	18	35	21
Week 22[1]=	0	5	8	8	16	14	21	18	14	30	27

1 Last observation carried forward

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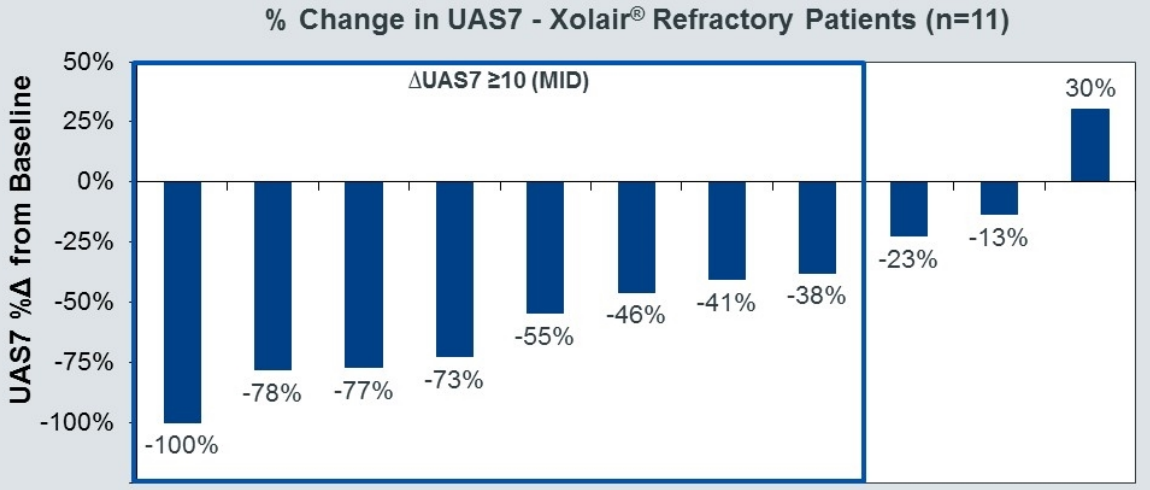
8/11 (73%) XR Patients Achieved ΔUAS7≥10 (MID)



BL=	28	24	36	29	35	26	35	28	18	35	21
Week 22[1]=	0	5	8	8	16	14	21	18	14	30	27

1 Last observation carried forward

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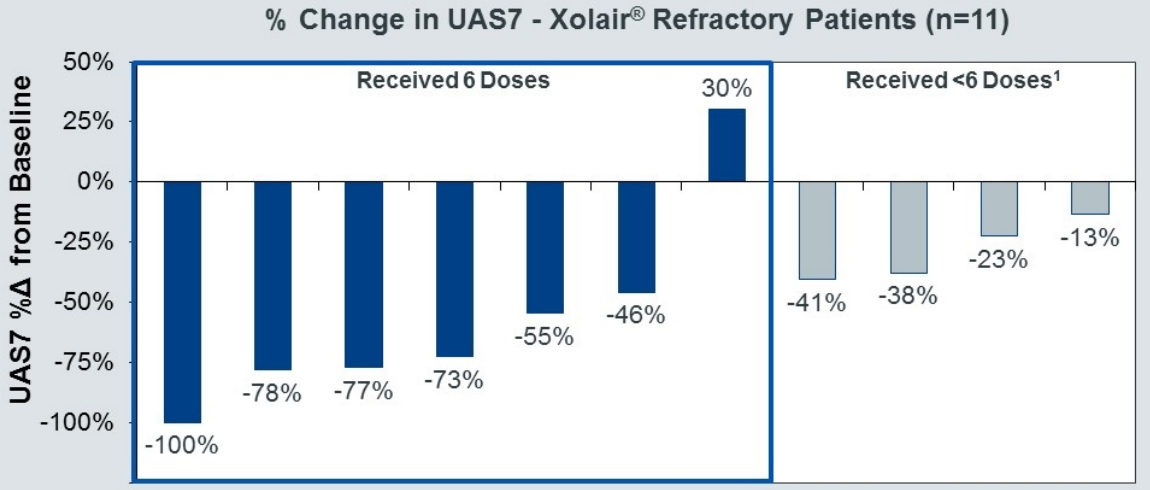
61% Improvement in UAS7 in Xolair® Refractory Patients Who Received 6 AK002 Doses



