

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): June 25, 2024

Allakos Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

825 Industrial Road, Suite 500
San Carlos, California
(Address of Principal Executive Offices)

001-38582
(Commission File Number)

45-4798831
(IRS Employer
Identification No.)

94070
(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 June 25, 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 June 25, 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: June 25, 2024

By: /s/ H. Baird Radford, III
H. Baird Radford, III
Chief Financial Officer



Corporate Presentation

June 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.



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

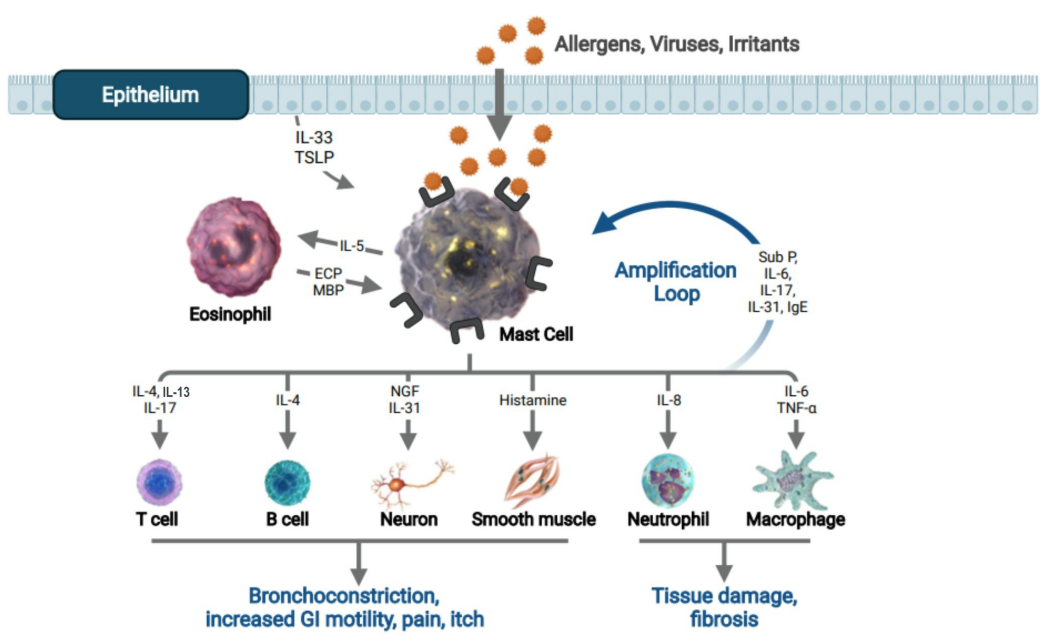
- AK006 has the potential to treat a broad range of mast cell driven diseases
- AK006 to be tested in Chronic Spontaneous Urticaria (CSU) and one additional proof-of-concept study

Upcoming Data Catalysts and Expected Milestones

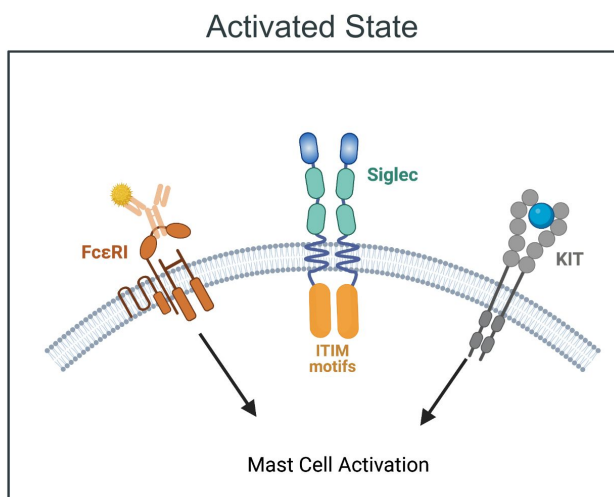
Milestones

- 3Q24 – Report safety, PK, and PD results from the Phase 1 trial of subcutaneous AK006 in healthy volunteers
- YE24 – Report topline Phase 1 data of AK006 in patients with CSU

