



# Astria Therapeutics STAR-0215 ALPHA-STAR Phase 1b/2 Initial Proof-of- Concept Results

March 25, 2024

# Forward Looking Statements

This presentation contains forward-looking statements within the meaning of applicable securities laws and regulations including, but not limited to, statements regarding: our expectations regarding the potential significance of the initial results from the Phase 1b/2 ALPHA-STAR clinical trial of STAR-0215 and the timing and nature of additional results from the Phase 1b/2 ALPHA-STAR clinical trial of STAR-0215, and that favorable results from such trial will allow us to move directly into a Phase 3 trial of STAR-0215 as a potential treatment for hereditary angioedema (HAE); the expected timing of initiation and design of the planned Phase 3 trials of STAR-0215; the potential best-in-class profile of STAR-0215, the potential therapeutic benefits of STAR-0215 as a treatment for HAE, the potential market impact of STAR-0215 as a treatment for HAE and our vision and goals for the STAR-0215 program; expectations regarding the timing of regulatory filings for STAR-0310; expectations regarding the timing of initiation and planned design of clinical trials for STAR-0310 in atopic dermatitis; expectations regarding the timing and nature of anticipated data from planned trials of STAR-0310; our goals and vision for STAR-0310; our anticipated cash runway; and our corporate strategy and vision, including the goal to meet the unmet needs of patients with rare and niche allergic and immunological diseases. The use of words such as, but not limited to, “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “goals,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” or “vision,” and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Astria’s current beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, future financial performance, results of pre-clinical and clinical results of the Astria’s product candidates and other future conditions. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks and uncertainties related to: changes in applicable laws or regulations; the possibility that we may be adversely affected by other economic, business, and/or competitive factors; risks inherent in pharmaceutical research and development, such as: adverse results in our drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies may not be replicated in clinical trials, that the preliminary, initial or interim results from clinical trials may not be indicative of the final results, that the results of early stage clinical trials, such as the initial results from the ALPHA-STAR Phase 1b/2 clinical trial, may not be replicated in later stage clinical trials, the risk that we may not be able to enroll sufficient patients in our clinical trials on a timely basis, and the risk that any of our clinical trials may not commence, continue or be completed on time, or at all; decisions made by, and feedback received from, the U.S. Food and Drug Administration and other regulatory authorities on our regulatory and clinical trial submissions and other feedback from potential clinical trial sites, including investigational review boards at such sites, and other review bodies with respect to STAR-0215, STAR-0310, and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and drug product for STAR-0215, STAR-0310, and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulations for STAR-0215, STAR-0310, and any other future product candidates that are patient-friendly and competitive; our ability to develop biomarker and other assays, along with the testing protocols therefor; our ability to obtain, maintain and enforce intellectual property rights for STAR-0215, STAR-0310 and any other future product candidates; our potential dependence on collaboration partners; competition with respect to STAR-0215, STAR-0310, or any of our other future product candidates; the risk that survey results, modeling data and market research may not be accurate predictors of the commercial landscape for HAE, the ability of STAR-0215 to compete in HAE and the anticipated position and attributes of STAR-0215 in HAE based on clinical data to date, its preclinical profile, pharmacokinetic modeling, market research and other data; risks that any of our clinical trials of STAR-0310 may not commence, continue or be completed on time, or at all; risks that results of preclinical studies of STAR-0310 will not be replicated in clinical trials; our ability to manage our cash usage and the possibility of unexpected cash expenditures; our ability to obtain necessary financing to conduct our planned activities and to manage unplanned cash requirements; the risks and uncertainties related to our ability to recognize the benefits of any additional acquisitions, licenses or similar transactions; and general economic and market conditions; as well as the risks and uncertainties discussed in the “Risk Factors” section of our Annual Report on Form 10-K for the period ended December 31, 2023 and in other filings that we may make with the Securities and Exchange Commission. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Astria may not actually achieve the forecasts or expectations disclosed in our forward-looking statements, and investors and potential investors should not place undue reliance on Astria’s forward-looking statements.

