# 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): October 10, 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 October 10, 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 October 10, 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: October 10, 2024

By: /s/ H. Baird Radford, III

**H. Baird Radford, III**
**Chief Financial Officer**

Exhibit 99.1

Allakos

# Corporate Presentation

October 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 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.

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' 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.



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# Allakos Opportunity

**Novel Target**

- AK006 (anti-Siglec-6 mAb) selectively inhibits multiple modes of mast cell activation
  - Inhibits IgE-dependent and IgE-independent mast cell activation pathways, including IgE, KIT and MRGPRX2
  - Depletes mast cells by ADCP in the presence of activated macrophages

**Significant Need for New Agents**

- AK006 has the potential to treat a broad range of mast cell driven diseases
- IV and SC formulations of AK006 achieved high Siglec-6 occupancy on skin mast cells
- SC Formulation of AK006 has high bioavailability and was well-tolerated
- AK006 is being tested in Chronic Spontaneous Urticaria (CSU)

**Upcoming Data Catalysts and Expected Milestones**

**Milestones**

- Early Q1’25 – Report topline Phase 1 data of AK006 in patients with CSU

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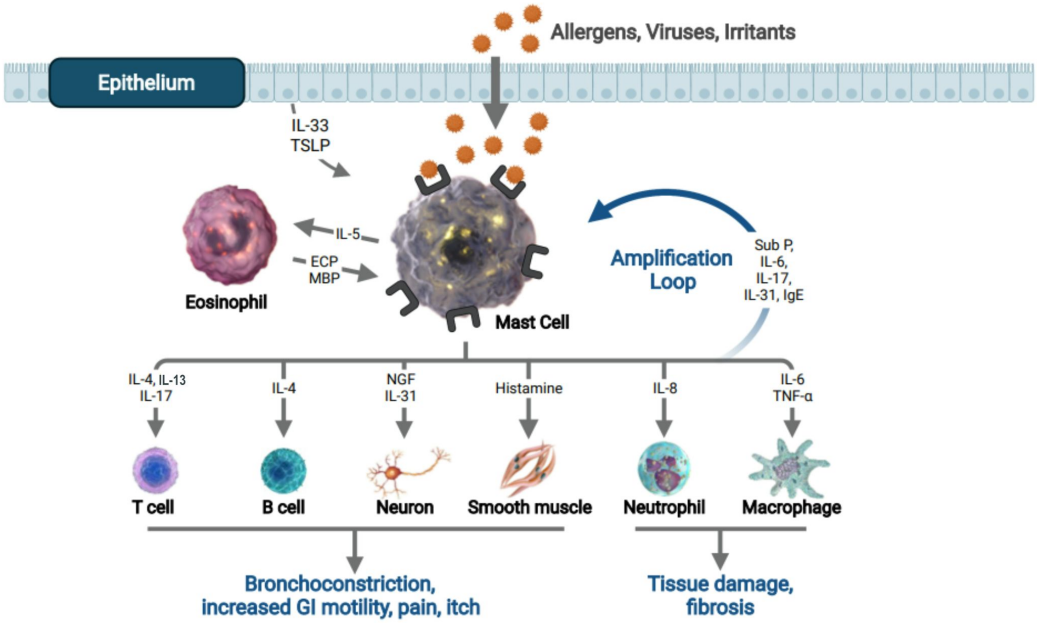
# Mast Cells Are Key Drivers of Inflammatory Disease