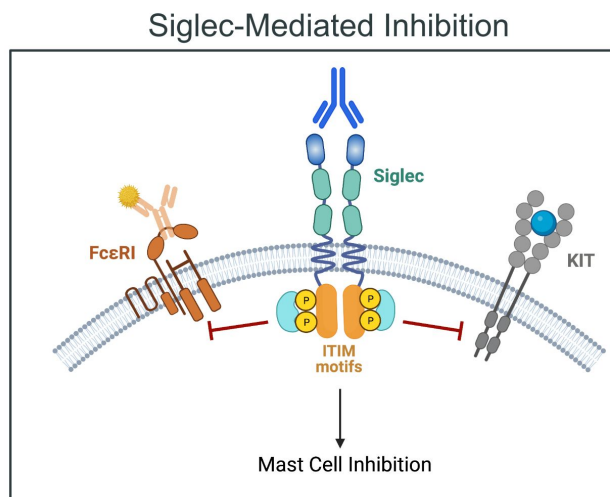
Mast Cells Are Key Drivers of Inflammatory Disease



Leveraging the Native Inhibitory Function of Siglecs on Mast Cells



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

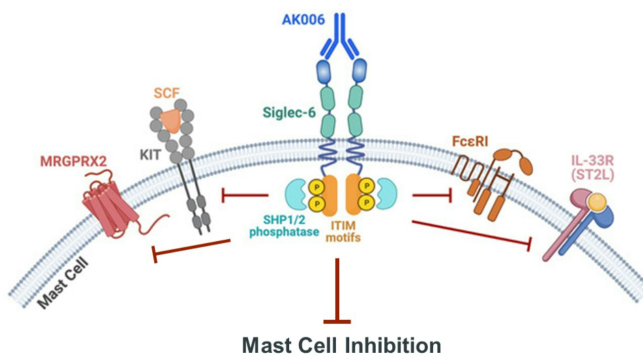


Activation of Siglec-6 with an agonistic antibody activates inhibitor machinery inside cell which attenuates activating signals

AK006 is Engineered for Deep Mast Cell Inhibition

AK006 (Anti-Siglec-6)

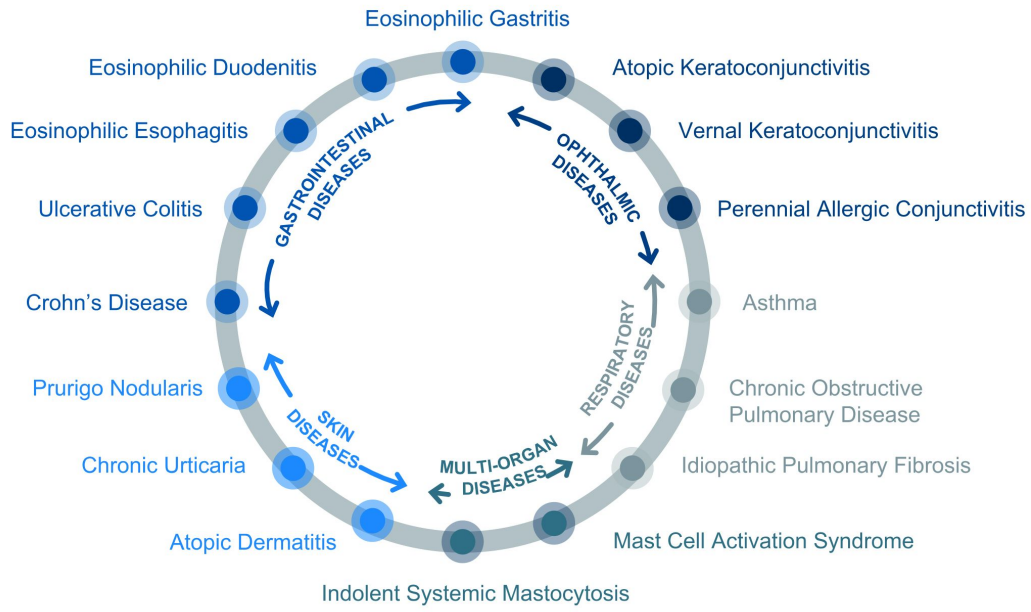
- AK006 is a Siglec-6 mAb that selectively inhibits mast cells and reduces their numbers
 - Engineered for deep mast cell inhibition
 - Reduces mast cells via ADCP in presence of activated macrophages
- AK006 inhibits multiple mast cell activation pathways including IgE, IL-33, KIT, C5a and MRGPRX2
- The Phase 1 study of AK006 consists of single and multiple ascending doses administered in healthy volunteers, followed by a randomized, double-blind, placebo-controlled, CSU cohort





