

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)
May 7, 2019

Allakos Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38582
(Commission
File Number)

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, including area code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001	ALLK	The Nasdaq Global Select Market

Item 8.01 Other Events.

On May 7, 2019, Allakos Inc. (the “Company”) hosted a conference call and webcast to present detailed results from its Phase 1 trial in Patients with Severe Allergic Conjunctivitis. 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Phase 1 SAC Results Presentation dated May 7, 2019.</u>

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: May 7, 2019

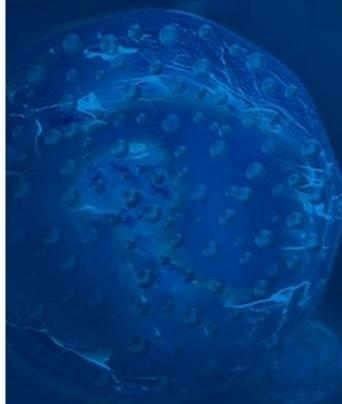
By: _____
/s/ Robert Alexander
Robert Alexander
President and Chief Executive Officer

Allakos



Developing Therapeutic Antibodies Targeting Allergic, Inflammatory and Proliferative Diseases

Phase 1b SAC Results
May 7, 2019





Disclaimer

This presentation contains forward-looking statements. All statements other than statements of historical fact contained in this presentation, including statements regarding the financial position of Allakos Inc. ("Allakos" 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.



Agenda

Robert Alexander, PhD <ul style="list-style-type: none">▪ Introductions▪ AK002	5:00 – 5:15 PM
Henrik Rasmussen, MD PhD <ul style="list-style-type: none">▪ Review of Clinical Program	5:15 – 5:20 PM
C. Stephen Foster, MD & Stephen Anesi, MD <ul style="list-style-type: none">▪ Overview of Ocular Allergy▪ AK002 in Severe Allergic Conjunctivitis Phase 1b Study	5:20 – 6:00 PM
Q&A	6:00 – 6:20 PM

Introduction

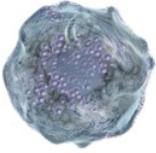
Robert Alexander, PhD
CEO – Allakos

Executive Summary

- **Clinical stage company focused on the development of AK002, an anti-Siglec-8 mAb**
- **Lead indication is Eosinophilic Gastritis and/or Gastroenteritis**
 - Phase 2 study results expected July/August 2019
- **Recently reported AK002 clinical activity**
 - Rapid depletion of blood eosinophils in healthy volunteers and all studies to date
 - Studies show symptom and quality of life improvements in multiple diseases including:
 - Indolent Systemic Mastocytosis, Chronic Spontaneous Urticaria and two forms of Chronic Inducible Urticaria
- **Today**
 - Positive data from AK002 Severe Allergic Conjunctivitis Phase 1 clinical study
 - Significant improvements in comorbid atopic dermatitis, asthma, and rhinitis