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# Agenda

## 1 Introduction & Executive Summary

**Jill C. Milne, PhD**

Chief Executive Officer

## 2 STAR-0215 Phase 1b/2 Initial Proof-of-Concept Results

**Christopher Morabito, MD**

Chief Medical Officer

## 3 STAR-0215 Phase 3 Plans

**Christopher Morabito, MD**

Chief Medical Officer

## 4 Building a Leading Allergy and Immunology Company

**Jill C. Milne, PhD**

Chief Executive Officer

## 5 Q&A

**Jill C. Milne, PhD** Chief Executive Officer

**Christopher Morabito, MD** Chief Medical Officer

**Noah Clauser** Chief Financial Officer

**Andrew Komjathy** Chief Commercial Officer

**Andrea Matthews** Chief Business Officer

# Astria: Building a Leading Allergy & Immunology Company

## Focus:

Develop first-choice products that improve the health and outcomes of patients with allergic and immunological diseases

## Approach:

Advance a pipeline of products with meaningfully differentiated profiles based on validated mechanisms



Potential first-choice preventative treatment to help normalize the lives of **hereditary angioedema (HAE)** patients



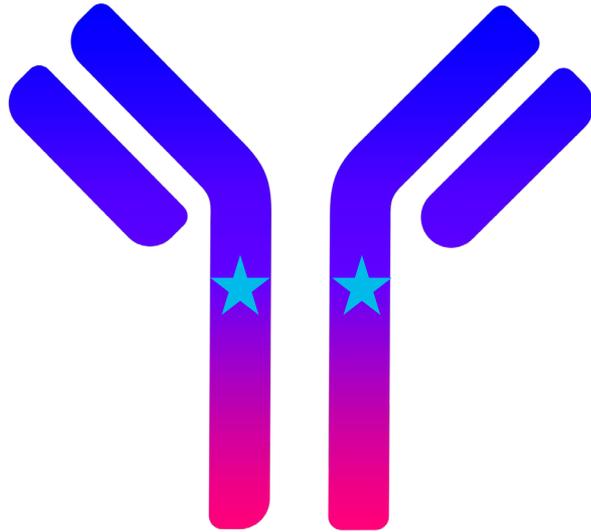
Potential best-in-class OX40 program for **atopic dermatitis (AD)** and expansion into additional allergic and immunological indications



Experienced team with established track records and strong cash position into mid-2027

# STAR-0215

## Potential First-Choice Preventative Treatment for HAE



**STAR-0215**

- **Validated mechanism of action and modality**
  - Potent mAb inhibitor of plasma kallikrein
  - Same mechanism and modality as market leader TAKHZYRO® (lanadelumab)
- **Potential to reduce both treatment and disease burden**
  - Robust and durable reduction in attack frequency
  - Potential for infrequent subcutaneous dosing 2 to 4 times per year
- **Favorable characteristics**
  - YTE half-life extension to potentially enable Q3 and Q6 month (M) dosing
  - Designed for self-administration
  - Formulated to reduce injection site pain
- **Novel IP<sup>1</sup> through 2042+**

# ALPHA-STAR Phase 1b/2 Initial Data Demonstrates Proof-of-Concept for **STAR-0215**

## Key Elements of the Target Product Profile Assessed in ALPHA-STAR

## Initial Results from ALPHA-STAR Support Profile

80-90% reduction in monthly attack rate, similar to lanadelumab



90-96% reduction in monthly attack rate at 3 and 6 months, exceeding our expectations