Program	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Milestone
AK006 (Anti-Siglec-6)	Healthy Volunteers & CSU	[Progress bar]					Expected SC results from healthy volunteers in 3Q24; Expected CSU results at YE24
AK068 (Siglec-6/Siglec-8 Bispecific)	Inflammatory Diseases	[Progress bar]					Ongoing
T Cell Immunomodulatory Receptors	Inflammatory Diseases	[Progress bar]					Ongoing
AK007 (Anti-Siglec-10)	Immuno-Oncology	[Progress bar]					Ongoing

Mast Cells Play a Significant Role in Many Diseases



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

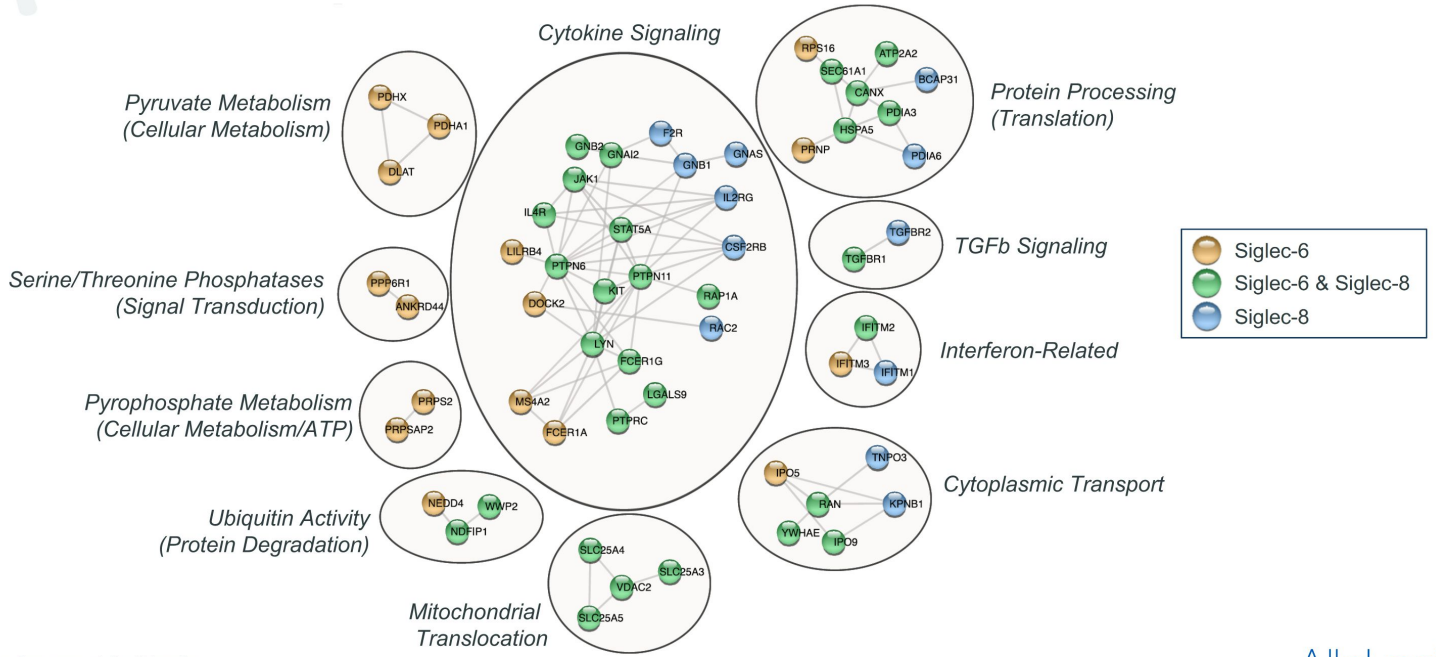


Siglec-6 Biology and AK006

