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): January 16, 2024

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.)**
825 Industrial Road, Suite 500 San Carlos, California		**94070**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 650 597-5002

(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:

☐ 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))

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

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 7.01 Regulation FD Disclosure.

On January 16, 2024, Allakos Inc. (the "Company") released an updated corporate presentation. A copy of the presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

All of the information in this Item 7.01 and Item 9.01 of this Form 8-K, including the attached Exhibit 99.1, is intended to be furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Corporate Presentation dated January 16, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Allakos Inc.

Date: January 16, 2024

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer

Exhibit 99.1

Allakos

Corporate Update

January 2024

Developing Therapeutic Antibodies Targeting Allergic, Inflammatory and Proliferative Disease

Disclaimer

This presentation contains forward-looking statements. All statements other than statements of historical fact contained in this presentation, including statements regarding the financial position of Allakos Inc. (“Allakos,” the “Company,” “we” or “our”); estimated lirentelimab closeout, severance and other costs; the timing of payment of restructuring expenditures; estimated ending 2023 and 2024 cash, cash equivalents and investments; estimated cash runway; 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 initiation, design, timing and results of our clinical studies, preclinical studies and research and development programs, including the timing and availability of data from such studies; our preclinical, clinical and regulatory development plans for our product candidates; and our anticipated milestones 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 stages of clinical drug development; the Company’s ability to timely initiate and complete clinical trials for AK006; the Company’s ability to obtain required regulatory approvals for its clinical trials; 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 clinical trials, regardless of the outcomes of preclinical testing and prior clinical trials; the Company’s ability to advance additional product candidates beyond AK006; the Company’s ability to obtain additional capital to finance its operations; general economic and market conditions; 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’ 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.

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, CEO
- Introduction

Craig Paterson, CMO
- Results of ATLAS and MAVERICK Phase 2 Studies

Baird Radford, CFO
- Restructuring and Financial Implications

Robert Alexander, CEO
- AK006 Program Update

Q&A

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ATLAS: Phase 2 Study of Lirentelimab in Atopic Dermatitis

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Phase 2 Atopic Dermatitis Study Design

Study Design

- Multi-center, randomized, DB, placebo-controlled
- Chronic disease that has been present ≥3 years
  - EASI score ≥16
  - Involvement of ≥10% of body surface area
  - IGA score ≥3
  - Inadequate control by topical treatments
- Includes patients with prior biologics treatment
- 131 adult patients (1:1 randomization)
  - 300 mg Q2W subcutaneous lirentelimab
  - Placebo
- Enrolled from 53 Sites in the US and Germany

Endpoints

- **Primary Endpoint**
  - Proportion of patients who achieve eczema area and severity index (EASI)-75 at week 14
- **Key Secondary Endpoints**
  - Percent change in EASI from baseline to week 14
  - Proportion of patients who achieve an IGA score of 0 or 1 AND a ≥2-point improvement in Investigator Global Assessment (IGA) at week 14

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ATLAS: Baseline Demographics & Patient Characteristics

Baseline Characteristics (mITT population)	Phase 2 ATLAS (AD)		
	Lirentelimab n=61	Placebo n=61	All n=122
Age (years), median (IQR)	39 (31-54)	35 (26-49)	37 (26-53)
Female sex, n (%)	32 (52.5%)	34 (55.7%)	66 (54.1%)
White, n (%)	39 (63.9%)	33 (54.1%)	72 (59.0%)
From US Sites, n (%)	49 (80.3%)	49 (80.3%)	98 (80.3%)
BMI (kg/m^2), median (IQR)	27.5 (24.1-34.3)	29.3 (24.0-31.9)	28.1 (24.0-33.3)
Duration of AD diagnosis (years), median (IQR)	22.4 (7.7-32.3)	21.9 (11.9-29.4)	22.0 (10.2-29.6)
Prior biologic use for AD, n (%)	10 (16.4%)	12 (19.7%)	22 (18.0%)
Peripheral blood eosinophils (cells/µL), median	180	290	230
IgE (kU/L), median	250.0	391.0	355.8
Baseline EASI [0-72], median (IQR)	26.8 (23.6-30.6)	26.9 (23.7-33.4)	26.9 (23.6-32.1)
Baseline IGA=4, n (%)	32 (52.5%)	31 (50.8%)	63 (51.6%)
Baseline BSA [0-100%], median (IQR)	42.0 (31.0-57.3)	46.6 (39.0-58.9)	46.0 (33.5-58.9)
Baseline SCORAD [0-103], median (IQR)	66.2 (59.7-73.2)	69.6 (59.4-75.5)	68.7 (59.5-74.3)
Baseline ppNRS [0-10], median (IQR)	7.8 (6.9-8.6)	7.2 (6.3-8.1)	7.5 (6.3-8.3)
Baseline DLQI [0-30], median (IQR)	15 (10-21)	14 (10-20)	14 (10-21)

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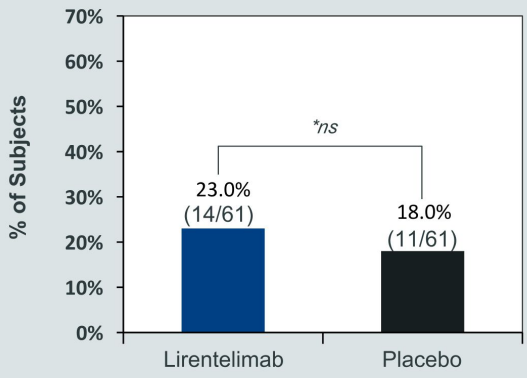
ATLAS Primary Efficacy Endpoint