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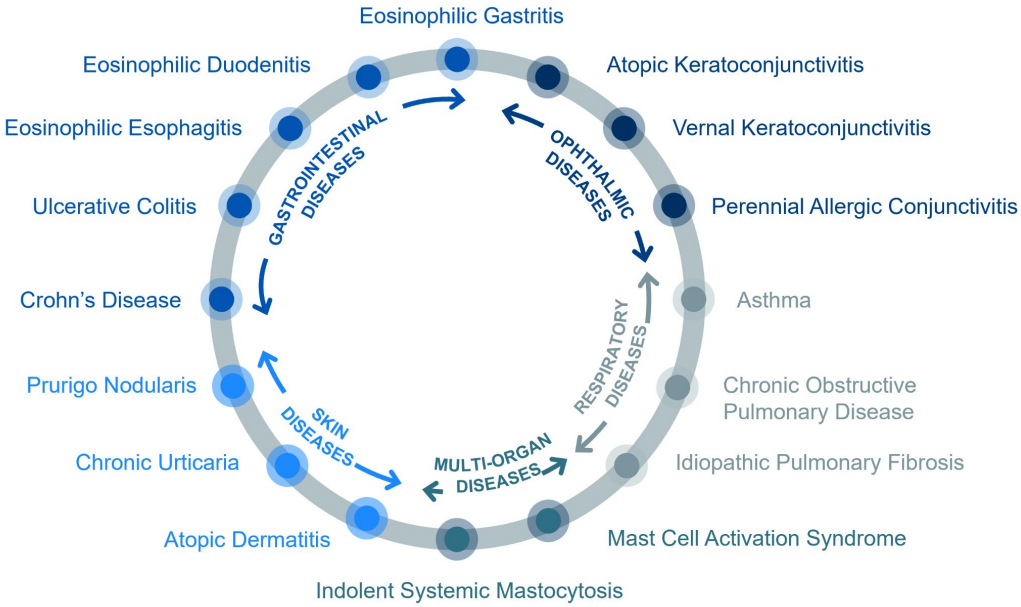
# Mast Cells Play a Significant Role in Many Diseases

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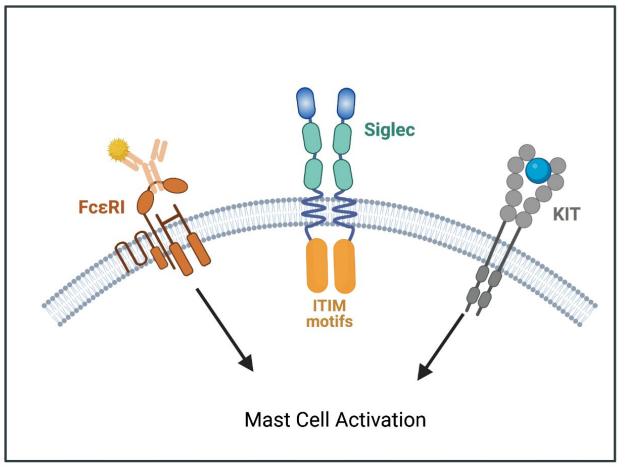
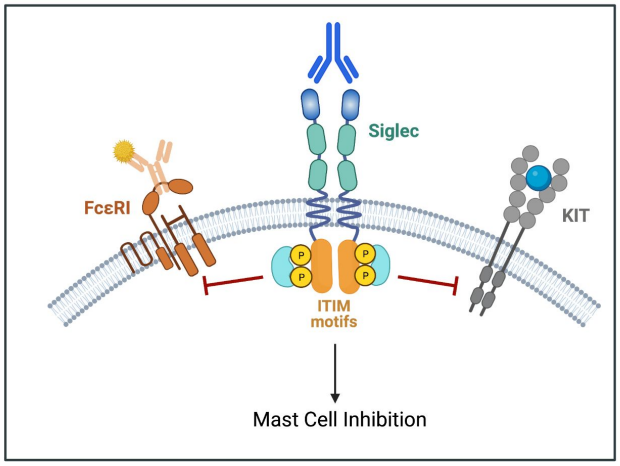
# Leveraging the Native Inhibitory Function of Siglecs on Mast Cells

## Activated State




Mast cells can be activated by numerous receptors leading to mast cell degranulation and release of histamine, TNFα and other inflammatory mediators

## Siglec-Mediated Inhibition




Activation of Siglec-6 with an agonistic antibody activates inhibitor machinery inside cell which attenuates activating signals