AK006 Targets a Different Receptor Than AK002 with Different Underlying Biology

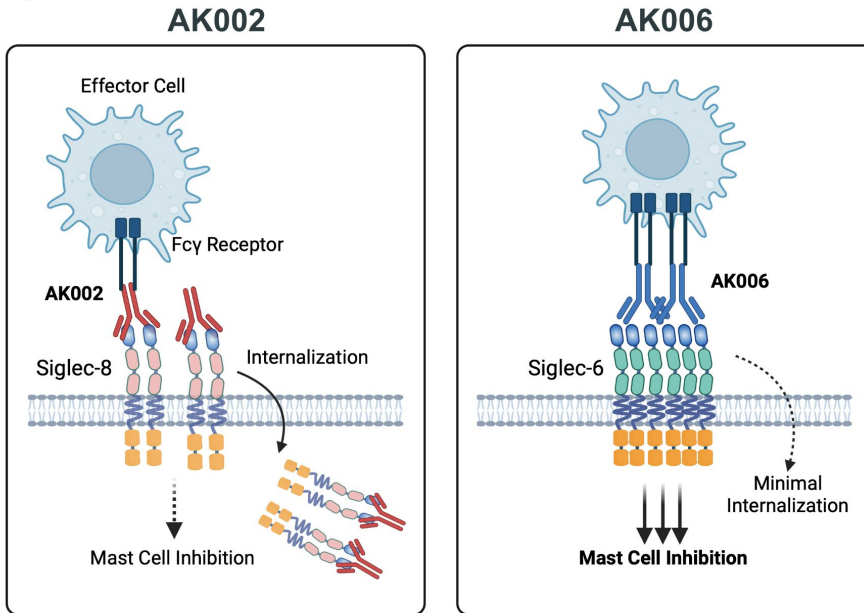
- **Siglec-6 is a more potent inhibitory receptor than Siglec-8**
 - Siglec-6 regulates more cellular processes than Siglec-8:
 - Signal Transduction
 - Transcription
 - Translation
 - Cellular metabolism
 - Degranulation
- **AK006 has two key attributes**
 - Long residence time on the cell surface which correlates to increased inhibitory activity
 - Antibody Dependent Cellular Phagocytosis (ADCP)

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



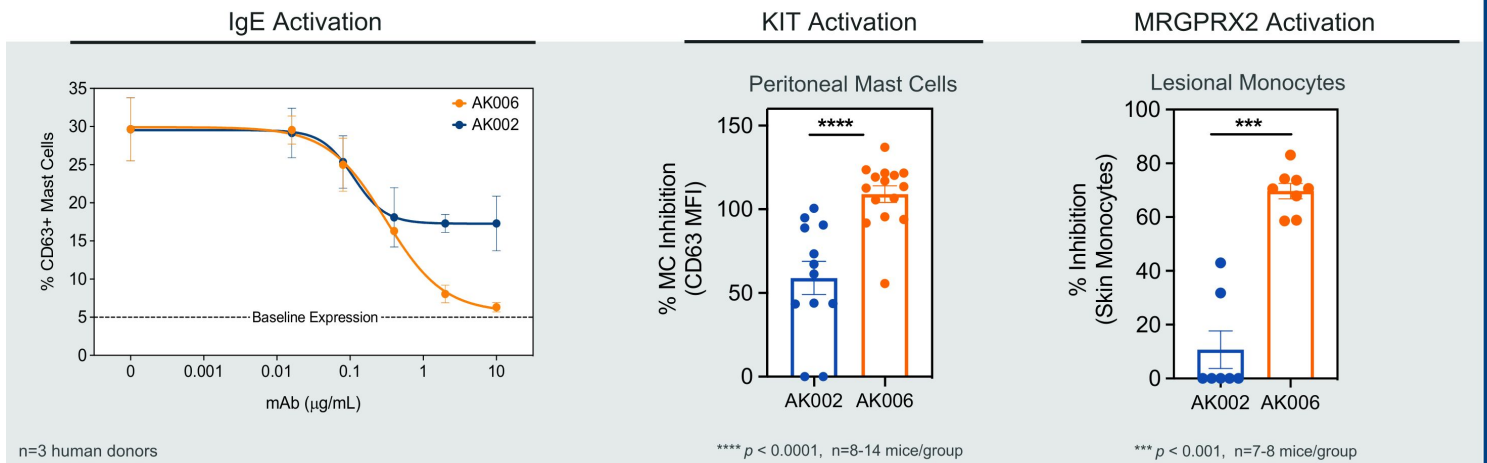
Gray lines represent direct interaction
 SOURCE: Korver, W. et al Allergy 2024.