Proportion of EASI-75 Responders at Week 14 (mITT)



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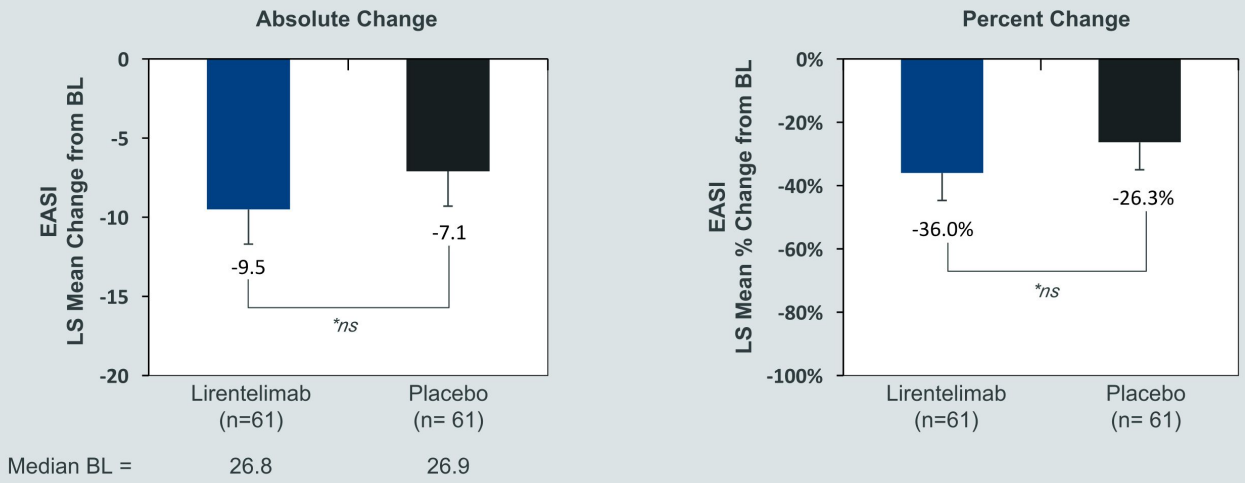
Secondary Endpoint: Change in EASI Score

Change in EASI Score from Baseline to Week 14 (mITT)



	Lirentelimab (n=61)	Placebo (n= 61)
Median BL =	26.8	26.9

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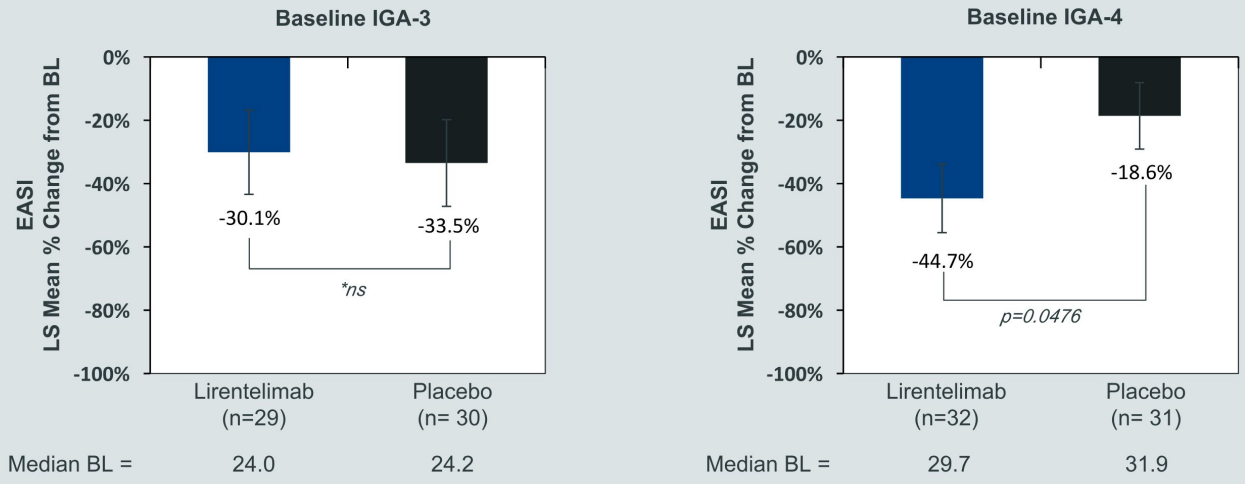
Significant Change in EASI Scores in Patients with Higher Inflammatory Disease Burden

Percent Change in EASI Score from Baseline to Week 14 (mITT)



	Lirentelimab (n=29)	Placebo (n= 30)	Lirentelimab (n=32)	Placebo (n= 31)
Median BL =	24.0	24.2	29.7	31.9