SOURCE: O'Sullivan J et al. Seminars in Immunology. 2023 Jul; 4; 69:101799

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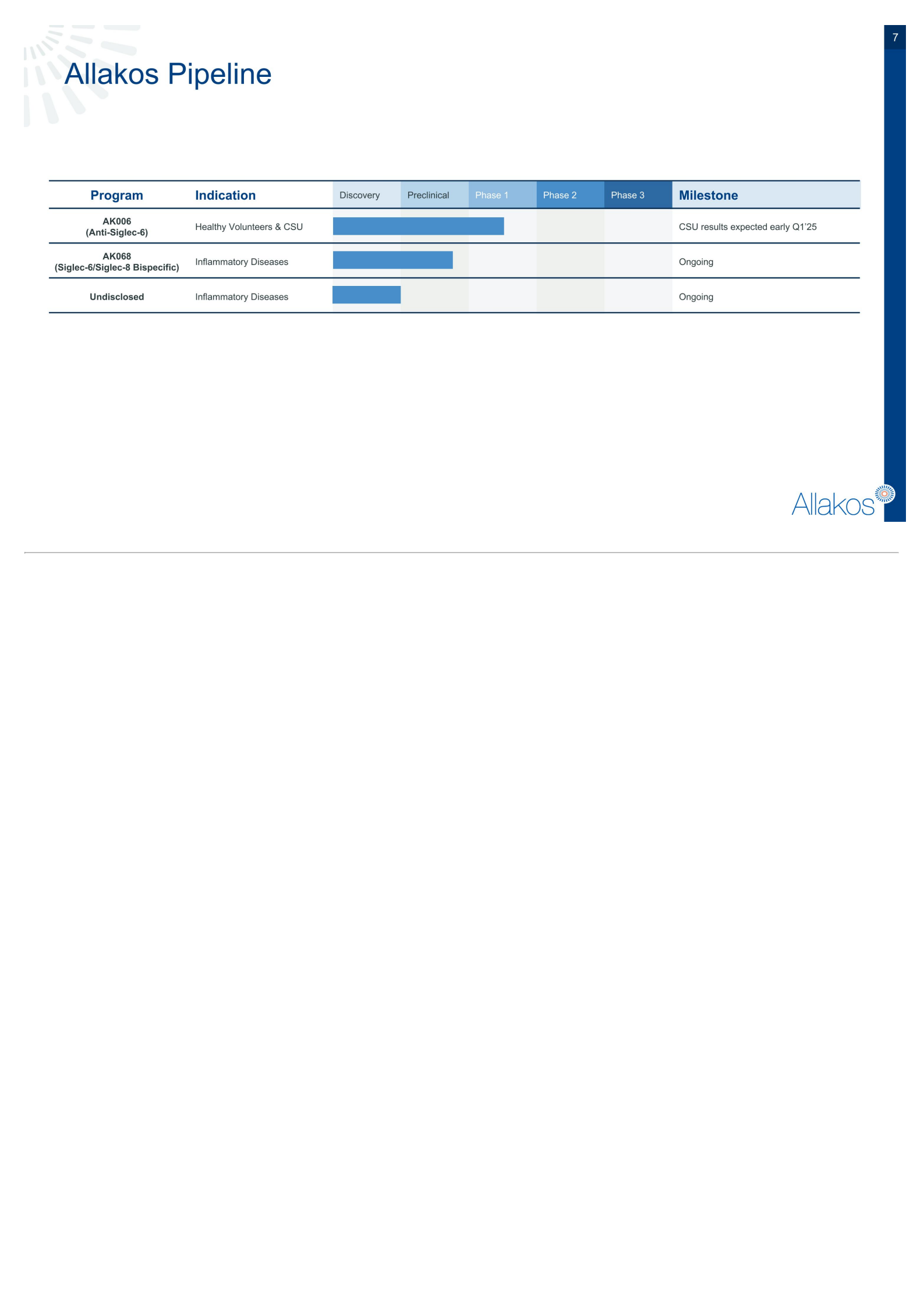
# Allakos Pipeline

| Program | Indication | Discovery | Preclinical | Phase 1 | Phase 2 | Phase 3 | Milestone |
|---|---|---|---|---|---|---|---|
| **AK006 (Anti-Siglec-6)** | Healthy Volunteers & CSU | | | | | | CSU results expected early Q1'25 |
| **AK068 (Siglec-6/Siglec-8 Bispecific)** | Inflammatory Diseases | | | | | | Ongoing |
| **Undisclosed** | Inflammatory Diseases | | | | | | Ongoing |