AK006 was Designed to Drive Deep Mast Cell Inhibition



- Mast cell inhibition for AK002 and AK006 requires Fc-Fc γ receptor interaction
- Binding of AK006 leads to minimal receptor internalization, resulting in greater mast cell inhibition
- AK006 displays a high residence time on mast cells which is associated with optimal inhibition
- AK006 induces antibody dependent cellular phagocytosis

AK006 Displays Greater Mast Cell Inhibition than AK002 in Preclinical Studies

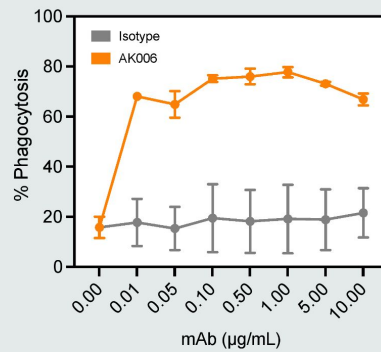
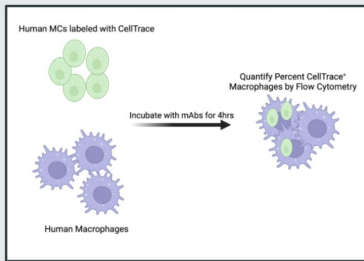


AK006 inhibits IgE-dependent and IgE-independent modes of mast cell activation better than AK002

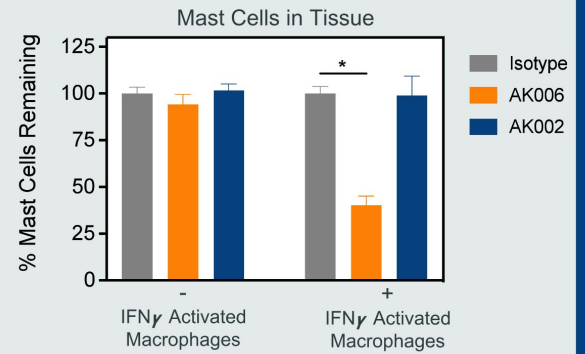
SOURCE: Korver, W. et al *Allergy* 2024; Benet Z, et al. AAAAI 2024 Presentation.