Administered subcutaneously Q3M and Q6M



Proof-of-concept as a Q3M and Q6M treatment

Rapid onset of action



Rapid attack prevention observed

Safe and well-tolerated, with low incidence of injection site pain



Favorable safety profile and tolerability with no reports of injection site pain

# Key Takeaways

We Are Driven to Change the Way Patients Live with HAE



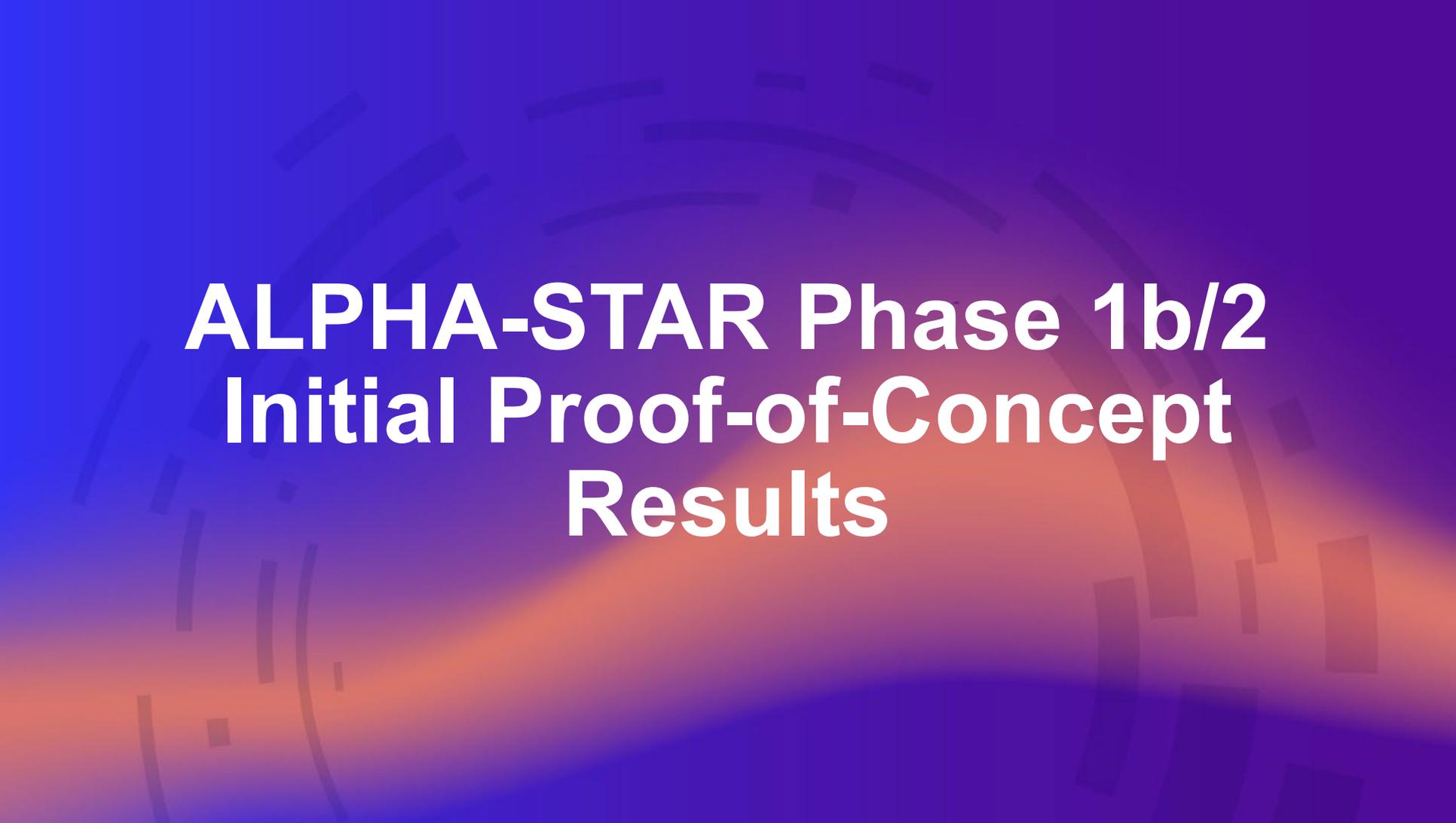
**Positive proof-of-concept results**  
support the potential of STAR-0215 to be dosed **2 or 4 times per year**



We plan to initiate the **STAR-0215 Phase 3** trial in **Q1 2025** with top-line **results** expected by **YE 2026**