BL=	28	24	36	29	35	26	21	35	28	18	35
Week 22[1]=	0	5	8	8	16	14	27	21	18	14	30

1 Last observation carried forward: Four patients did not receive all 6 doses; 3 due to study extension, 1 patient died due to MI not related to drug

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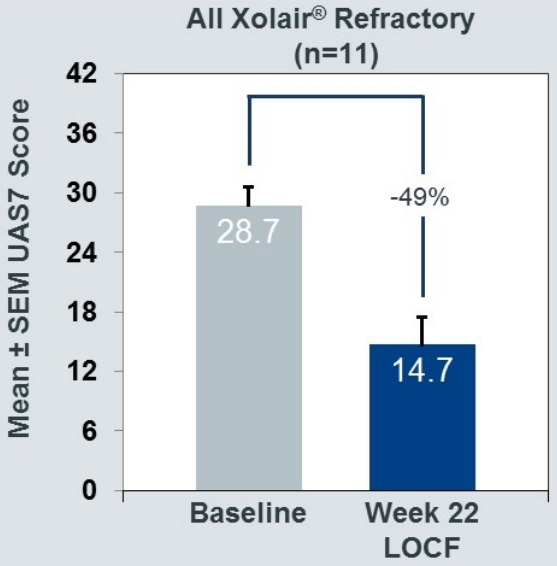
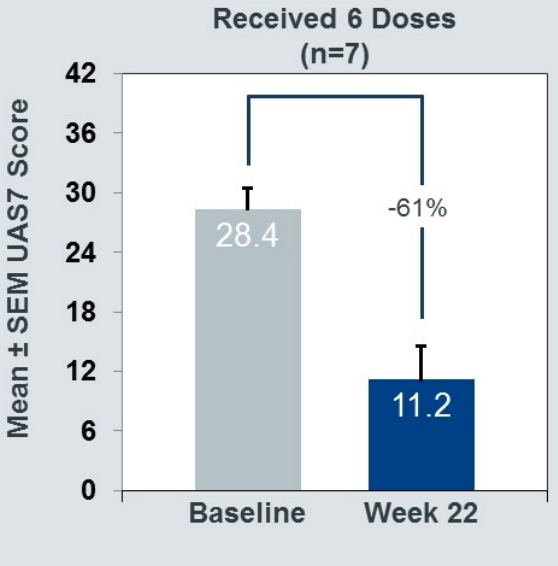
Xolair® Refractory: Mean UAS7 Score





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Meaningful Responses in CSU Xolair® Refractory Patients

Endpoint	Baseline	Week 22
UCT Complete Response	-	4/11 (36%)
UCT Partial Response	-	2/11 (18%)
UCT No Response	-	5/11 (45%)
Average UAS7 Score	28.7	14.7 (-49%)
Average UAS7, Patients with 6 doses	28.4	11.2 (-61%)
Patients with UAS7 ≤ 6	0 (0%)	2/11 (18%)
Patients with UAS7 =0	0 (0%)	1/11 (9%)
Patients with ΔUAS7 ≥10 (MID)	-	8/11 (73%)

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AK002 Clinical Activity Summary in CSU

CSU: XOLAIR® NAÏVE

- 12/13 (92%) patients achieved complete response (UCT)
- 9/13 (69%) patients reached complete response within 4 weeks (UCT)
- 75% mean reduction of symptoms by Week 22 (UAS7)
- 10/13 (77%) patients had no hives at Week 22 (HSS7=0)