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

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



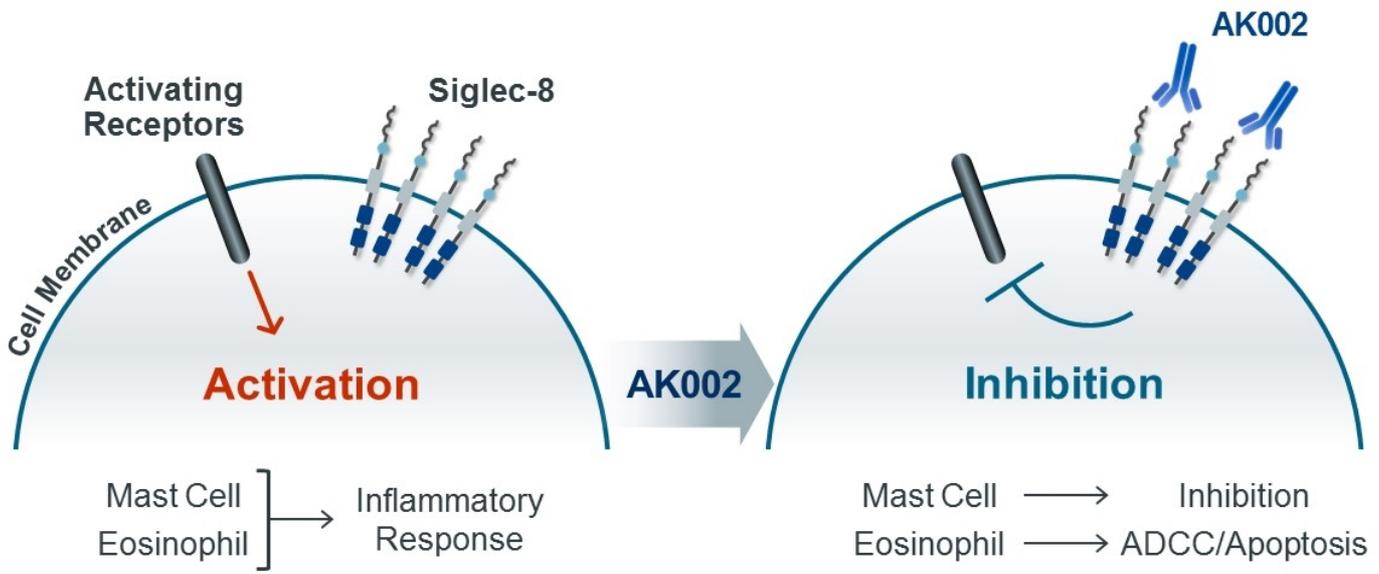
MAST CELLS



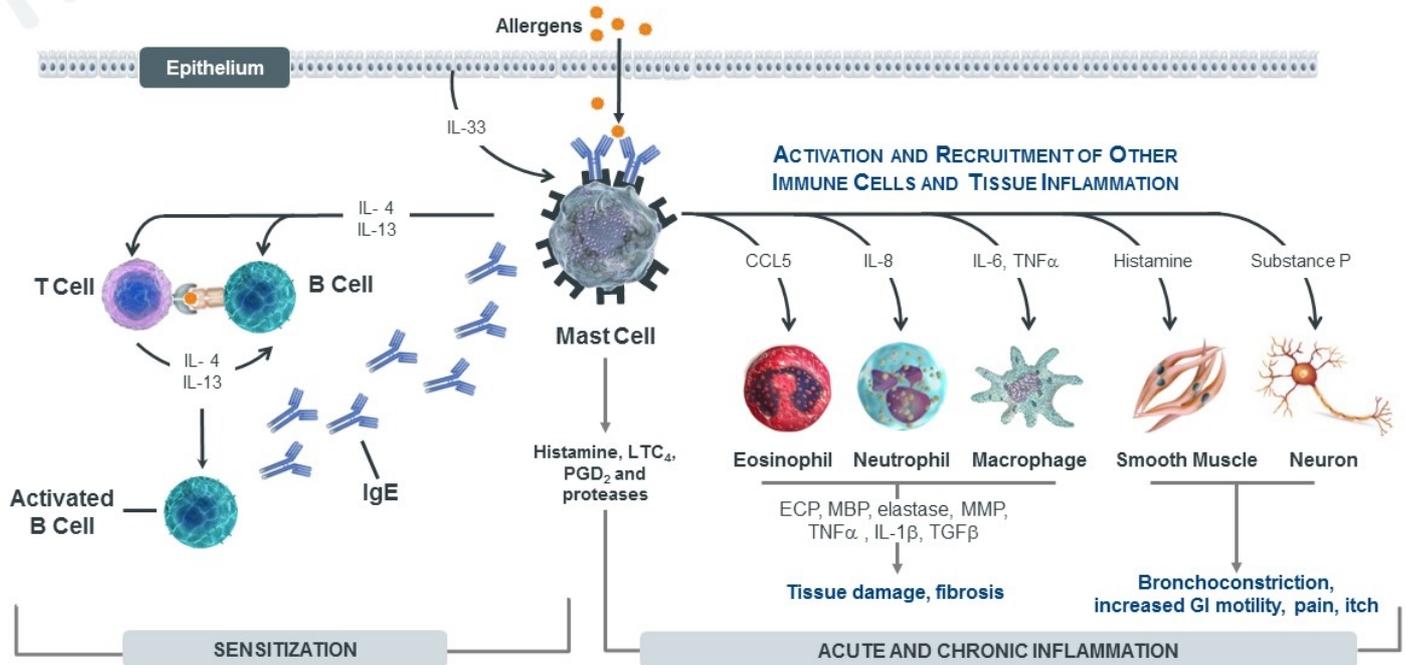
EOSINOPHILS

- 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

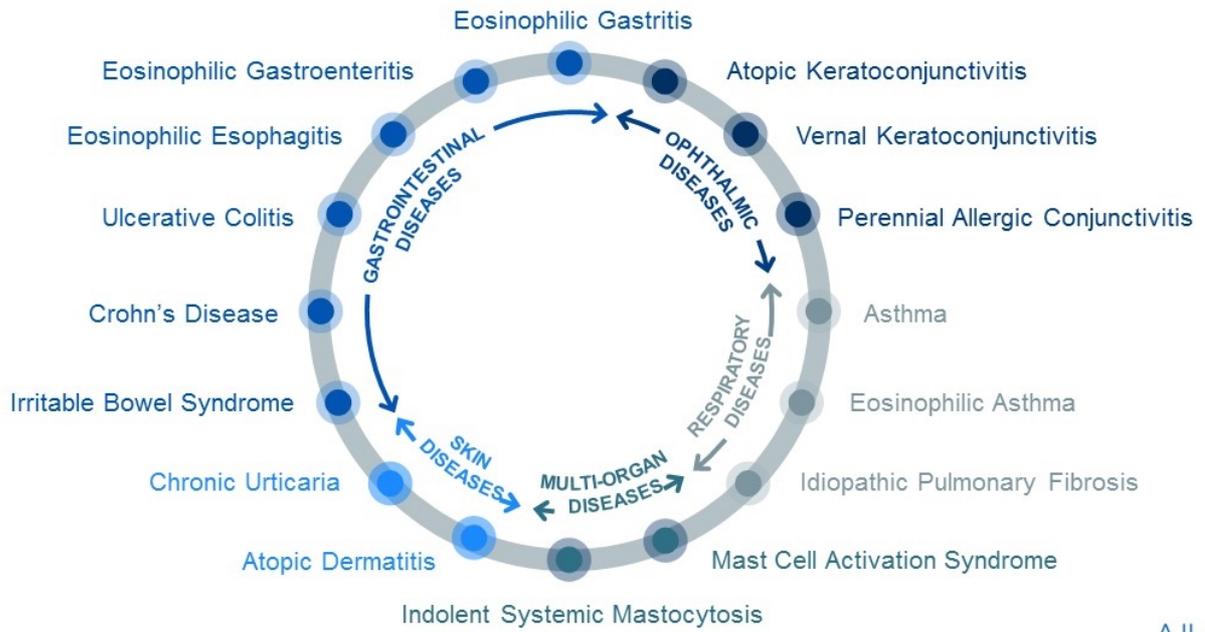
AK002 Developed to Target Siglec-8 on Mast Cells and Eosinophils



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



Eosinophils and Mast Cells Play a Significant Role in Many Diseases



AK002 Clinical Development Overview

Henrik Rasmussen, MD PhD
CMO – Allakos



Current AK002 Development Status

AK002	Preclinical	Phase 1	Phase 2	Data Expected
Eosinophilic Gastritis			<div style="width: 75%;"></div>	July/August 2019
Chronic Urticaria			<div style="width: 75%;"></div>	Presented Q1 2019
Indolent Systemic Mastocytosis				Presented Q1 2019
Severe Allergic Conjunctivitis				Presented Today



AK002 Clinical Data to Date

	Key Findings
Healthy Volunteers	<ul style="list-style-type: none">• Rapid depletion of eosinophils• Dose-dependent duration of eosinophil depletion
Chronic Urticaria	<ul style="list-style-type: none">• High response rates in multiple forms of antihistamine-resistant chronic urticaria, including omalizumab-refractory and inducible urticaria
Indolent Systemic Mastocytosis	<ul style="list-style-type: none">• Significant symptom and quality of life improvement



AK002 Safety Summary

PRECLINICAL

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

CLINICAL

- Approximately 180 subjects exposed to drug in clinical studies
- Generally well-tolerated
- Mild to moderate infusion reactions (flushing, feeling of warmth, headache, nausea, or dizziness) consistent with other mAbs with ADCC activity
 - ~19% IRR rate on first infusion
 - ~2% IRR rate on subsequent infusions

Severe Allergic Conjunctival Disease Phase 1b Study

Design	Key Endpoints		Status
<ul style="list-style-type: none"> • Open-label, pilot study • 30 patients – 3 cohorts <ul style="list-style-type: none"> – Atopic keratoconjunctivitis – Vernal keratoconjunctivitis – Perennial allergic conjunctivitis • Dosed once monthly for 6 months • 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	<ul style="list-style-type: none"> • Safety and tolerability 	<ul style="list-style-type: none"> • 29 patients <ul style="list-style-type: none"> – 13 AKC – 15 PAC – 1 VKC • Topline data presented today
	Secondary	<ul style="list-style-type: none"> • Allergic Conjunctivitis Symptom (ACS) PRO: <ul style="list-style-type: none"> – Itching, photophobia, foreign body sensation, ocular pain, and lacrimation • Ocular Symptom Score (OSS) Investigator assessment: <ul style="list-style-type: none"> – Itching, redness, tearing, and chemosis • Atopic comorbidities assessment: <ul style="list-style-type: none"> – Atopic dermatitis – Asthma – Rhinitis 	

C. Stephen Foster, MD and Stephen Anesi, MD



MASSACHUSETTS
EYE RESEARCH &
SURGERY INSTITUTION



C. Stephen Foster, MD - Principal Investigator

- Founder and president of MERSI
- Professor, Ophthalmology & Adjunct Professor, Allergy & Immunology, Harvard
- Developed standard of care in treating uveitis/ocular inflammatory diseases
- Currently serves on >10 committees, including International Society of Ocular Pharmacology and Pharmaceutics and the International Uveitis Study Group
- >20 editorial board positions
- >800 peer reviewed publications, >100 books and chapters



Stephen Anesi, MD - Sub-Investigator

- Associate partner at MERSI
- Completed fellowship in Ocular Immunology and Uveitis under Dr. Foster
- >15 peer reviewed publications, >5 books and book chapters