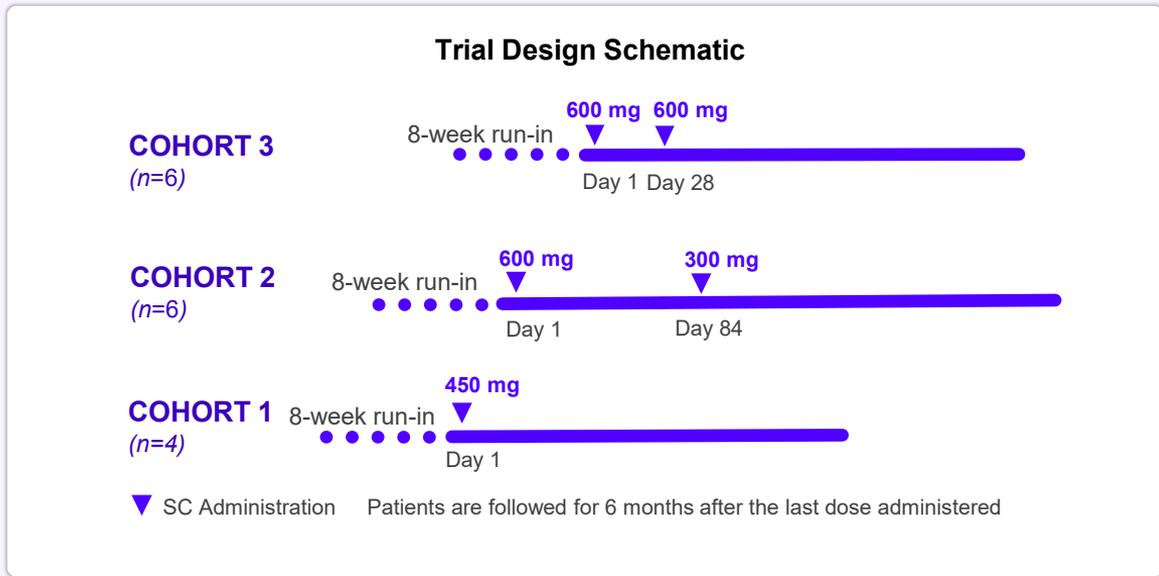


Opportunity for **STAR-0215** to become the **market-leading HAE product** as the **first-choice** preventative treatment



# **ALPHA-STAR Phase 1b/2 Initial Proof-of-Concept Results**

# ALPHA-STAR Phase 1b/2 Initial Proof-of-Concept Results Include up to 6 Months of Follow-Up



- Ongoing Phase 1b/2 single and multiple dose proof-of-concept trial in adults with HAE Type 1 or Type 2
- Target enrollment has been achieved; all doses have been administered

SC = subcutaneous. Run-in period is at least 8 weeks (56 days) to measure baseline HAE attacks. Initial data with data cut-off of 13-Mar-2024 for efficacy and safety data. In cohort 1, all 4 participants have completed 3 and 6 months of follow-up. In cohort 2, all 6 participants have completed 3 months of follow-up and 3 of the 6 have completed 6 months of follow-up. In cohort 3, 4 of 6 participants have completed 3 months of follow-up and no participants have completed 6 months of follow-up. Figures show baseline data for all participants and follow-up data for participants who completed 3 or 6 months of follow-up. Data cut-off of 8-Jan-2024 for PK and PD data.

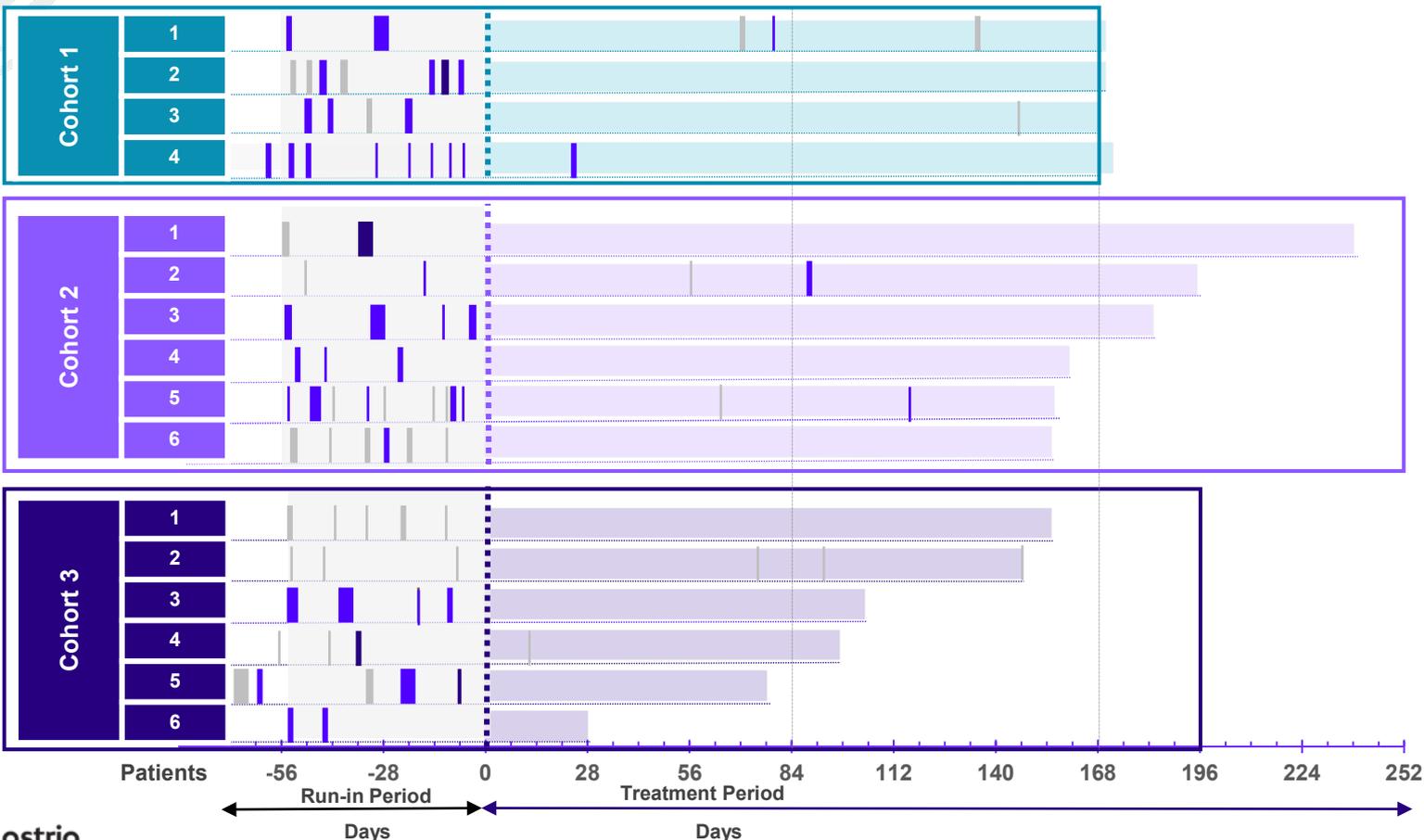
# ALPHA-STAR Phase 1b/2 Baseline Characteristics