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

In Vitro ADCP Assay



Ex Vivo Human Tissue Mast Cells

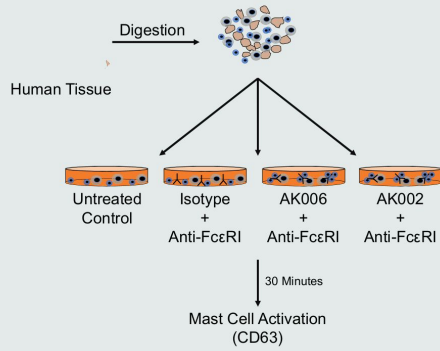


In addition to mediating broad inhibition, AK006 can reduce mast cell numbers

AK006 Inhibits IgE-Mediated Mast Cell Activation Similar to Remibrutinib

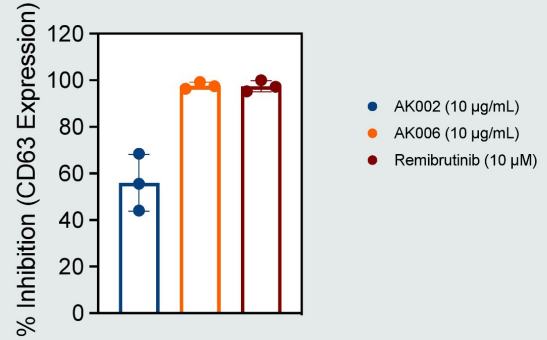
Human Mast Cell Activation Assay

IgE-Activated Human Tissue Mast Cells



n=3 human donors

Mast Cell Inhibition

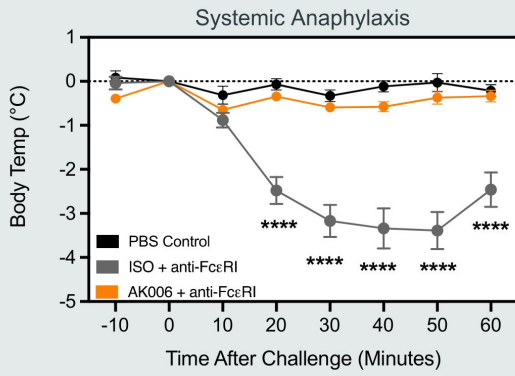


AK006 inhibits IgE-mediated mast cell activation

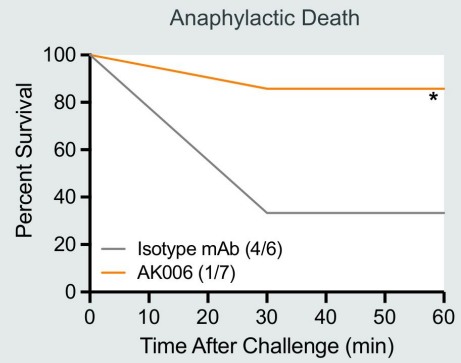
SOURCE: Korver W, et al. EAACI 2023 Presentation.

AK006 Protects Against Systemic Anaphylaxis in Humanized Mice

Humanized Mouse Model of Anaphylaxis



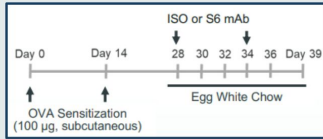
Humanized Model of Anaphylactic Death



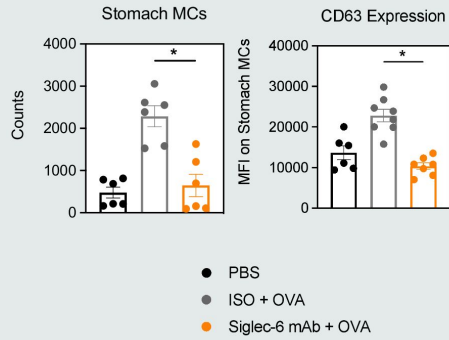
AK006 inhibits IgE-mediated mast cell activation in vivo

AK006 Resolves Gastric Inflammation in Oral Food Challenge Model

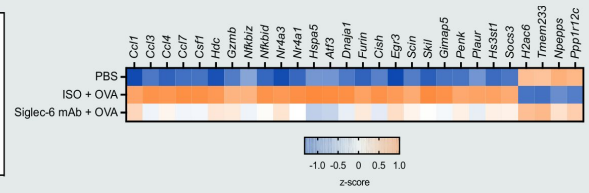
Model of OVA-Induced Allergic Enteritis



Stomach Mast Cells



Transcriptional Profiling of Stomach Mast Cells



* $p < 0.01$, $n=6$ mice/group

AK006 shows inhibitory and depleting effects in food challenge model

SOURCE: Benet Z, et al. EMBRN 2022 Presentation.