Phase 1b: AK002 in Patients with Severe Allergic Conjunctivitis

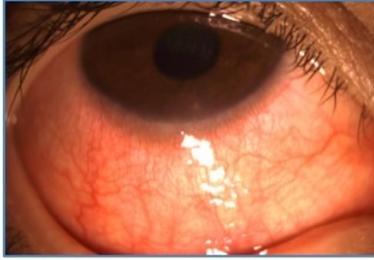
C. Stephen Foster, MD

Stephen Anesi, MD

AKC, PAC, & VKC are Severe Forms of Allergic Conjunctivitis

	CLINICAL FEATURES	IMPACT
Symptoms	Extreme Itching, Photophobia, Pain, Sensation of Foreign Body, Burning, Watering, Mucous Discharge	Poor Quality of Life
Signs	Redness (Hyperemia), Swelling (Chemosis, Periorbital Edema), Tarsal Papillae, Cicatricial Changes, Corneal Damage (Keratitis, Epithelial Erosion, Ulcers)	Vision Loss, Poor Quality of Life
Atopic Comorbidities	Common Atopic Comorbidities Include Atopic Dermatitis, Asthma, and Rhinitis	High Systemic Disease Burden, Poor Quality of Life

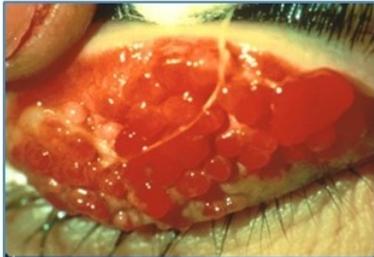
Severe Allergic Conjunctivitis



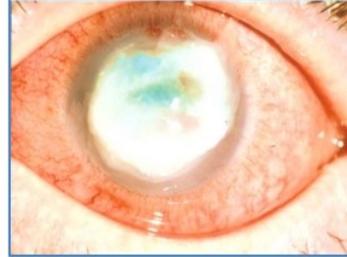
**Redness,
Chemosis**



**Photophobia,
Watering,
Periorbital
Swelling**



**Giant
Papillae**



**Corneal
Ulcer
(Vision Loss)**

Immune Cells Involved in Allergic Conjunctivitis

	Perennial Allergic Conjunctivitis (PAC)	Vernal Keratoconjunctivitis (VKC)	Atopic Keratoconjunctivitis (AKC)
Mast Cells	+++	+++	++
Eosinophils	++	++	+++
T and B cells	+	++	+++
Fibroblasts		++	++

Mast cells and eosinophils are key effector cells in allergic conjunctivitis

Source: Leonardi A. "Immunopathogenesis of ocular allergy: a schematic approach to different clinical entities." *Curr Opin in Allergy Clinical Immunol.* 2007, 7:429-435; Tsubota K. "Detection by brush cytology of mast cells and eosinophils in allergic and vernal conjunctivitis." *Cornea.* 1991;10(6):525.

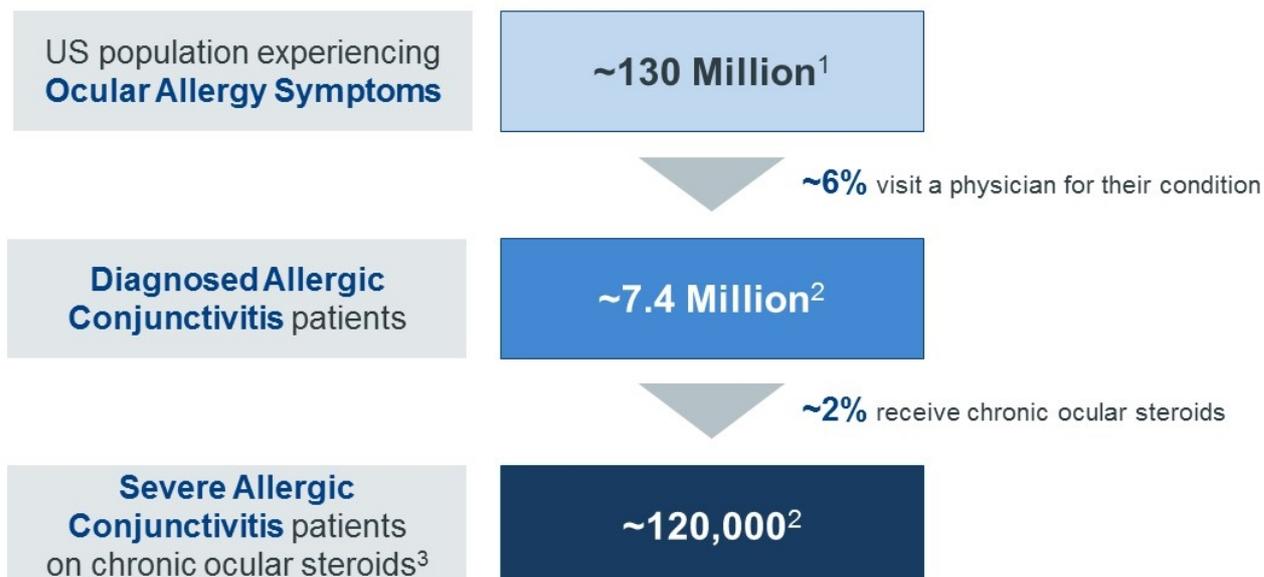


Limitations of Current Treatment Options

- **Antihistamines / Mast Cell Stabilizers**
 - Require frequent dosing (up to 4 times per day)
 - Typically ineffective in severe cases
- **Ocular Topical Steroids**
 - Associated with multiple adverse effects, including cataracts and glaucoma
 - Chronic, long-term use significantly increases risk of irreversible vision loss
 - Require frequent monitoring of intraocular pressure (every 1 to 5 weeks)
- **Calcineurin Inhibitors**
 - Limited efficacy and safety data
 - Access and reimbursement often challenging due to lack of labeled indication



US Prevalence of Severe Allergic Conjunctivitis



(1) 40% of US population, Singh et al. *J Allergy Clin Immunol.* 2010 and Bielory et al. *Allergy Asthma Proc.* 2014; (2) Allakos analysis of Symphony Health PatientSource claims;

(3) chronic use defined as 2 or more prescriptions for ocular steroids per year for 2 or more consecutive years



Severe Allergic Conjunctivitis – Unmet Need

~120,000 patients in the US have antihistamine-refractory severe allergic conjunctivitis

Significant disease burden, which can lead to blindness

There are no safe chronic treatment options available

Severe Allergic Conjunctival Disease Phase 1b Study

Design	Key Endpoints		Status
<ul style="list-style-type: none"> • Open-label, pilot study • 30 patients – 3 cohorts <ul style="list-style-type: none"> – Atopic keratoconjunctivitis – Vernal keratoconjunctivitis – Perennial allergic conjunctivitis • Dosed once monthly for 6 months • 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	<ul style="list-style-type: none"> • Safety and tolerability 	<ul style="list-style-type: none"> • 29 patients <ul style="list-style-type: none"> – 13 AKC – 15 PAC – 1 VKC • Topline data presented today
	Secondary	<ul style="list-style-type: none"> • Allergic Conjunctivitis Symptom (ACS) PRO: <ul style="list-style-type: none"> – Itching, photophobia, foreign body sensation, ocular pain, and lacrimation • Ocular Symptom Score (OSS) Investigator assessment: <ul style="list-style-type: none"> – Itching, redness, tearing, and chemosis • Atopic comorbidities assessment: <ul style="list-style-type: none"> – Atopic dermatitis – Asthma – Rhinitis 	