# AK006: Siglec-6 mAb that Selectively and Potently Inhibits Mast Cells

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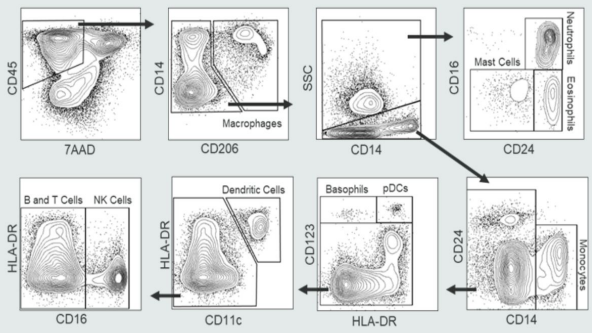
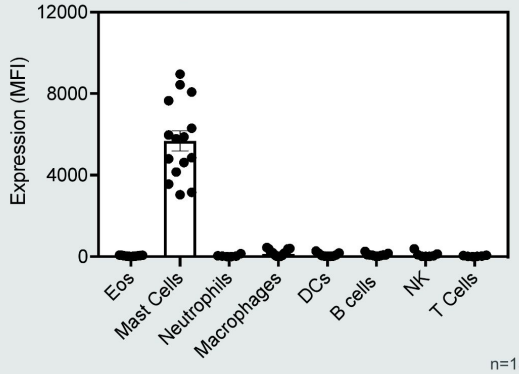
# Siglec-6 Is Selectively Expressed on Human Tissue Mast Cells

## Gating Strategy for Immune Cells in Human Tissue




## Siglec-6 Expression Profile




n=15 human donors

Siglec-6 represents a selective mast cell inhibitory receptor

SOURCE: Allakos data on file

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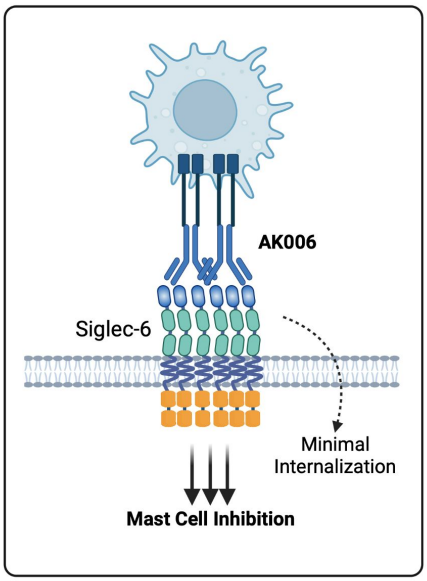
# AK006 was Designed to Activate the Native Function of Siglec-6




## AK006 Mechanism of Action

- The inhibitory mechanism has the potential to inhibit multiple modes of mast cell activation
- Mast cell inhibition by AK006 requires Fc-Fc$\gamma$ receptor interaction
- AK006 has high residence time due to minimal receptor internalization, potentially leading to higher levels of inhibition
- AK006 induces antibody dependent cellular phagocytosis in the presence of activated macrophages

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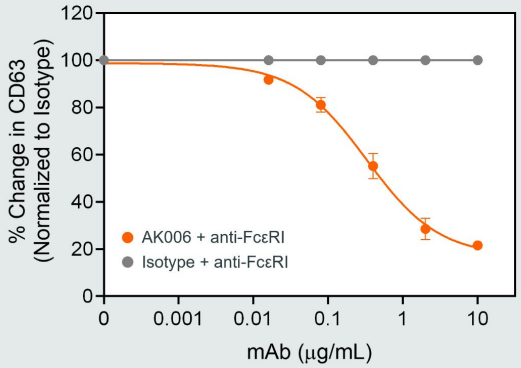
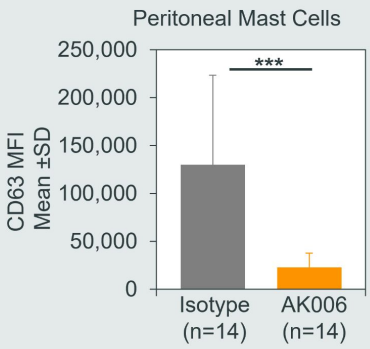
# AK006 Displays High levels of Mast Cell Inhibition in Preclinical Studies