## Adults with HAE Type 1 and 2

	Cohort 1 (N=4)	Cohort 2 (N=6)	Cohort 3 (N=6)	Total (N=16)
<b>Age</b>				
Mean (SD)	51.0 (21.2)	38.5 (15.4)	48.8 (23.5)	45.5 (19.6)
<b>Sex (F)</b>				
n (%)	3 (75%)	4 (66.7%)	2 (33.3%)	9 (56.3%)
<b>Weight (kg)</b>				
Mean (SD)	78.8 (21.4)	83.2 (11.5)	96.9 (24.9)	87.3 (20.1)
<b>HAE Type, n (%)</b>				
Type 1	4 (100%)	5 (83.3%)	5 (83.3%)	14 (87.5%)
Type 2	0	1 (16.7%)	1 (16.7%)	2 (12.5%)
<b>Baseline (run-in) monthly attack rate</b>				
Mean (SD)	2.7 (1.3)	2.3 (1.5)	1.8 (0.6)	2.2 (1.2)
Median	2.9	1.9	1.7	2.0

# STAR-0215 Achieved Rapid and Durable Reductions in HAE Attacks

HAE Attacks for Each Participant To Date

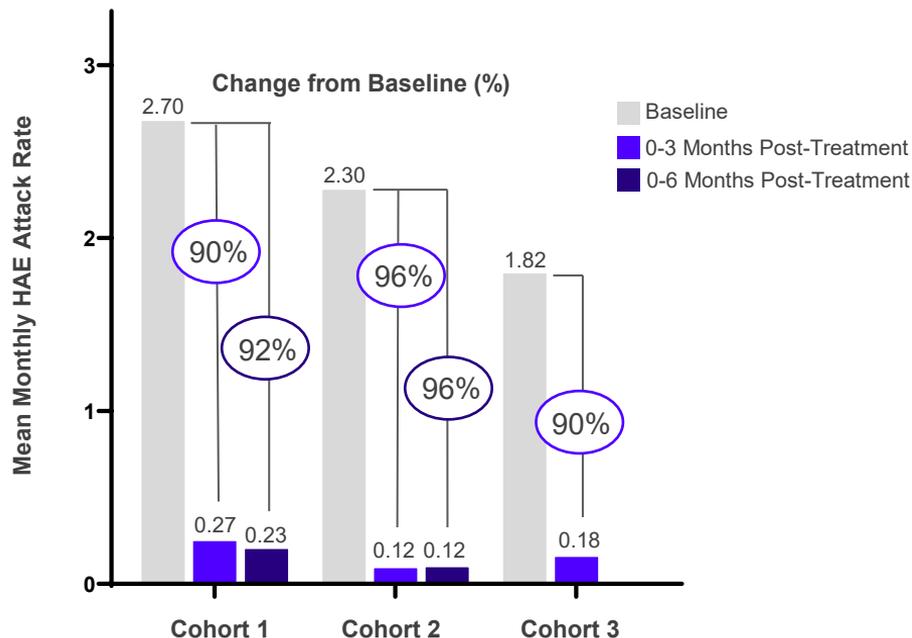


**HAE Attack:**

- Mild
- Moderate
- Severe

Duration of HAE attack correlates with thickness of each vertical bar.  
 Shaded bars are duration of follow-up at time of data cut-off. Vertical lines indicate efficacy analyses at Day 84 (3 months) and Day 168 (6 months).