Baseline Characteristics

	AKC (N=13)	VKC (N=1)	PAC (N=16)	Total (N=30)
Age, Median (Range)	50 (23-72)	25	55 (29-79)	52 (23-79)
Female	38%	0	63%	50%
Age of AC Onset, Median (Range)	36 (7-72)	12	46 (19-69)	43 (7-72)
Years with AC, Median (Range)	6 (0-38)	13	4 (0-19)	6 (0-38)
Atopic Comorbidities ¹	≥1 Comorbidity	85%	100%	88%
	≥2 Comorbidities	69%	100%	44%
	Atopic Dermatitis	85%	0	44%
	Asthma	54%	100%	25%
	Rhinitis	54%	100%	75%

(1) By medical history

AK002 Clinical Activity Measured by PRO & Investigator Assessments

ALLERGIC CONJUNCTIVITIS SYMPTOM (ACS)

- **Daily patient questionnaire**
- Total ACS (0 – 50 point scale):
 - Itching (0-10)
 - Light sensitivity (0-10)
 - Eye pain (0-10)
 - Foreign body sensation (0-10)
 - Watering eyes (0-10)

OCULAR SYMPTOM SCORE (OSS)

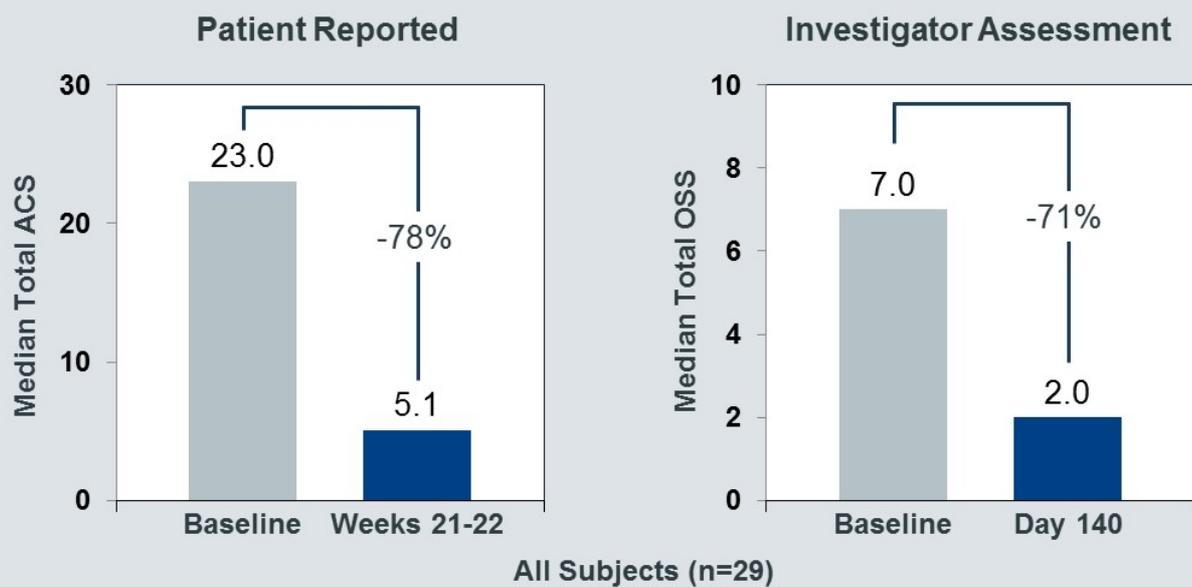
- **Monthly investigator assessment**
- Total OSS (0 – 13 point scale):
 - Itching (0-4)
 - Redness (0-3)
 - Tearing (0-3)
 - Chemosis (0-3)

COMORBID ATOPIC DISEASE ASSESSMENTS

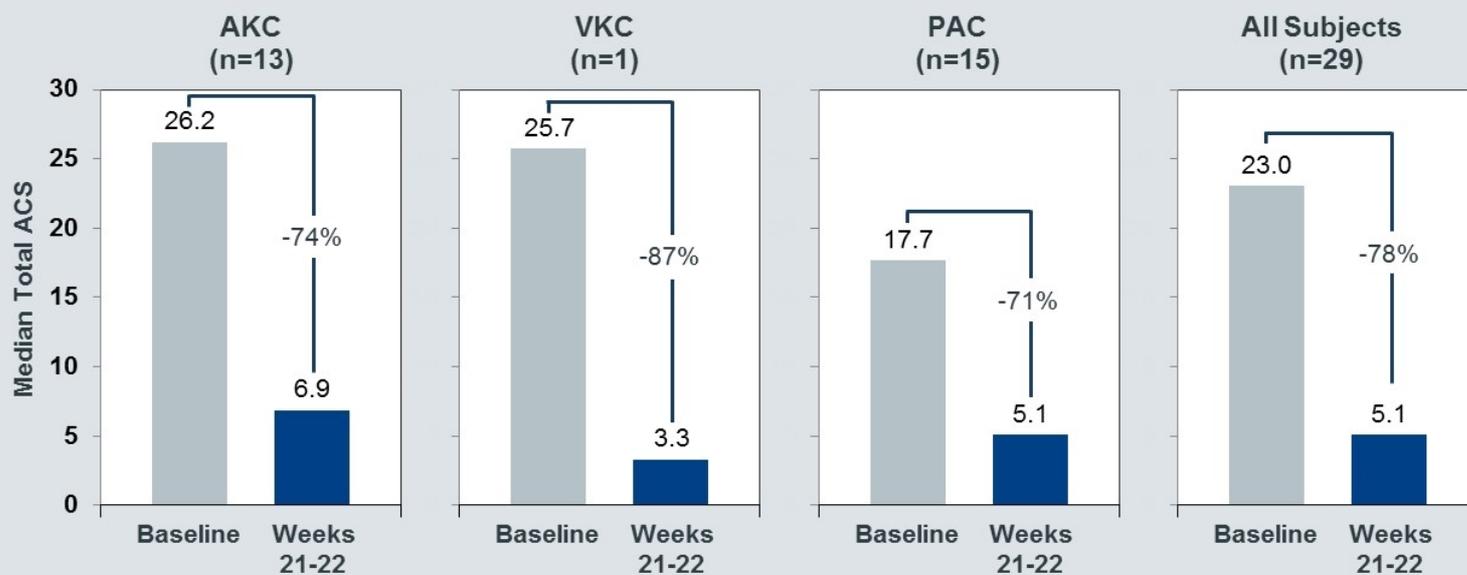
- **Daily patient questionnaire** for patients with comorbid atopic dermatitis, asthma and/or rhinitis
- 0 – 10 point scale grading global disease severity