CSU: XOLAIR® REFRACTORY

- 49% reduction in UAS7
- 8/11 (73%) patients achieved meaningful symptom relief (MID: ΔUAS7 ≥10)
- 6/7 (86%) patients who received 6 doses, achieved a response (UCT)
- 61% reduction in UAS7 for those who received 6 doses (n=7)

Substantial symptom improvement on AK002 in broad CSU patient population including those with inadequate response to Xolair®

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AK002 in CSU

AK002 demonstrated clear clinical activity in CSU

Significant activity in patients that failed Xolair®

Novel anti-Siglec-8 mechanism may have broader activity than existing therapies

AK002 is well-positioned in CSU

Chronic Inducible Urticarias (CIndU)

Symptomatic Dermographism Cohort

Cholinergic Urticaria Cohort

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7/10 (70%) Response Rate in Symptomatic Dermographism

Endpoint	Baseline	Week 22
UCT Complete Response	-	4/10 (40%)
UCT Partial Response	-	3/10 (30%)
UCT No Response	-	3/10 (30%)
FRIC Test Itch Response	0%	5/10 (50%)
FRIC Test Hives Response (CFT)	0%	4/10 (40%)

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9/11 (82%) Complete Response Rate in Cholinergic Patients

Endpoint	Baseline	Week 22
UCT Complete Response	-	9/11 (82%)
UCT Partial Response	-	0/11 (0%)
UCT No Response	-	2/11 (18%)
PCE Exercise Test Response	0%	7/7 (100%)

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7/7 (100%) Response Rate by PCE Test in CholU Patients

Cholinergic Patients	Baseline		Week 22/EOS	
	Response to Provocation[1]	Hives Severity (# of hives)	Response to Provocation	Hives Severity (# of hives)
CholU-1	+	21 - 50	-	**No Hives**
CholU-2	+	1 - 20	-	**No Hives**
CholU-3	+	1 - 20	-	**No Hives**
CholU-4	+	>50	-	**No Hives**
CholU-5[2]	+	Positive at BL	-	**No Hives**
CholU-6	+	>50	-	**No Hives**
CholU-7	+	>50	-	21 - 50

AK002 increased trigger threshold in patients with Cholinergic Urticaria

1 Provocation - exercise on stationary bike elevates body temperature to trigger symptoms, positive response if occurring in ≤10 minutes from start
2 Bad osteoarthritis of knees, patient had warm damp cloth applied that caused wheals and itching. Patient terminated early, not due to any drug related Aes

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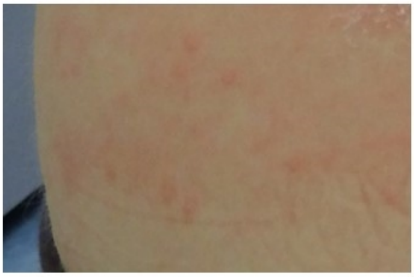
Cholinergic Patient Case

Baseline

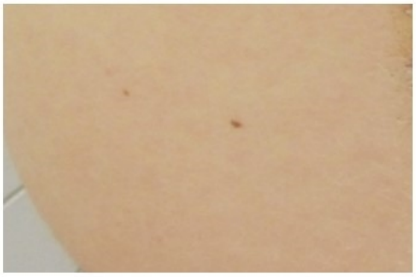
PCE Test: hives appear 5 mins post-sweat



- Daily itchy hives on whole body except on face (severe: >50)
- Inadequate response on 4x dose of antihistamines

On AK002 Treatment

PCE Test: no hives



- Complete response by 4th dose of AK002
- 4 weeks post last dose, symptoms returned
- Would like to be back on AK002

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CU Phase 2a Safety Summary

- Generally well-tolerated
- No drug-related Serious Adverse Events
- Most common adverse event was mild to moderate infusion-related reactions (IRRs; flushing, feeling of warmth, headache, nausea, or dizziness)
  - 34% IRRs rate on first infusion
  - 4.7% IRRs rate on subsequent infusions