Difference from placebo p-values derived using MMRM

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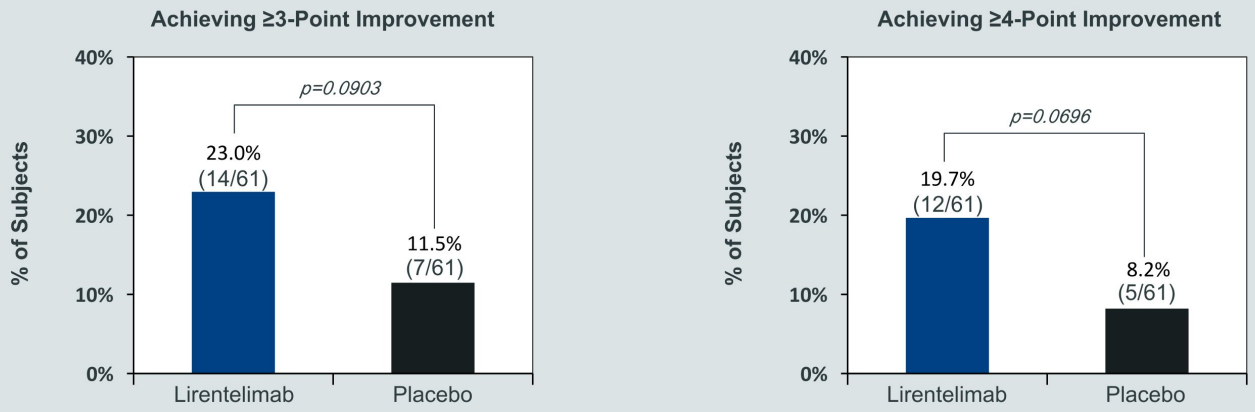
Exploratory Endpoint: Improvement in ppNRS (Itch)

Proportion of ppNRS Responders at Week 14 (mITT)



Difference from placebo p-values derived using Cochran-Mantel-Haenszel (CMH)
Includes all subjects regardless of baseline ppNRS. No minimum ppNRS required for study entry.

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MAVERICK: Phase 2b Study of Lirentelimab in Chronic Spontaneous Urticaria

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Phase 2b Chronic Spontaneous Urticaria Study

Study Design

- Multi-center, randomized, DB, placebo-controlled
- Active moderate-to-severe symptoms
- CSU diagnosis with onset ≥6 months prior to screening
- Diagnosis of CSU refractory to antihistamines
  - Presence of itch and hives despite current use of antihistamines
  - UAS7 score ≥16 and HSS7 score ≥8 at baseline
- Includes patients with prior biologics treatment
- 127 adult patients (1:1 randomization)
  - 300 mg Q2W subcutaneous lirentelimab
  - Placebo
- Enrolled from 56 Sites in the US, Germany, and Poland

Endpoints

- **Primary Endpoint**
  - Change from baseline in UAS7 at week 12
- **Key Secondary Endpoints**
  - Absolute change in ISS7
  - Absolute change in HSS7
  - Proportion of patients who achieve UAS7=0

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MAVERICK: Baseline Demographics & Patient Characteristics

Baseline Characteristics (mITT population)	Phase 2 MAVERICK (CSU)		
	Lirentelimab n=64	Placebo n=59	All n=123
Age, mean ± SD	42 ± 14	46 ± 16	44 ± 15
Female sex, n (%)	48 (75.0%)	55 (93.2%)	103 (83.7%)
White, n (%)	52 (81.3%)	42 (71.2%)	94 (76.4%)
From US Sites, n (%)	55 (85.9%)	53 (89.8%)	108 (87.8%)
BMI (kg/m^2), mean ± SD	29.7 ± 7.1	30.8 ± 6.3	30.2 ± 6.8
Duration of CSU diagnosis (years), median (range)	4.8 (0.5-47.3)	4.4 (0.5-53.3)	4.5 (0.5-53.3)
History of CSU-associated Angioedema, n (%)	23 (35.9%)	25 (42.4%)	48 (39.0%)
Prior omalizumab use, n (%)	22 (34.4%)	18 (30.5%)	40 (32.5%)
Peripheral blood eosinophils (cells/µL), median	130	120	120
IgE (kU/L), median	105	58.1	77.3
Baseline UAS7 [0-42], mean ± SD	31.4 ± 7.2	32.4 ± 7.4	31.9 ± 7.3
Baseline UAS7 28-42, n (%)	40 (62.5%)	43 (72.9%)	83 (67.5%)
Baseline HSS7 [0-21], mean ± SD	15.1 ± 4.1	16.0 ± 3.9	15.6 ± 4.0
Baseline ISS7 [0-21], mean ± SD	16.3 ± 4.4	16.3 ± 4.2	16.3 ± 4.3
Baseline UCT [0-16], mean ± SD	3 ± 2	3 ± 3	3 ± 3
Baseline DLQI [0-30], mean ± SD	16 ± 8	15 ± 8	16 ± 8

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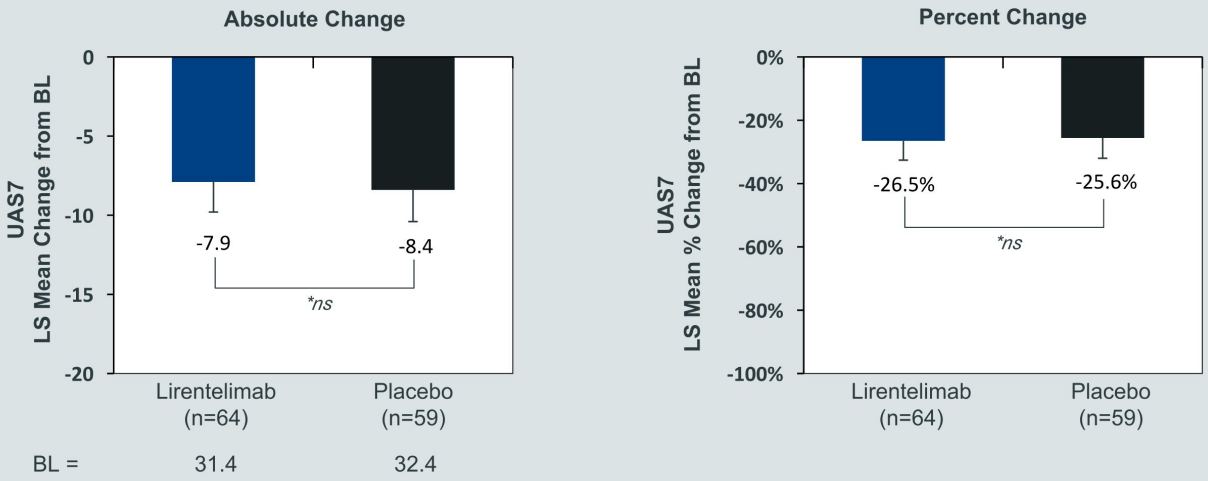
MAVERICK Primary Efficacy Endpoint