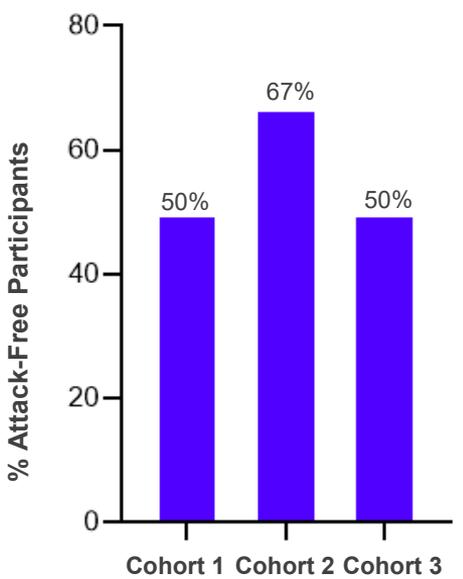
# STAR-0215 Monthly HAE Attack Reduction Exceeds Expectations Through 6 Months



- 90-96% reduction in monthly attack rate after STAR-0215 compared to baseline at 3 and 6 months
- Rapid and robust attack rate reduction up to 6 months after a single dose
- 91-94% cumulative all available follow-up attack rate reduction

# A Substantial Percentage of Participants Were Attack-Free with STAR-0215

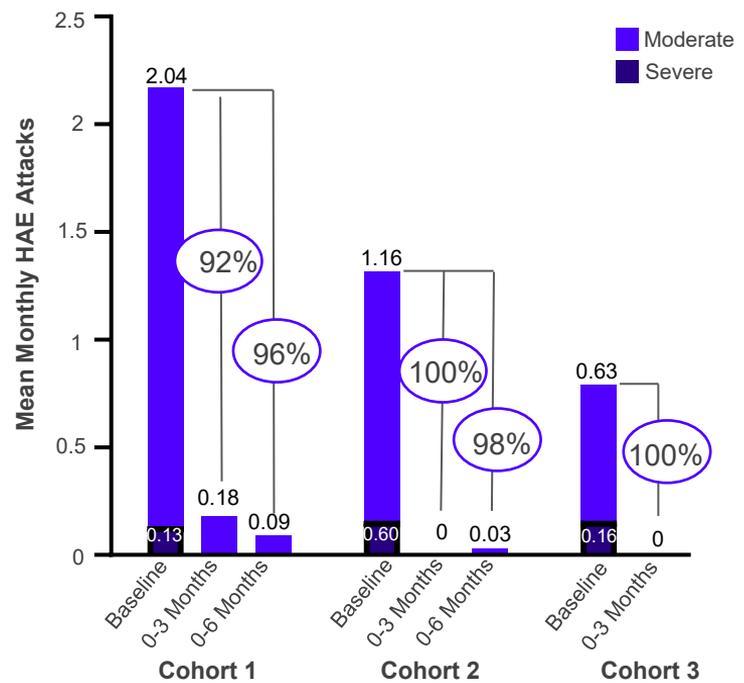
Attack-Free Rate for 0-3 Months



- For the first 3 months following STAR-0215 treatment, 50-67% of participants were attack-free
- Q3M dosing in Cohort 2 showed 67% attack-free rate through 6 months

# STAR-0215 Reduced the Severity of HAE Attacks Through 3 and 6 Months

Changes in Moderate and Severe Attacks Per Month (Mean)



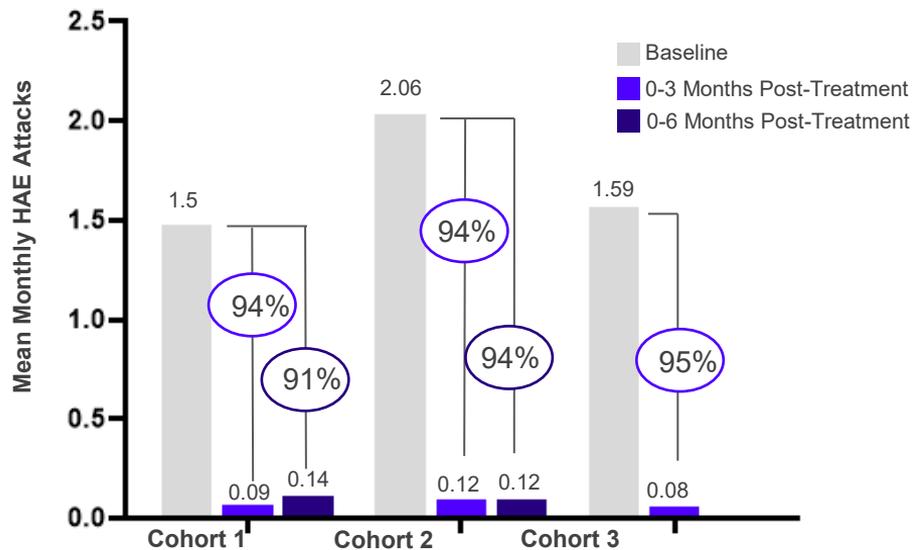
- 92-100% decrease in moderate or severe attacks compared to baseline at 3 and 6 months
- No severe attacks after receiving STAR-0215

Moderate and severe HAE attacks are shown.