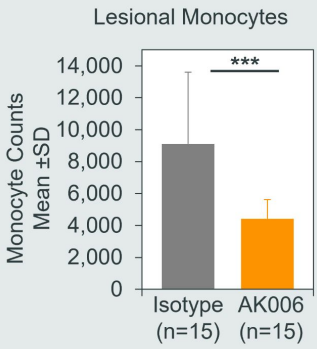
## IgE Activation




## KIT Activation




## MRGPRX2 Activation




n=3 human donors

AK006 inhibits IgE-dependent and IgE-independent modes of mast cell activation

*** $p < 0.001$

SOURCE: Korver, W. et al *Allergy* 2024; Allakos data on file

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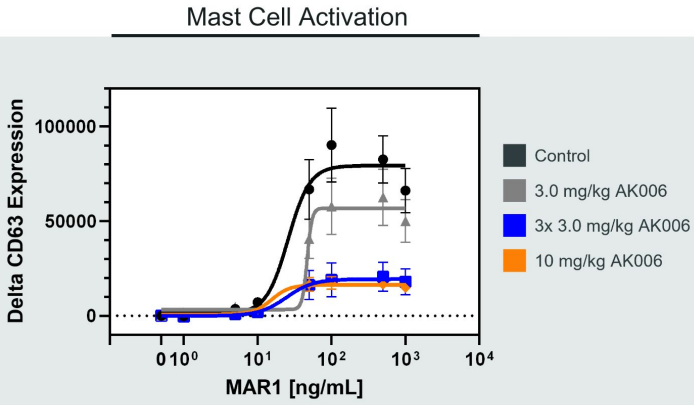
# Systemic Administration of AK006 Prevents Ex-Vivo IgE Activation of Mast Cells

i.v. AK006 3 mg/kg or
i.v. AK006 10 mg/kg or
i.v. AK006 3 mg/kg Q4D

d14

Activate Mast Cells *ex vivo*

Peritoneal Mast Cells are isolated and challenged with anti-FcεRI antibody for 20 minutes.




Multiple dosing of AK006 provides more potent Mast Cell inhibition

N = 4-6 mice per group
SOURCE: Allakos data on file

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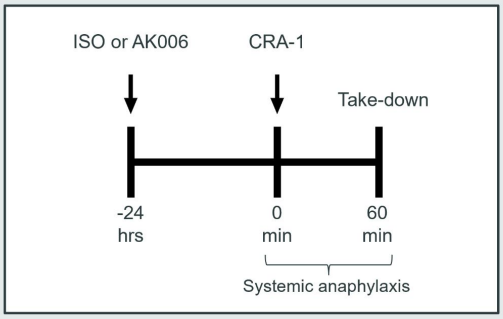
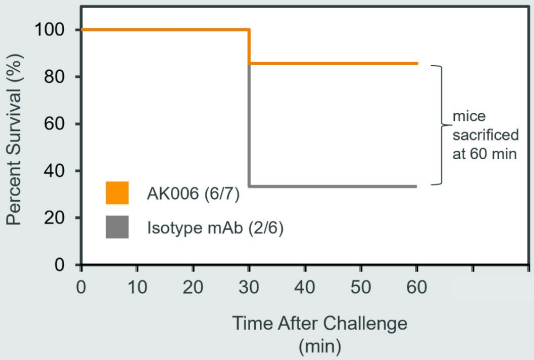
# AK006 Protects Against Systemic Anaphylaxis in Humanized Mice

## Humanized Model of Anaphylactic Death

### Experimental Design




### Kaplan-Meier




AK006 protects mice from IgE-induced anaphylactic death

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

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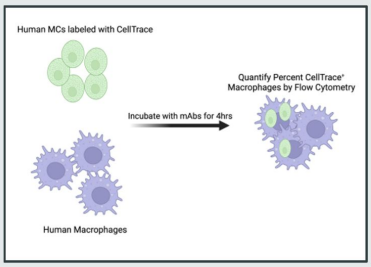
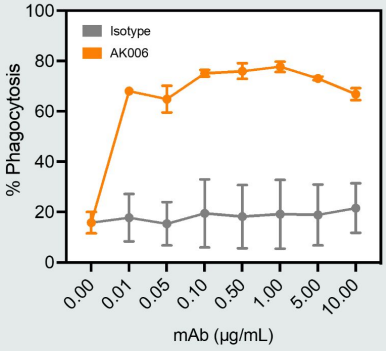
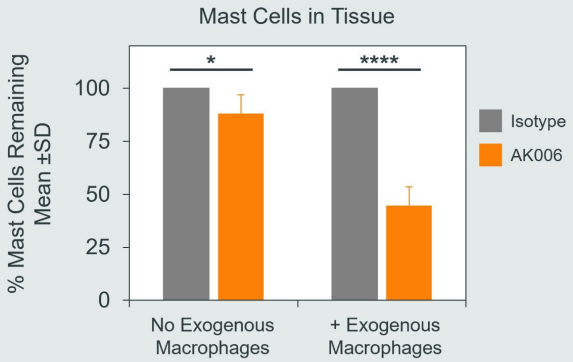
# AK006 Reduces Human Mast Cells via Antibody-Dependent Cellular Phagocytosis in Preclinical Studies