Change in UAS7 from Baseline to Week 12 (mITT)



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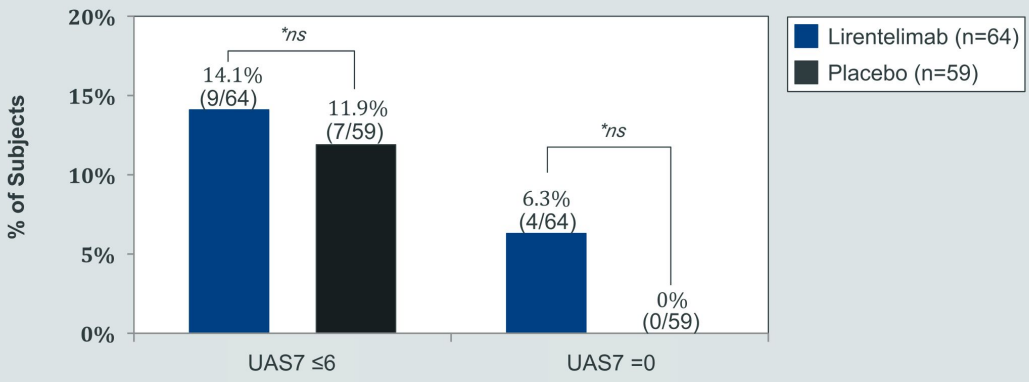
UAS7 Response vs. Placebo

Proportion of Subjects Achieving UAS7 ≤6 and UAS7 =0 at Week 12 (mITT)



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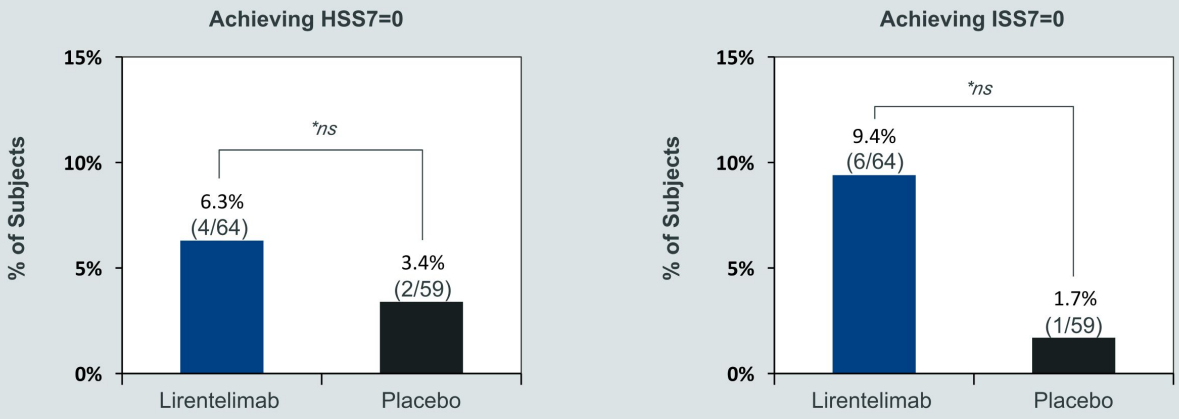
Complete Response in Hives and Itch

Proportion of Complete Responders in Hives and Itch at Week 12 (mITT)



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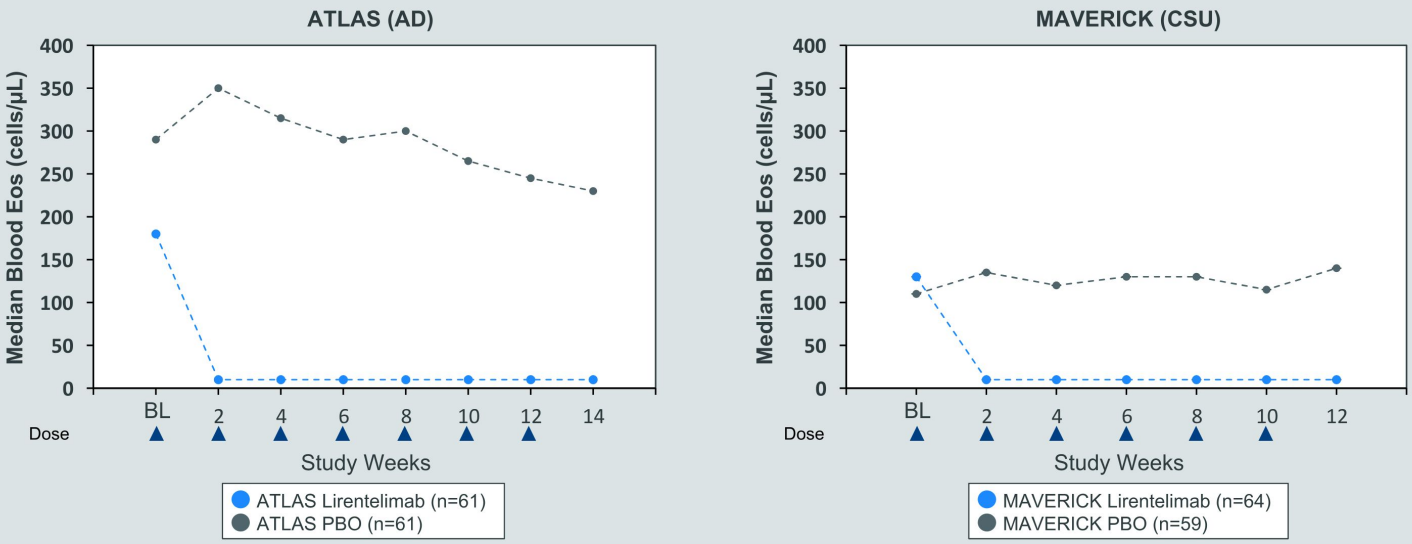
Robust Depletion of Blood Eosinophils with SC Lirentelimab