Improvements in Allergic Conjunctivitis Signs & Symptoms



Substantial Improvements in Multiple Forms of Severe AC

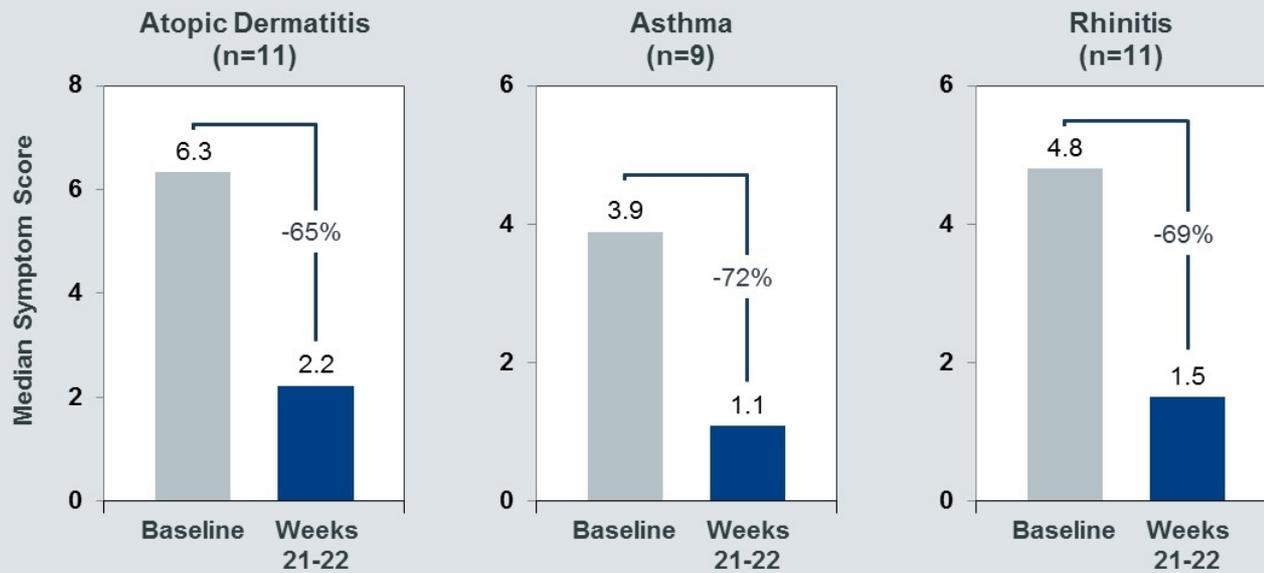


Consistent Improvements Across Signs & Symptoms

	Symptom	Median % Δ from BL to Wk 21-22
Allergic Conjunctivitis Symptom (ACS) Patient Reported - Daily	Itching	-75%
	Light Sensitivity	-57%
	Eye Pain	-75%
	Foreign Body Sensation	-80%
	Watering Eyes	-76%

	Symptoms & Signs	Median % Δ from BL to Day 140
Ocular Symptom Score (OSS) Investigator Assessment - Monthly	Itching	-67%
	Redness	-67%
	Tearing	-50%
	Chemosis	-100%

Substantial Improvement in Atopic Comorbidities





Severe Allergic Conjunctivitis Phase 1b: Safety Summary

- Generally very 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)
 - 16.7% IRRs rate on first infusion
 - 0.7% IRRs rate on subsequent infusions

Patient Case Studies

C. Stephen Foster, MD

Stephen Anesi, MD

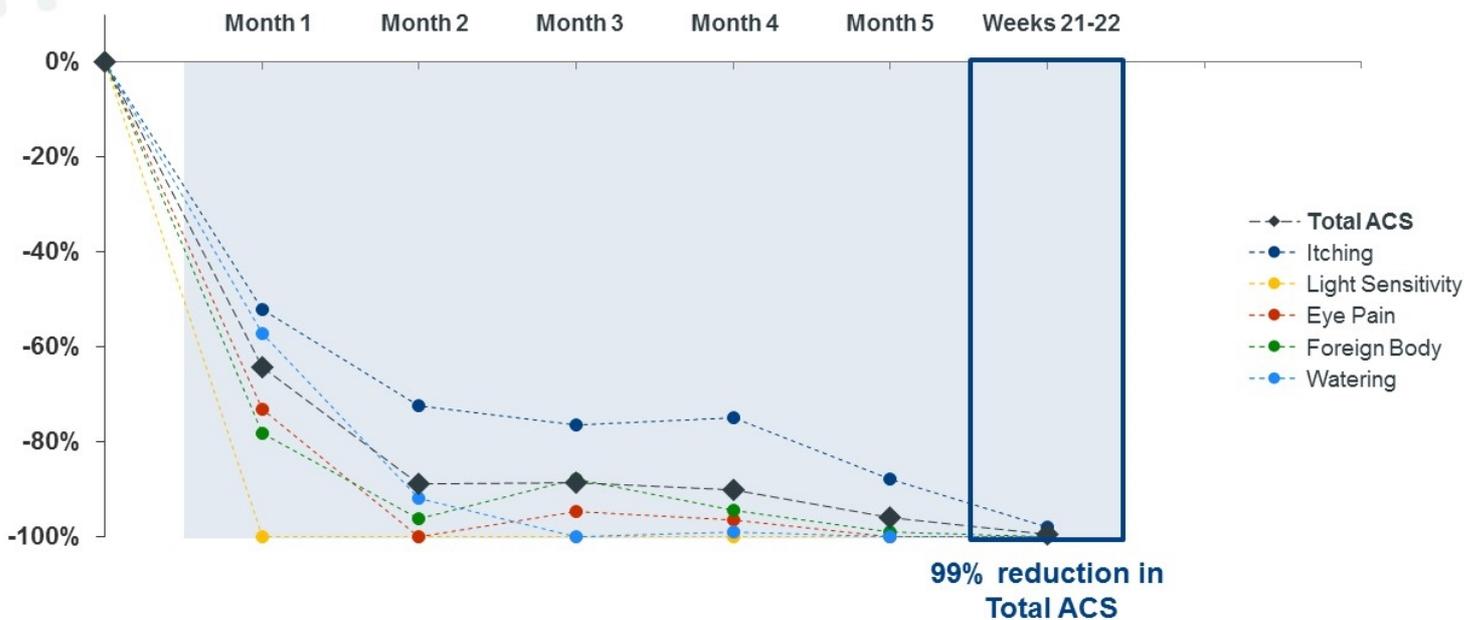
Case Study 1:

AKC with Comorbid Atopic Dermatitis & Rhinitis

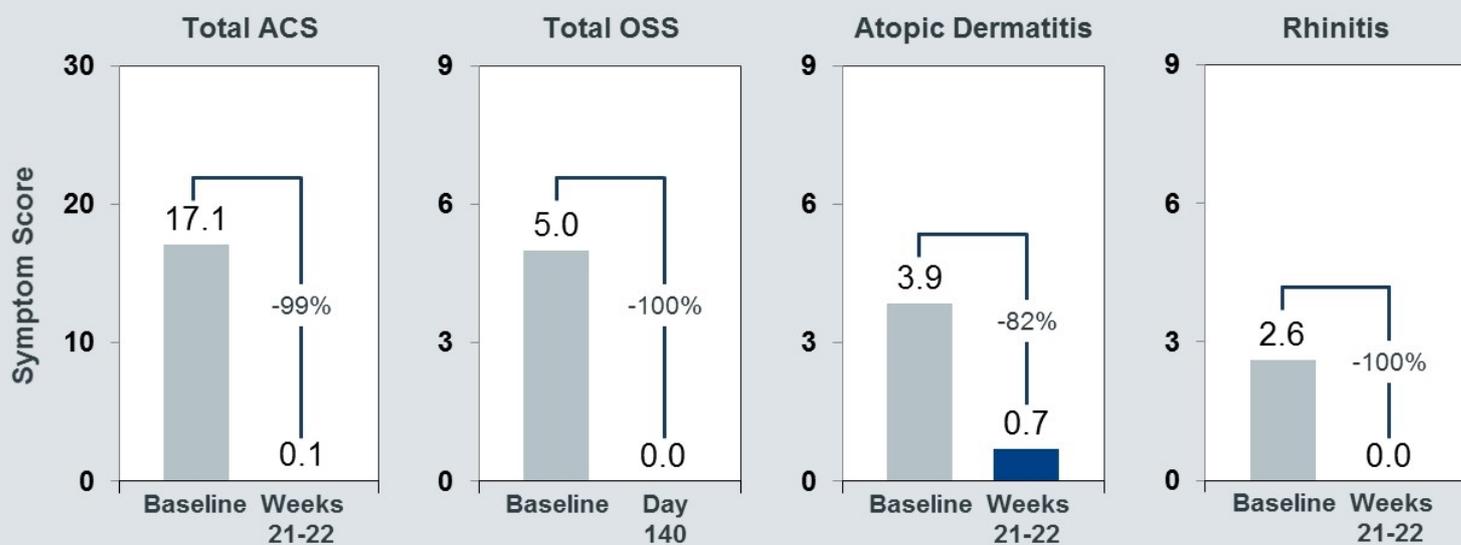
Medical History

- 27 year-old male with severe AKC, atopic dermatitis, and rhinitis
- Baseline normal peripheral blood eosinophils (190 eos/ μ L)
- Suffered from severe symptoms despite treatment
 - Itching, foreign body sensation, and watering
 - Hyperemia (redness) and palpebral papillae
 - Moderate comorbid atopic dermatitis & rhinitis
- Treatment history
 - AKC: topical antihistamines, topical corticosteroids
 - Atopic Dermatitis: oral antihistamines
 - Rhinitis: oral antihistamines

Case Study 1: Improvement in Ocular Symptoms



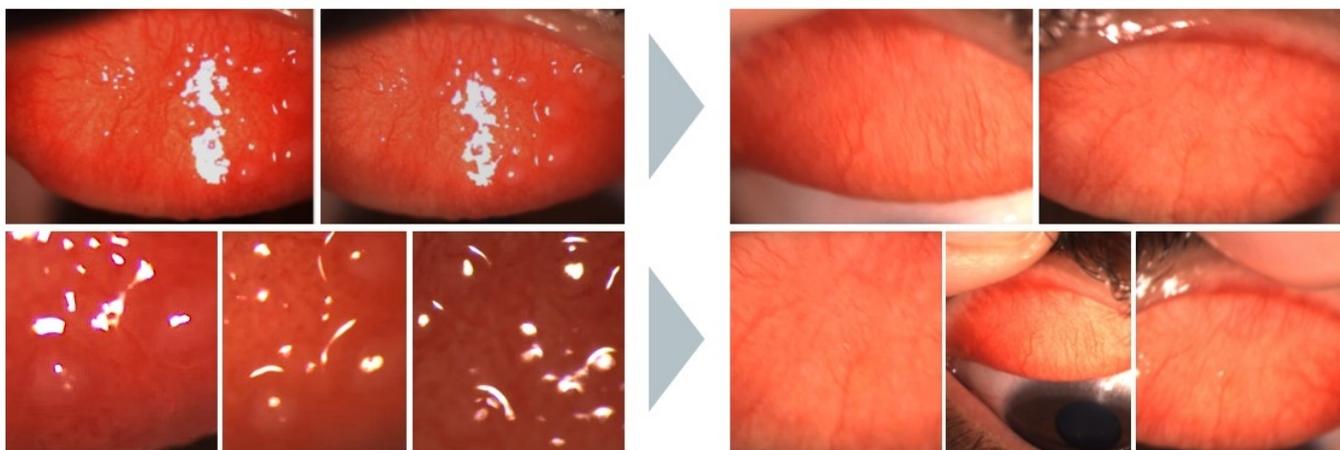
Case Study 1: Improvement in Ocular Signs and Symptoms and Comorbid Atopic Dermatitis and Rhinitis