## In Vitro ADCP Assay




## Ex Vivo Human Tissue Mast Cells




In addition to mediating broad inhibition, AK006 can reduce mast cell numbers

* $p < 0.05$; **** $p < 0.0001$; n=2 human donors
SOURCE: Benet Z, et al. AAAAI 2023 Presentation; Allakos data on file

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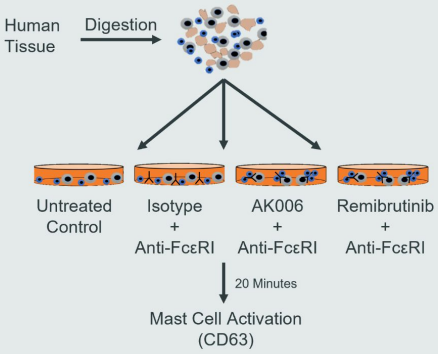
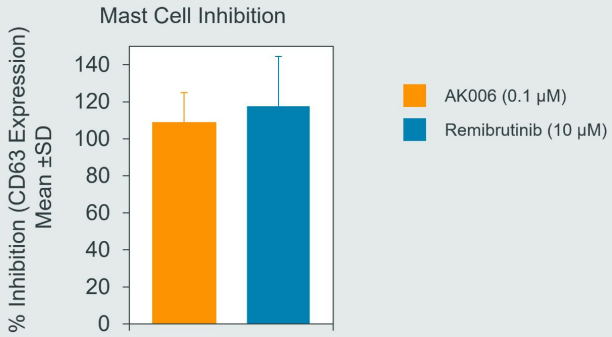
# AK006 Inhibits IgE-Mediated Mast Cell Activation Similar to Remibrutinib

## Human Mast Cell Activation Assay




## IgE-Activated Human Tissue Mast Cells




n=5 human donors
SOURCE: Allakos data on file

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# AK006 in Phase 1 Clinical Study in Healthy Volunteers and Chronic Spontaneous Urticaria

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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
- Safety and tolerability

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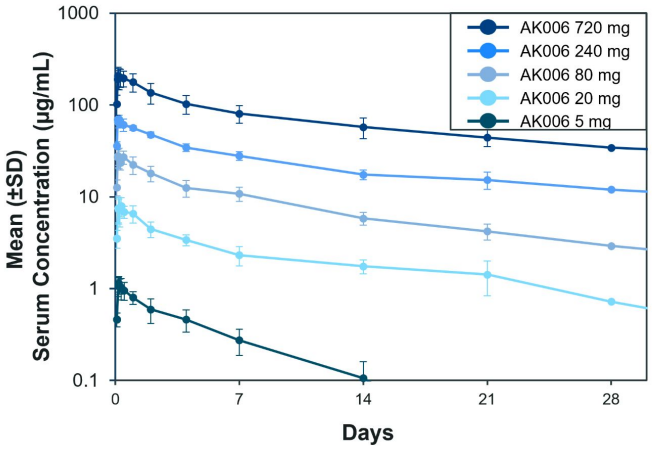
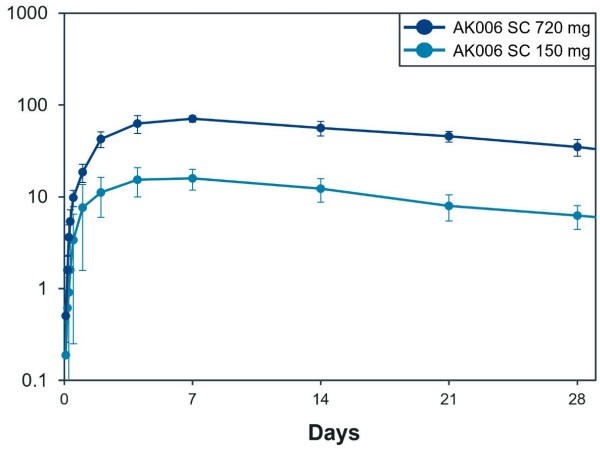
# Subcutaneous AK006 has 77% Bioavailability

Single-dose IV




Single-dose SC




SC and IV AK006 have good pharmacokinetic properties with a half life of 12-22 days

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# High Siglec-6 Occupancy is Observed at Low Doses