In cohort 1, all 4 participants have completed 3 and 6 months of follow-up. In cohort 2, all 6 participants have completed 3 months of follow-up and 3 of the 6 have completed 6 months of follow-up. In cohort 3, 4 of 6 participants have completed 3 months of follow-up and no participants have completed 6 months of follow-up. Figures show baseline data for all participants and follow-up data for participants who completed 3 or 6 months of follow-up.

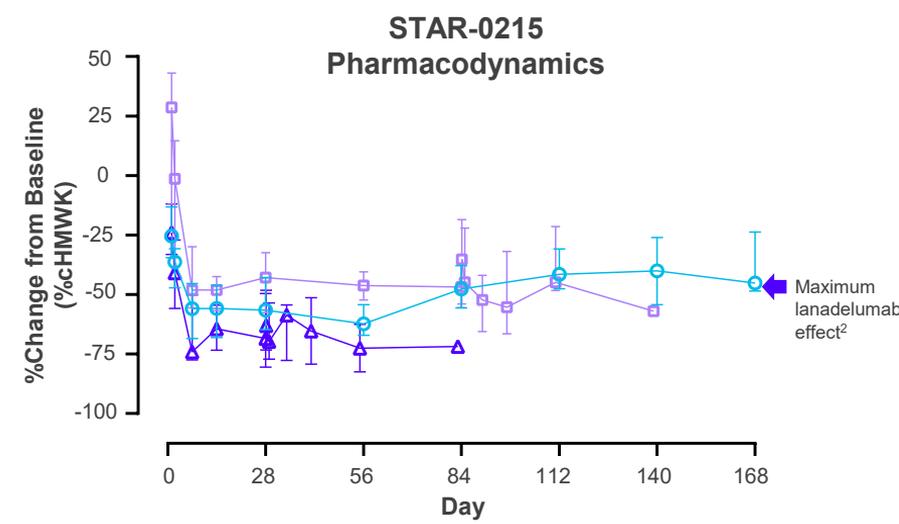
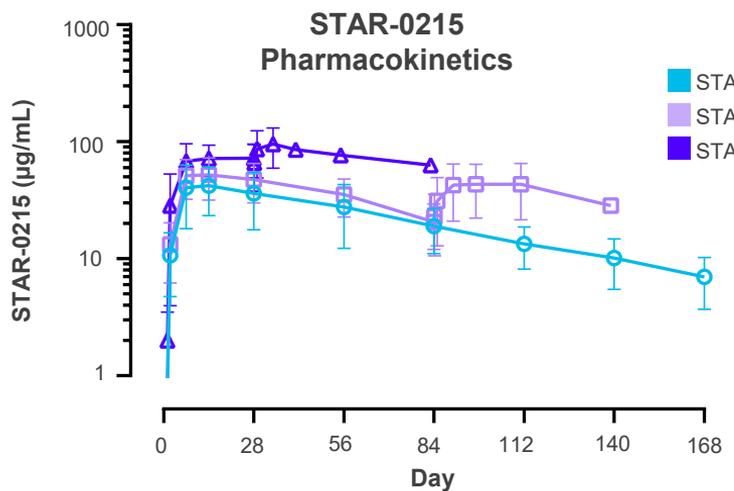
# STAR-0215 Reduced the Number of Attacks Requiring Rescue Medications

Change in Monthly Attacks Requiring Rescue Medication



- 91-95% fewer attacks required rescue medication after STAR-0215 compared to baseline at 3 and 6 months

# Results Have Shown STAR-0215 PK and PD Are Consistent with Clinical Benefit



- Cohort 1 concentrations remain above target threshold<sup>2</sup> for more than 3 months
- Cohorts 2 and 3 remain well above target threshold for the duration of available follow-up

- Initial PD (%cHMWK<sup>1</sup>) showed sustained inhibition of plasma kallikrein activity similar to lanadelumab<sup>2</sup>