Blood Eosinophils over Time (mITT)



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Safety

Overall Safety Summary

- Safety profile of SC lirentelimab was consistent with previously reported lirentelimab studies
- Most common adverse events were injection-related reactions (IRRs)
  - ATLAS (AD): 18.5% lirentelimab experienced IRRs vs. 6.2% placebo
  - MAVERICK (CSU): 18.2% lirentelimab experienced IRRs vs 8.2% placebo

Common IRR symptoms included Headache, Chills, Nausea, Dizziness, and Flushing

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Financial Update

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Expected Cash Runway into Middle of 2026

Restructuring Actions

The Company will halt lirentelimab-related activities across clinical, manufacturing, research and administrative functions

Reduce our workforce by almost 50%

The Company anticipates that the significant majority of the restructuring expenditures will be paid in the first half of 2024

Estimated 2024 Net Cash Used in Operating Activities	
Estimated net cash used in operating activities (GAAP)	$85 to $90 million
Less: estimated lirentelimab closeout, severance and other costs	($30 million)
Adjusted net cash used in operating activities (non-GAAP)	$55 to $60 million

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AK006 Development Plans and Update

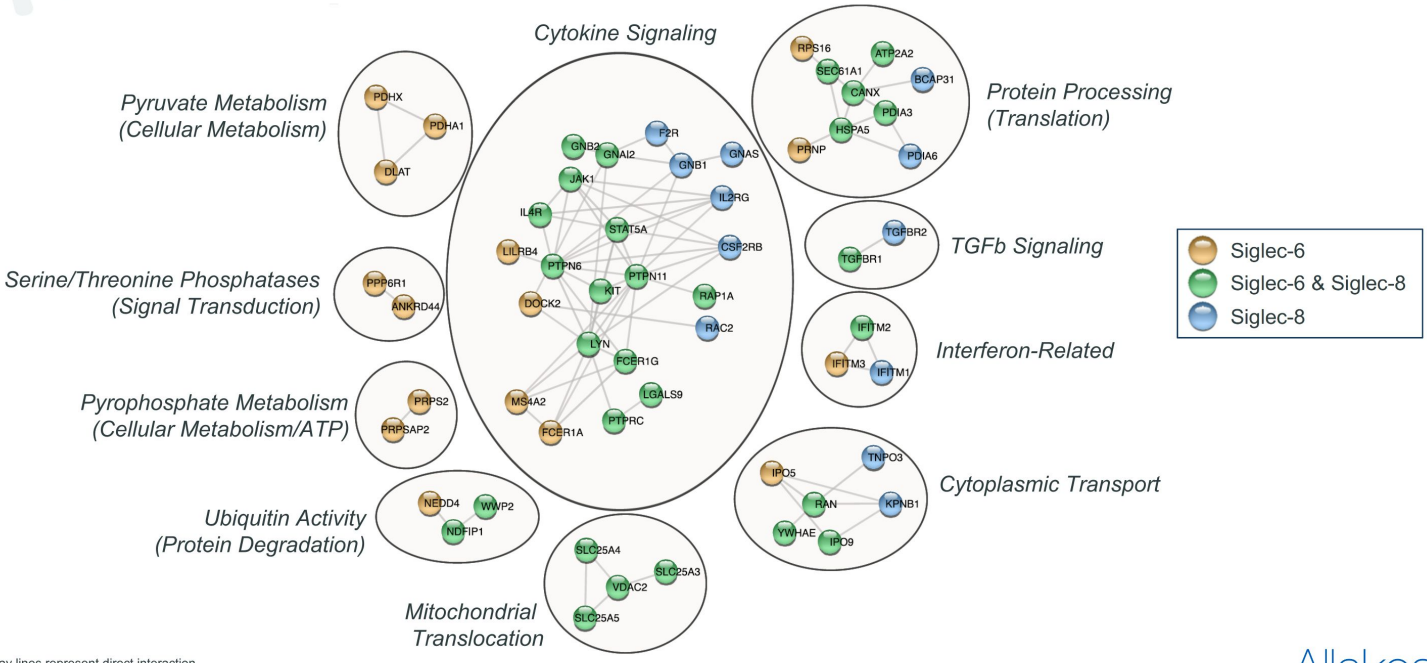
Siglec-6 Biology and AK006

AK006 Targets a Different Receptor with Different Underlying Biology

- **Siglec-6 is a more potent inhibitory receptor than Siglec-8**
  - Siglec-6 regulates more cellular processes than Siglec-8:
    - Signal Transduction
    - Transcription
    - Translation
    - Cellular metabolism
    - Degranulation

- **AK006 has two key attributes**
  - Long residence time on the cell surface which correlates to increased inhibitory activity
  - Antibody Dependent Cellular Phagocytosis (ADCP)

Siglec-6 and Siglec-8 Differentially Interact with Proteins that Regulate Mast Cell Activity



Gray lines represent direct interaction

SOURCE: Korver, W. et al Allergy 2024.