Case Study 1: Reversal of Neovascular and Inflammatory Changes

Prior to AK002

After 3 Doses of AK002

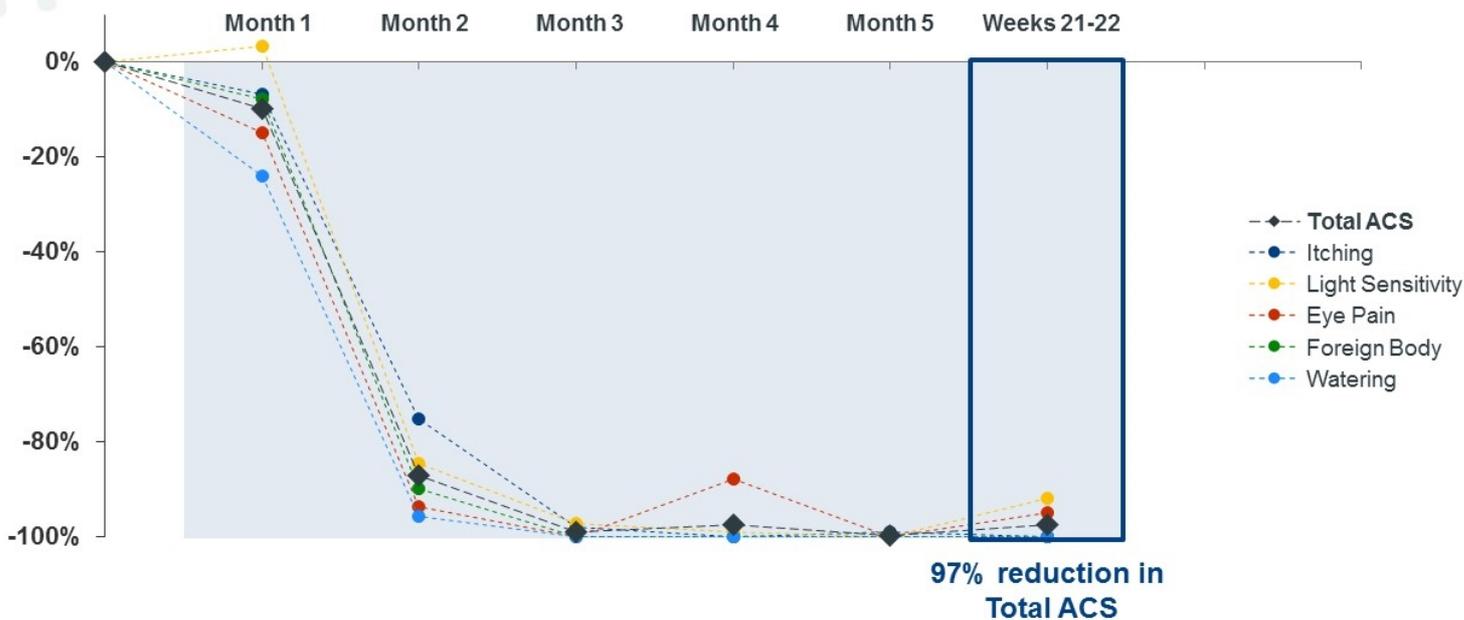


Case Study 2: AKC with Comorbid Atopic Dermatitis & Asthma

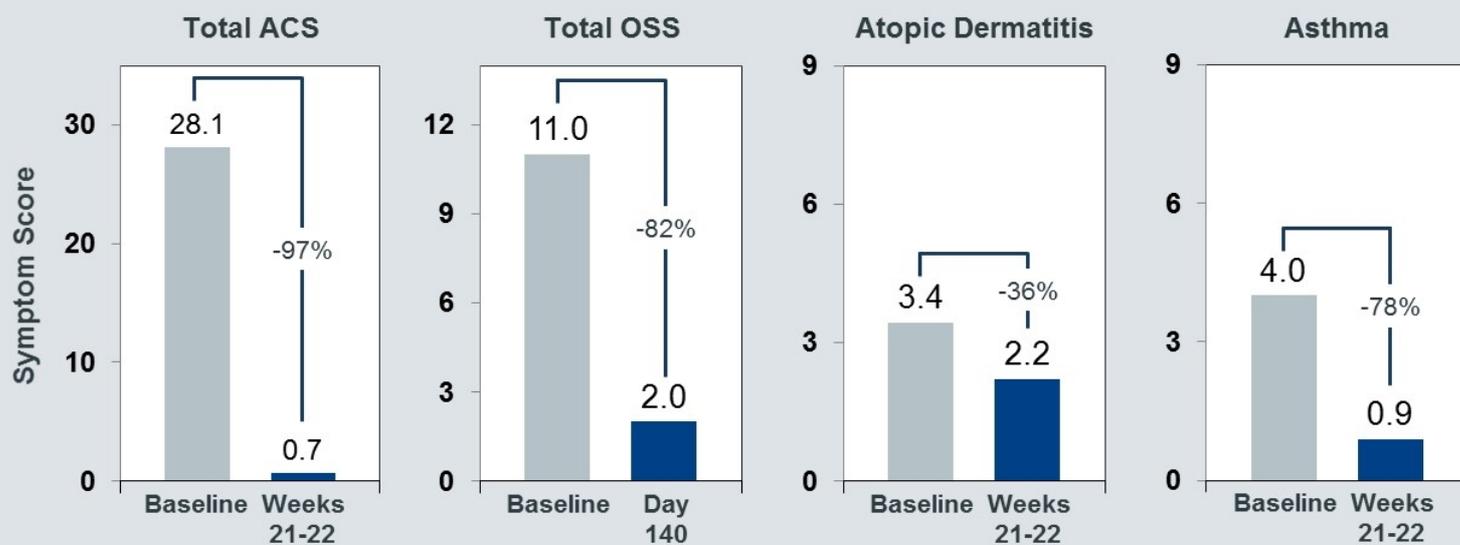
Medical History

- 49 year-old male with severe AKC, atopic dermatitis, and asthma
- Baseline high peripheral blood eosinophils (1350 eos/ μ L)
- Suffered from severe symptoms despite treatment
 - Photophobia, conjunctival hyperemia, and chemosis
 - Periorbital atopic dermatitis and edema
 - Moderate-to-severe comorbid asthma
- Treatment history
 - AKC: topical corticosteroids, topical antihistamines, topical cromolyn
 - Atopic Dermatitis: dupilumab, topical corticosteroids, topical tacrolimus
 - Asthma: daily ICS/LABA, cromolyn, albuterol

Case Study 2: Improvement in Ocular Symptoms



Case Study 2: Improvement in Ocular Signs and Symptoms and Comorbid Atopic Dermatitis and Asthma

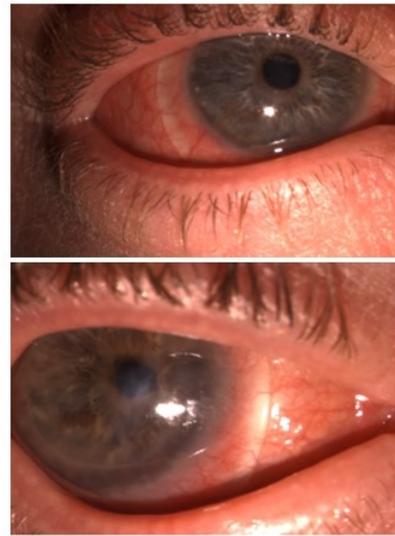


Case Study 2: Substantial Clinical Improvements

Prior to AK002



After 3 Doses of AK002

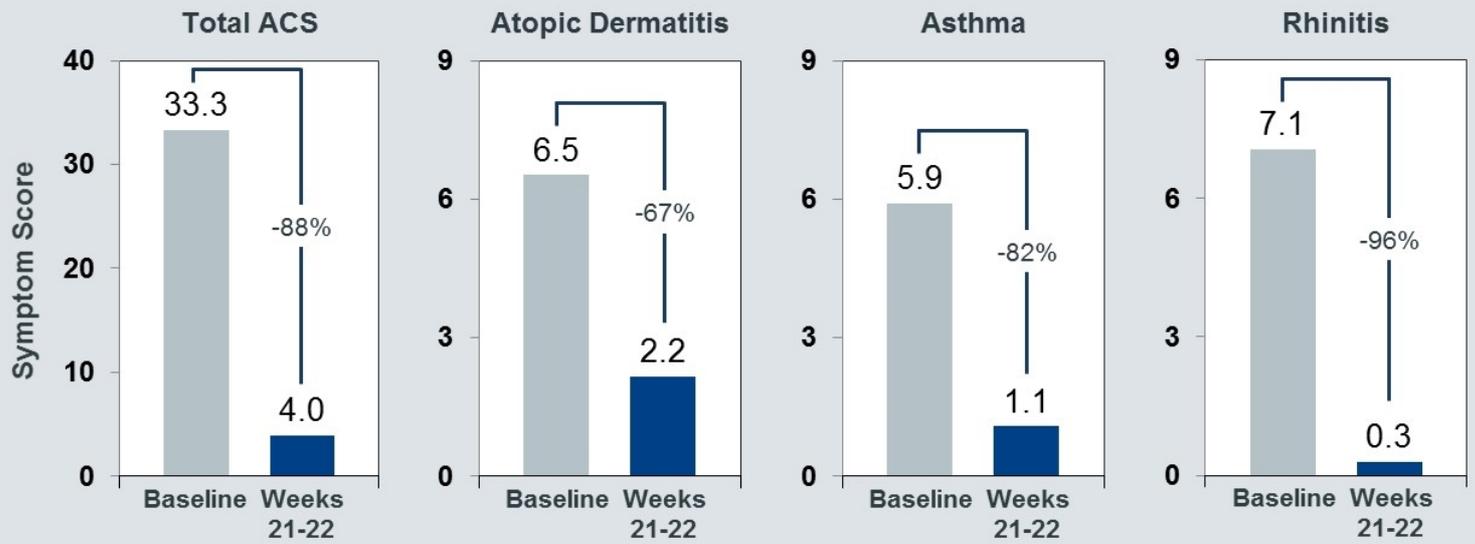


Case Study 3: AKC with Comorbid Atopic Dermatitis, Asthma, and Rhinitis

Medical History

- 53 year-old male with AKC, atopic dermatitis, asthma, and rhinitis
- Baseline normal peripheral blood eosinophils (120 eos/ μ L)
- Suffered from severe symptoms despite treatment
 - Itching, photophobia, foreign body sensation, redness, & chemosis
 - Severe comorbid atopic dermatitis & asthma
- Treatment history
 - AKC: topical corticosteroids, topical antihistamines
 - Atopic Dermatitis: dupilumab, topical corticosteroids
 - Asthma: daily ICS/LABA, albuterol
 - Rhinitis: oral antihistamines