The high occupancy levels on skin mast cells from healthy volunteer biopsies confirm that systemically administered AK006 has good distribution into the skin

SC and IV AK006 provided mean Siglec-6 receptor occupancy >90% with low receptor internalization

High doses of AK006 provided high occupancy at Day 113 suggesting the potential for infrequent dosing

## Siglec-6 Receptor Occupancy
(mean, %)

| Route | Dose Cohort (mg) | n | S6 % Receptor Occupancy | | | % Surface Siglec-6 |
|---|---|---|---|---|---|---|
| | | | Baseline | Day 29 | Day 113* | Day 29† |
| IV & SC | PBO | 19 | 0 | 2 | 2 | 103 |
| SAD IV | 5 | 7 | 0 | 45 | - | 82 |
| | 20 | 6 | 0 | 92 | - | 68 |
| | 80 | 6 | 0 | 96 | - | 133 |
| | 240 | 6 | 0 | 94 | 93 | 162 |
| | 720 | 6 | 0 | 101 | 94 | 139 |
| SC | 150 | 6 | 0 | 78 | 54 | 88 |
| | 720 | 6 | 0 | 94 | 98 | 102 |

Each patient (n) received a biopsy at (1) baseline and (2) either Day 8 or Day 29;
* Day 113 samples were not collected for 5mg, 20mg, 80mg dose groups
† % Total Siglec-6 on cell surface at Day 29 relative to baseline

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# AK006 was Well-Tolerated with a Favorable Safety Profile

- Single and multiple doses of IV AK006 and single doses of SC up to 720 mg were well-tolerated with a favorable safety profile. In the safety profile to date:
  - No treatment emergent SAEs in subjects on AK006
  - There were no treatment emergent adverse events leading to discontinuation of AK006
  - There were no dose limiting toxicities
  - The most common adverse events (≥10%) occurring more frequently in subjects on AK006 were headache and dysmenorrhea, all of which were mild-to-moderate in severity

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# AK006 for Chronic Spontaneous Urticaria

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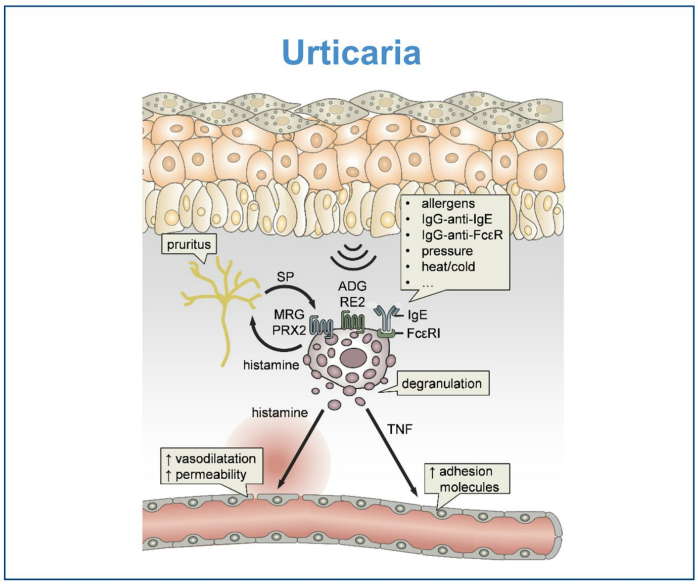
# AK006 May Inhibit Disease Driving Pathways in Urticaria

Activated mast cells drive the pathogenesis of urticaria via release of inflammatory mediators resulting in pruritis, vasodilation, and increased vascular permeability

IgE activation of mast cells, from autoantibodies or allergens, has been identified as driving pathogenesis in a proportion of patients with chronic urticaria

IgE-independent mast cell activation, via MRGPRX2 and other mast cell receptors, is also believed to contribute to symptoms

Blocking both IgE activation and IgE-independent mast cell activation could result in improved patient outcomes in CSU




SOURCE: Voss, M.; Int. J. Mol. Sci. 2021, 22, 4589. doi.org/10.3390/ijms22094589; Siiskonen H. Front Cell Neurosci. 2019;13:422. Published 2019 Sep 18. doi:10.3389/fncel.2019.00422