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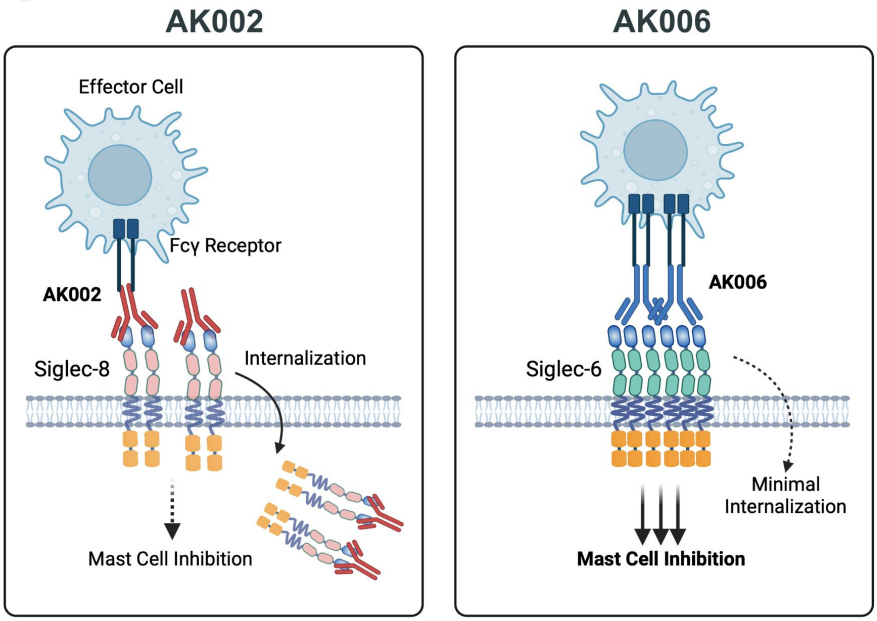
AK006 was Designed to Drive Maximal Mast Cell Inhibition



- Mast cell inhibition for AK002 and AK006 requires Fc-Fc□receptor interaction
- Binding of AK002 induces Siglec-8 internalization, limiting mast cell inhibition
- AK006 displays a high residence time on mast cells which is associated with optimal inhibition
- AK006 induces antibody dependent cellular phagocytosis

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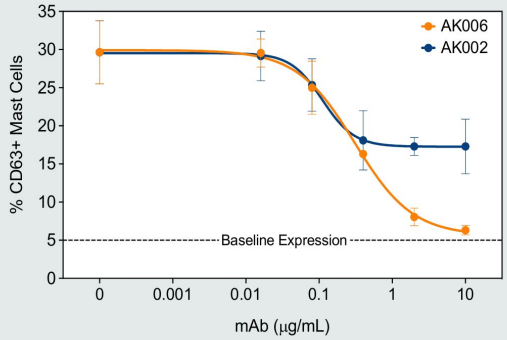
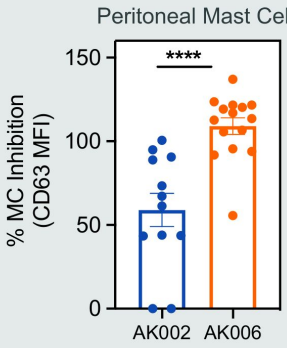
AK006 Displays Significantly Stronger MC Inhibition than AK002 in Preclinical Studies

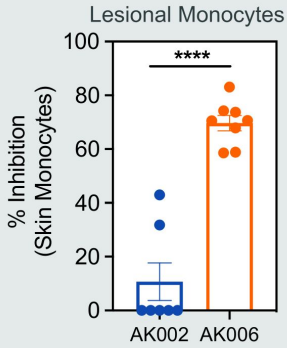
IgE Activation



KIT Activation



MRGPRX2 Activation



n=3 human donors

AK006 inhibits IgE-dependent and –independent modes of MC activation better than AK002

SOURCE: Korver, W. et al Allergy 2024.