Case Study 3: Improvements in Ocular Signs and Symptoms and Comorbid Atopic Dermatitis, Asthma, and Rhinitis

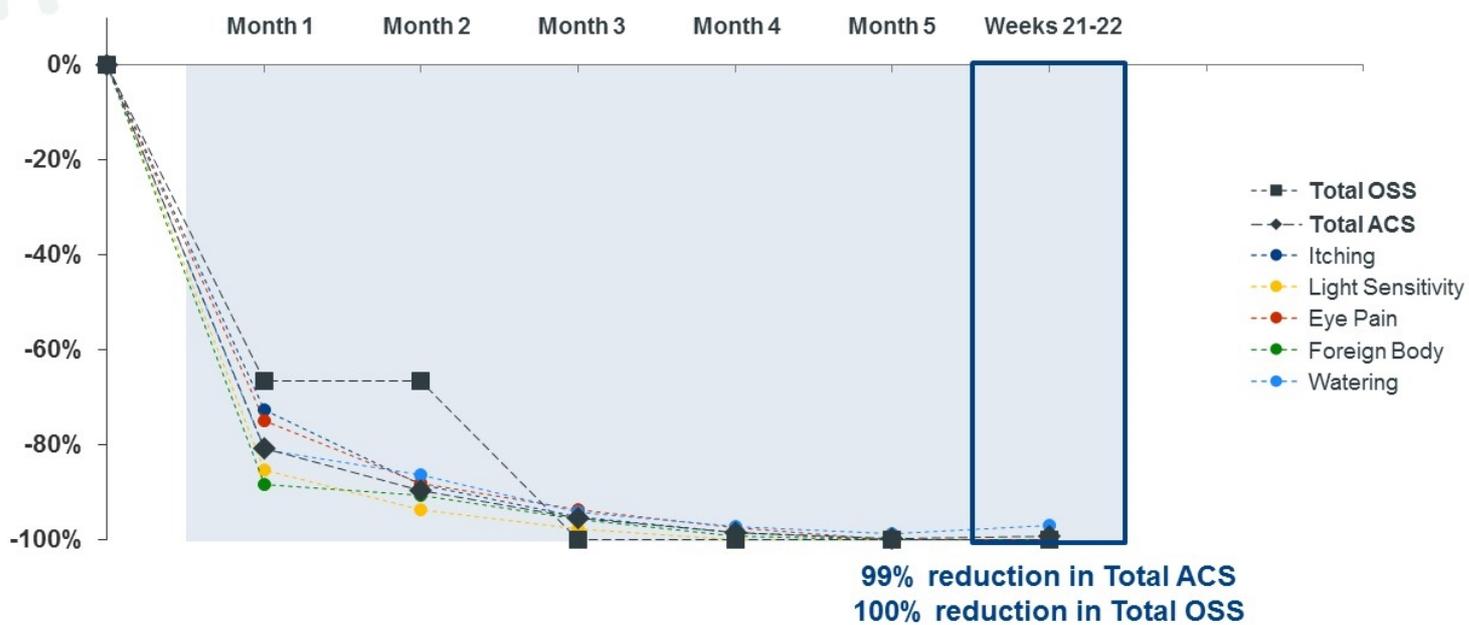


Case Study 4: AKC w/ Comorbid Esophagitis, Gastritis, Duodenitis, Urticaria

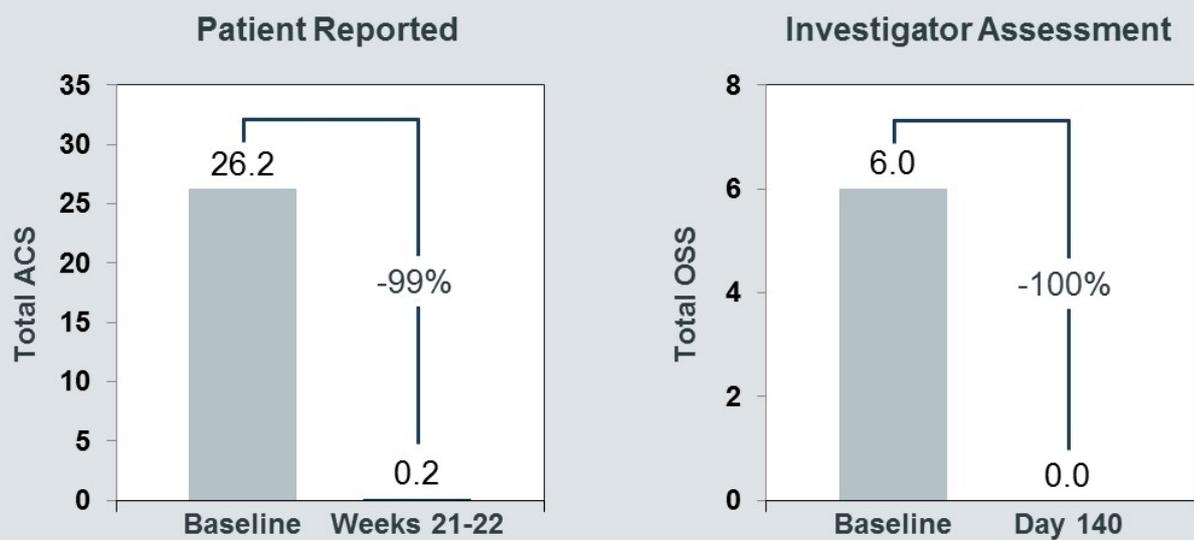
Medical History

- 45 year old female with severe AKC, GI disease, and chronic urticaria
- Baseline normal peripheral blood eosinophils (160 eos/ μ L)
- Suffered from severe symptoms despite treatment
 - Itching, photophobia, discomfort, and watering
 - Frequent and severe stomach pain, nausea, and diarrhea
 - Frequent and severe headaches / migraines
 - Frequent spontaneous and inducible urticaria (edema, hives, rash, and flushing)
- Treatment history
 - AKC: oral corticosteroids, topical cromolyn, oral antihistamines
 - Gastrointestinal Diseases: restricted diet, PPIs, oral cromolyn sodium
 - Urticaria: oral antihistamines, lifestyle modification / trigger avoidance

Case Study 4: Improvement in Ocular Symptoms



Case Study 4: Improvements in Ocular Signs and Symptoms



Case Study 4: AKC Patient



Summary

AK002 demonstrated clinical activity in severe allergic conjunctivitis

AK002 is a targeted therapy that may represent a novel alternative to chronic steroid use

Results suggest significant activity in systemic atopic comorbidities such as atopic dermatitis, asthma, and rhinitis

Executive Summary

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- **Today**
 - Positive data from AK002 Severe Allergic Conjunctivitis Phase 1 clinical study
 - Significant improvements in comorbid atopic dermatitis, asthma, and rhinitis

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

Q&A

Allakos



Thank you