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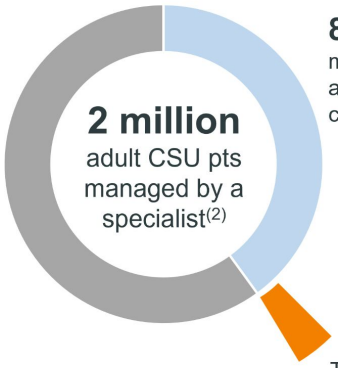
# Chronic Spontaneous Urticaria Opportunity

CSU affects up to 3 million adults in the U.S., with 2 million managed by a specialist (allergist or dermatologist)[1,2]

An estimated 800K adults with CSU are biologic-eligible, yet only approximately 10% of eligible patients are currently on a biologic[2,3]

Currently only Xolair is approved for the treatment of antihistamine CSU. Xolair® (omalizumab) global CSU sales were estimated to be $1.6 billion in 2021[4]

**Approximately 800k adult CSU patients are eligible for a biologic in the U.S.**




**800K** (40%)
moderate-to-severe and inadequately controlled with H1-AH(2)

**80K**
Treated with Xolair(3) (~10% of biologic-eligible patients)

**1.** Maurer M, et al. Allergy. 2011 Mar;66(3):317-30. **2.** Allakos allergist and dermatologist market research survey (N=208), Nov 2021. **3.** Decision Resources Chronic Urticaria Report, Nov 2020.
**4.** Novartis 2021 annual report and earnings call

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# Chronic Spontaneous Urticaria Landscape

| Drug Name | MOA | UAS7 Response | Opportunity |
|---|---|---|---|
| Xolair® (omalizumab) | Anti-IgE mAb | Dose Group[1] / 150 mg / 300 mg / Placebo<br>UAS7 / -14.4 (-48%) / -20.8 (-66%) / -8.0 (-26%)<br>UAS7=0 / 15% / 36% / 9% | • >50% of patients continue to have symptoms<br>• Black box for anaphylaxis[1] |
| Dupixent® (dupilumab) | Anti IL-4/IL-13R mAb | Dose Group[2] / 300 mg / Placebo<br>UAS7 / -20.5 (-65%) / -12.0 (-37%) | • Q2W dosing<br>• Slow onset of action<br>• No improvement in Xolair failures[3] |
| Barzolvolimab | Anti KIT mAb | Dose Group[4] / 75 mg Q4W / 150 mg Q4W / 300 mg Q8W / Placebo<br>UAS7 / -17 (-56%) / -23 (-75%) / -24 (-76%) / -10 (-35%)<br>UAS7=0 / 23% / 51% / 38% / 6% | • c-Kit is expressed on hematopoietic stem cells, melanocytes, CNS and germ cells[5] |
| Remibrutinib | BTK Inhibitor | Dose Group[6] / 25 mg BID / Placebo<br>UAS7 / -20 & -20 (-65% & -65%) / -12 to -14 (-40% to -46%)<br>UAS7=0 / 28% to 31% / 7% to 11% | • BTK is expressed on hematopoietic cells including B cells, myeloid cells, and platelets[7] |

SOURCE:1.) Xolair Label; UAS7 scores are calculated change from baseline and percentage change; 2.) Sanofi PR 7/29/21 3.) Sanofi PR 2/18/22 4.) Celldex Presentation 11/6/23 5.) N.F. Russkamp et al. Experimental Hematology 2021;95:31–45 6.) Saini S, et al. ACAAI 2023 Presentation 7.) Garg N et. al. J Clin Med 2022; 11(20):6039

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# Financial Overview & Key Milestones

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# Data Catalysts and Expected Milestones

- ✓ **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.
- **Early Q1 2025:** Report topline data from the Phase 1 trial of IV AK006 in patients with CSU.

# Balance Sheet and IP Protection

| | |
|---|---|
| Cash, Cash Equivalents and Investments in Marketable Securities as of December 31, 2023 | $170.8 M |
| – Estimated 2024 cash used in restructuring (lirentelimab closeout, severance and other costs) | $30 M |
| – Estimated 2024 cash used in ongoing business operations | $55 to $60 M |
| Estimated, Cash, Cash Equivalents and Investments in Marketable Securities at year end 2024 | $81 to $86 M |
| Common Shares Outstanding as of December 31, 2023 | 87.8 M |

Allakos expects that the restructuring activities will extend the cash runway into mid-2026

AK006 composition of matter to expire in 2042 without extensions

Planning subcutaneous AK006 for Phase 2 studies

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