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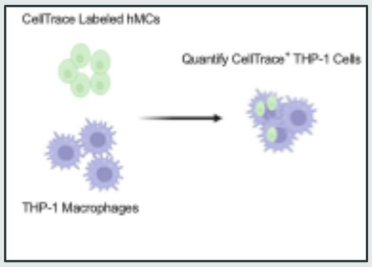
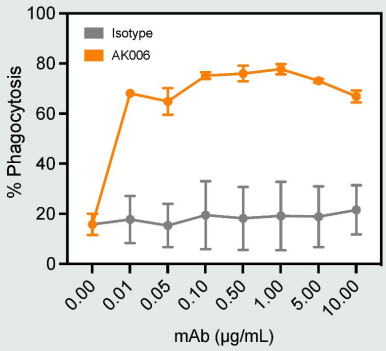
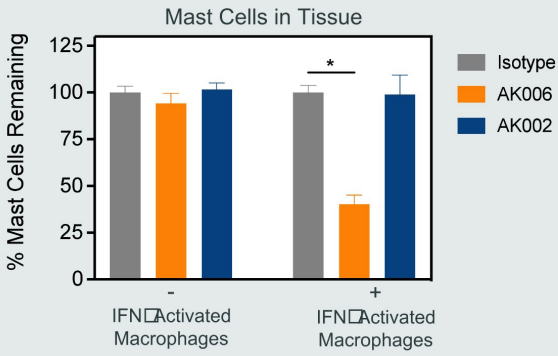
AK006 Reduces Human Mast Cells via Antibody-Dependent Cellular Phagocytosis in Preclinical Studies

In Vitro ADCP Assay





Ex Vivo Human Tissue Mast Cells



* $p < 0.01$; n=3 human donors

AK006 can reduce mast cell numbers and mediate broad inhibition

SOURCE: Schanin, J et al. *Communications Biology*, 2022

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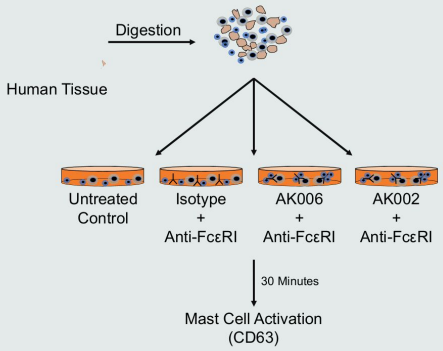
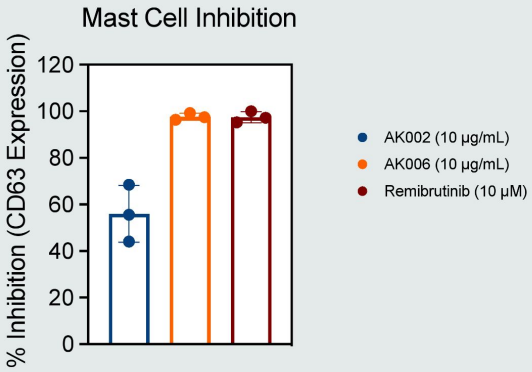
AK006 Inhibits Mast Cell Activation in Human Tissues

Human Mast Cell Activation Assay



IgE-Activated Human Tissue Mast Cells



n=3 human donors

AK006 inhibits IgE-mediated mast cell activation

SOURCE: Schanin J, et al. EAACI 2022 Presentation.

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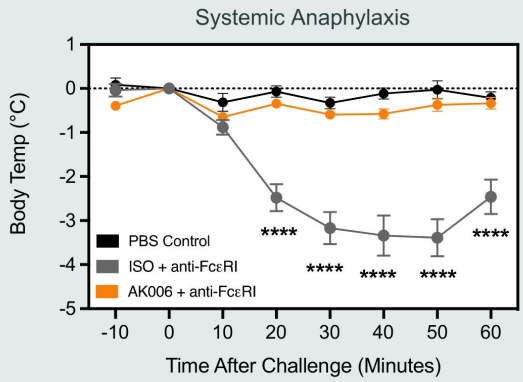
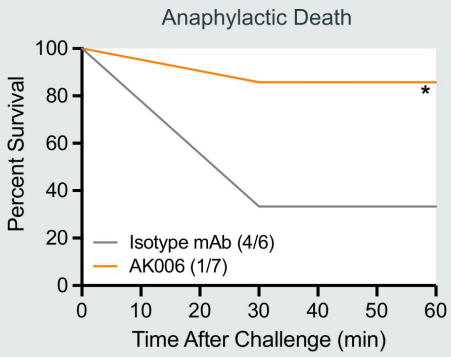
AK006 Protects Against Systemic Anaphylaxis in Humanized Mice

Humanized Mouse Model of Anaphylaxis



Humanized Model of Anaphylactic Death



AK006 inhibits IgE-mediated mast cell activation in vivo

SOURCE: Schanin, J et al. Communications Biology 2022

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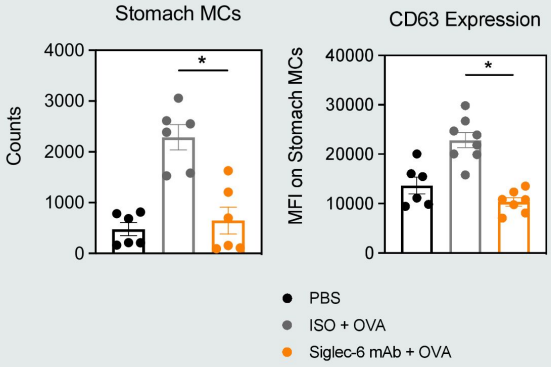
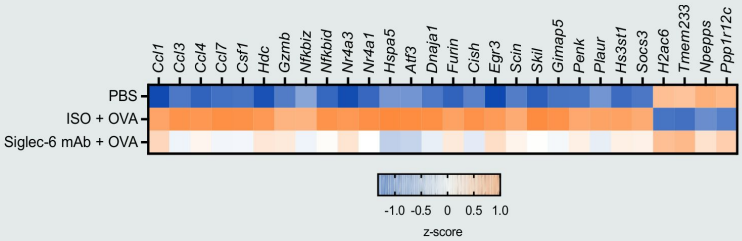
AK006 Reduces Allergic Enteritis in Siglec-6 Transgenic Mice

Stomach Mast Cells



Transcriptional Profiling of Stomach Mast Cells



- $p < 0.05$, n=6 mice/group

AK006 reduces allergen-mediated GI inflammation via mast cell inhibition in vivo

SOURCE: Allakos Data on File.