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



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

Phase 1 IV SAD & MAD Baseline Demographics and Characteristics

Characteristics	Single Ascending Dose (IV)						Multiple Ascending Dose (IV)			
	AK006 5mg	AK006 20mg	AK006 80mg	AK006 240mg	AK006 720mg	Placebo	AK006 80mg	AK006 240mg	AK006 720mg	Placebo
Subjects, n	12	6	6	6	6	12	6	6	6	6
Age (years), Median	26.0	23.5	26.5	26.5	29.5	26.5	24.0	33.0	27.0	27.0
Female (%)	16.7%	16.7%	16.7%	33.3%	50.0%	16.7%	16.7%	66.7%	16.7%	16.7%
Weight (kg), Median	82.4	71.4	80.6	81.5	70.0	75.4	83.2	72.6	78.2	79.9
BMI (kg/m ²), Median	27.3	25.3	27.1	27.7	26.2	25.0	26.6	26.3	24.6	26.4



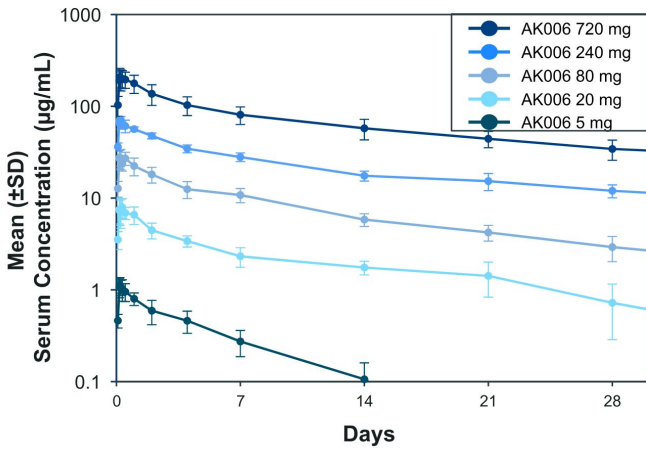
AK006 was Well-Tolerated with a Favorable Safety Profile

- Single and multiple IV doses of AK006 up to 720 mg were well-tolerated with a favorable safety profile
- There were no serious adverse events (SAEs)
- There were no treatment emergent adverse events leading to discontinuation of AK006
- There were no dose limiting toxicities
- The most common adverse events occurring in subjects on AK006 were headache and dysmenorrhea, all of which were mild-to-moderate in severity

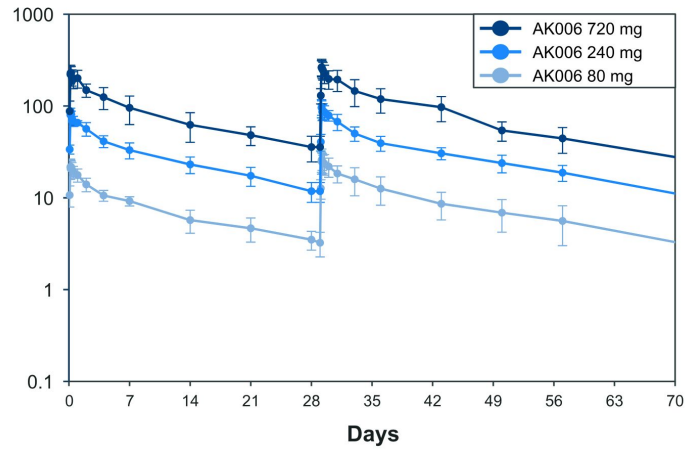
Safety follow up is ongoing

AK006 Shows Linear Exposure with a Half-life of 21 Days at 720mg

Single-dose concentration-time profile



Multi-dose concentration-time profile



AK006 achieved serum concentrations consistent with levels demonstrating inhibitory activity in preclinical experiments



High Siglec-6 Occupancy is Observed at Low Doses

Siglec-6 receptor occupancy on mast cell cells from skin biopsies was quantified in the Phase 1 study of AK006

Doses of AK006 ≥ 20 mg showed mean Siglec-6 receptor occupancy $>90\%$ on skin mast cells at Day 29

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

Siglec-6 Receptor Occupancy
(mean, %)

Route	Dose Cohort (mg)	n	Baseline	Day 8	Day 29
IV	PBO	9	0	9	24
SAD IV	5	7	0	98	45
	20	6	0	97	92
	80	6	0	87	96
	240	6	0	97	94
	720	6	0	94	101

Each patient (n) received a biopsy at (1) baseline and (2) either Day 8 or Day 29.