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AK002 Has a Differentiated Profile in Chronic Urticaria

Demonstrated activity in all forms of Chronic Urticaria tested

Significant activity in patients refractory to Xolair®

AK002 is well-positioned to be a biologic front-line treatment for Chronic Urticaria

Closing Remarks

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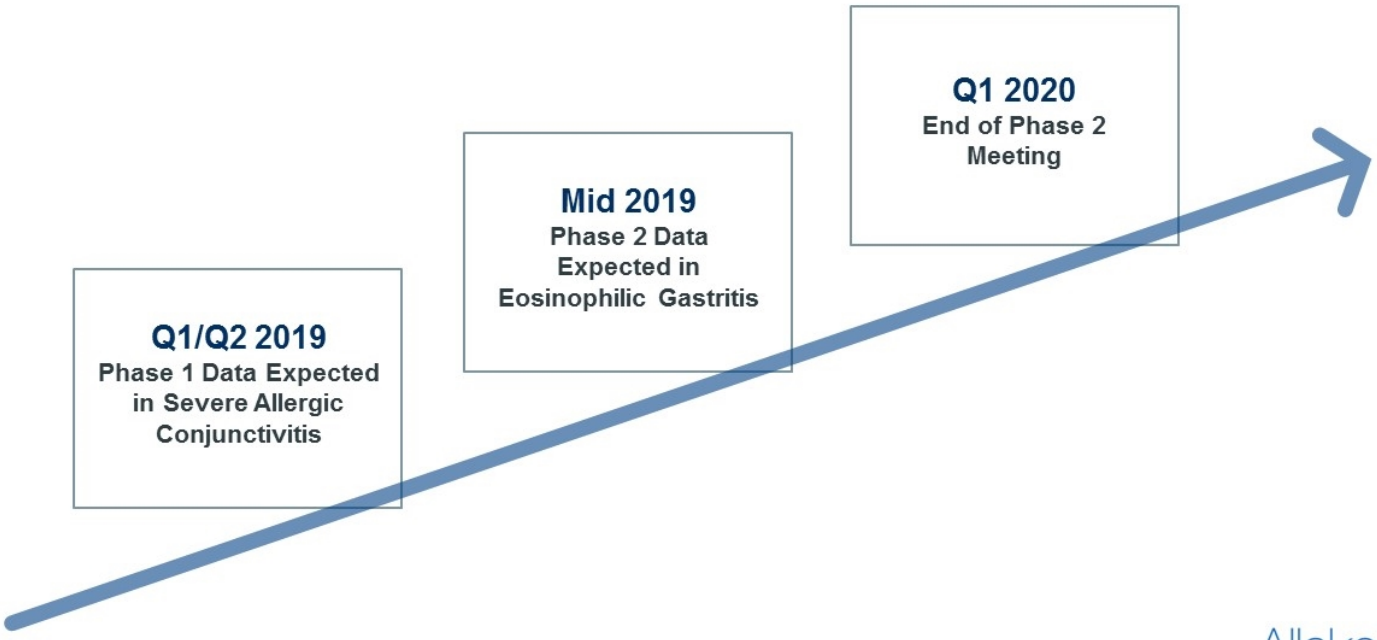
Near Term Catalysts



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Financing and IP

Cash and Investments as of September 30, 2018	$193.5M
Q3 2018 Operating Expenses	$12.0M ($30.2M YTD)

- AK002 US patents run until 2035
- Lonza currently manufactures AK002 at commercial scale

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Conclusions

- AK002 has shown clinical activity in multiple mast cell diseases
  - 3 forms of chronic urticaria (CU)
  - Indolent systemic mastocytosis (ISM)
- AK002 depletes eosinophils
  - Previously shown and confirmed in all studies to date
- Strong mechanistic and clinical support for AK002 activity in EG, EGE, & EoE

AK002 has the potential to be best-in-class in multiple mast cell and eosinophilic diseases

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Q&A

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