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AK006 Phase 1 Study Design

Trial Cohorts

Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) Cohorts in Healthy Volunteers

- Randomized, double-blind, placebo-controlled
- Intravenous AK006
  - SAD: 5, 20, 80, 240, 720 mg
  - MAD: 80, 240, 720 mg monthly
- Subcutaneous AK006
  - 150 and 720 mg

Planned CSU Cohort

- Randomized, double-blind, placebo-controlled
- Moderate-to-severe antihistamine refractory CSU
  - UAS7 score ≥16 and HSS7 score ≥8 at baseline
- Four doses of AK006 IV given monthly

Endpoints

SAD and MAD Cohort

- Safety and tolerability
- Pharmacokinetics
- Pharmacodynamics
- Target receptor engagement in skin biopsies
- SC Bioavailability

CSU Cohort

- Therapeutic activity assessed by changes in UAS7 at week 14

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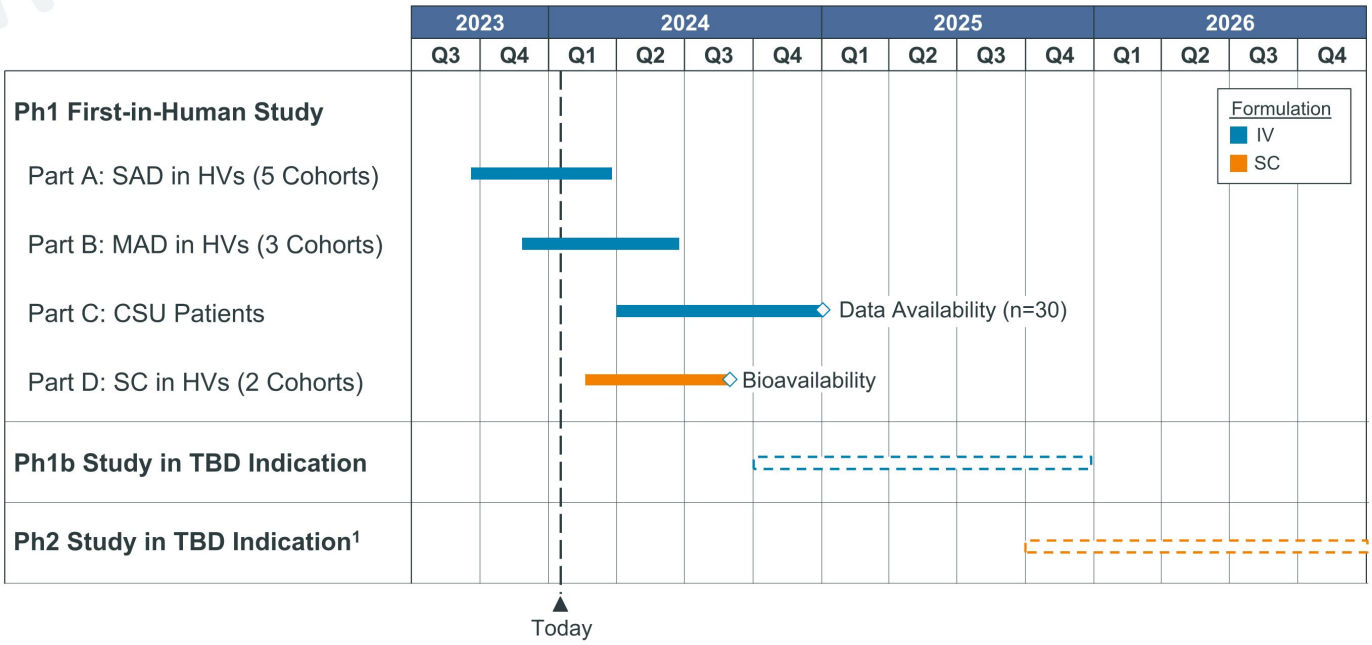
AK006 Clinical Development Plan



CSU, chronic spontaneous urticaria; HVs, healthy volunteers; MAD, multiple ascending dose; SAD, single ascending dose; SC, subcutaneous
1 = Phase 2 Study for timing purposes only, potential future investment for Phase 2 study not currently in budget

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Upcoming AK006 Milestones

- Q1 2024: Complete SAD and MAD dosing with Intravenous (IV) AK006 in healthy volunteers.
- Q1 2024: Initiate the randomized, double-blind, placebo-controlled subcutaneous (SC) AK006 cohort in healthy volunteers.
- Q2 2024: Report SAD and MAD safety, pharmacokinetics (PK), and pharmacodynamic (PD) results from the Phase 1 IV AK006 trial in healthy volunteers, including data to confirm Siglec-6 receptor occupancy in skin biopsy samples.
- Q2 2024: Initiate the randomized, double-blind, placebo-controlled Phase 1 trial of IV AK006 in patients with chronic spontaneous urticaria (CSU).
- Q3 2024: Report subcutaneous (SC) AK006 safety, PK, and PD results from the Phase 1 trial in healthy volunteers, including data to confirm Siglec-6 receptor occupancy in skin biopsy samples.
- Year End 2024: Report topline data from the Phase 1 trial of IV AK006 in patients with CSU.

Q&A

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Thank You