AK006 for Chronic Spontaneous Urticaria

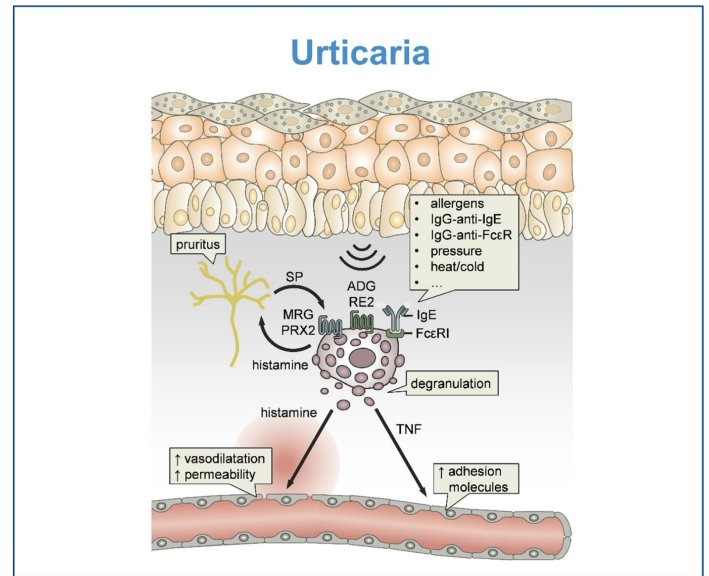
AK006 May Inhibit Disease Driving Pathways in Urticaria

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



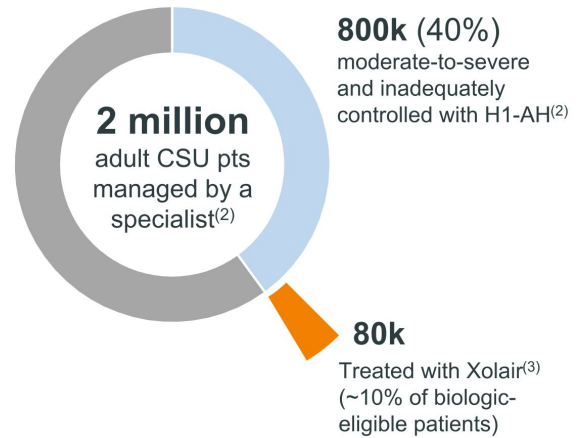
Chronic Spontaneous Urticaria Opportunity

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 2021⁴

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



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

Chronic Spontaneous Urticaria Landscape

Drug Name	MOA	UAS7 Response				Opportunity	
Xolair® (omalizumab)	Anti-IgE mAb	Dose Group ¹	150 mg	300 mg	Placebo	<ul style="list-style-type: none"> >50% of patients continue to have symptoms Black box for anaphylaxis¹ 	
		UAS7	-14.4 (-48%)	-20.8 (-66%)	-8.0 (-26%)		
		UAS7=0	15%	36%	9%		
Dupixent® (dupilumab)	Anti IL-4/IL-13R mAb	Dose Group ²	300 mg		Placebo	<ul style="list-style-type: none"> Q2W dosing No improvement in Xolair failures³ 	
		UAS7	-20.5 (-65%)		-12.0 (-37%)		
Barzolvolimab	Anti KIT mAb	Dose Group ⁴	75 mg Q4W	150 mg Q4W	300 mg Q8W	Placebo	<ul style="list-style-type: none"> c-Kit is expressed on hematopoietic stem cells, melanocytes, CNS and germ cells⁵
		UAS7	-17 (-56%)	-23 (-75%)	-24 (-76%)	-10 (-35%)	
		UAS7=0	23%	51%	38%	6%	
Remibrutinib	BTK Inhibitor	Dose Group ⁶	25 mg BID		Placebo		<ul style="list-style-type: none"> BTK is expressed on hematopoietic cells including B cells, myeloid cells, and platelets⁷
		UAS7	-20 & -20 (-65% & -65%)		-12 to -14 (-40% to -46%)		
		UAS7=0	28% to 31%		7% to 11%		

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

Financial Overview & Key Milestones



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.
- **YE 2024:** 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