# STAR-0215 Was Well-Tolerated and Demonstrated a Favorable Safety Profile

	Cohort 1 (N=4)	Cohort 2 (N=6)	Cohort 3 (N=6)	Total (N=16)
Treatment-Emergent Adverse Events (TEAE)*	6	1	1	8
Contusion	3	-	-	3
Nasopharyngitis	1	1	1	3
Headache	2	-	-	2
Related TEAEs	-	1	1	2
Dizziness	-	1	-	1
Injection Site Rash	-	-	1	1
N with Serious Adverse Events	-	-	-	-
N who have discontinued due to TEAE	-	-	-	-

\* Shown are events that occurred in at least 2 participants.

One participant experienced mild dizziness on day 6 after the first dose in Cohort 2 and one participant experienced an injection site reaction (rash) 5 days after the second dose in Cohort 3, lasting less than 1 day.

No injection site reactions of pain.

# Initial Results Establish Proof-of-Concept and Path for Potential Phase 3 Success

## ALPHA-STAR Phase 1b/2 Initial Results Summary

	Monthly Attack Rate Reduction (mean)	Attack-Free Rate for at Least 1 <sup>st</sup> 3 Months	Reduction in Moderate and Severe Attacks per Month	Reduction in Attacks Requiring Rescue Medication	Injection Site Pain	Doses Per Year <sup>1</sup>
STAR-0215, Summary	90-96%	50-67%	92-100%	91-95%	0%	2 or 4
Cohort 2: 600 mg Day 1, 300 mg Day 84, through 6M <sup>2</sup>	96%	67%	98%	94%	0%	4

## Lanadelumab Phase 3 Results Summary<sup>3,4</sup>

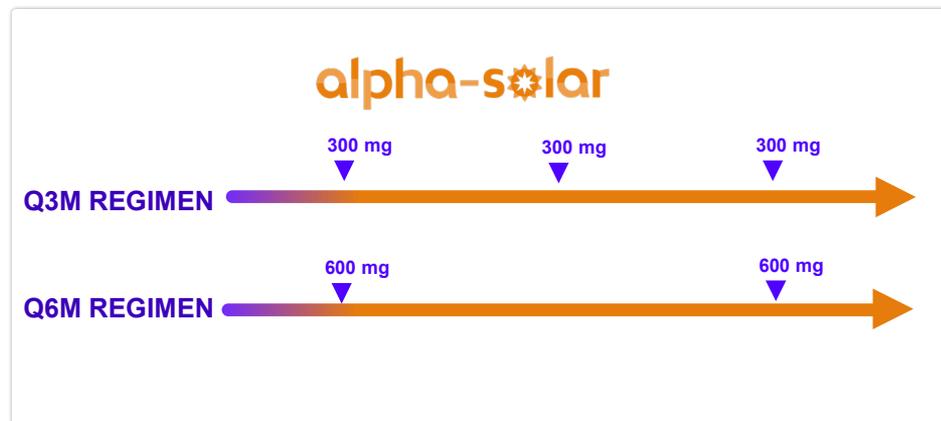
Lanadelumab 300 mg Q2W	87%	44%	83%	87%	52%	26
Lanadelumab 300 mg Q4W	73%	31%	73%	74%	31%	13

STAR-0215 efficacy endpoints are mean change from baseline. Initial data from adult participants with Type 1 or 2 HAE (n=16) were evaluated at 3 and 6 months after initiation of study drug, data cut-off 13-Mar-2024. Results from lanadelumab are from a separate, Phase 3, placebo-controlled trial in adults and adolescents with Type 1 or 2 HAE (n=125). Lanadelumab efficacy endpoints were compared with the placebo group using a Poisson regression model after 6-month treatment period. The comparison presented between STAR-0215 and the lanadelumab data represents a cross-trial comparison and does not involve data from a head-to-head clinical trial.

1. Planned administration for STAR-0215 2. Dosing regimen expected to be evaluated in the Phase 3 Q3M trial 3. Banerji et al (2018), JAMA 4. TAKHZYRO US Prescribing Information (Feb 2023)

# ALPHA-SOLAR Long-Term Open-Label Trial Ongoing

- Open to participants from ALPHA-STAR
- Trial assessing long-term safety, tolerability, and clinical activity of STAR-0215 Q3M and Q6M
  - Build dataset to support potential regulatory approvals
- **Primary Endpoint:**
  - Safety and tolerability
- **Secondary Endpoints:**
  - Efficacy including attack rate, attack-free participants, PK, and PD
- Expanding enrollment in ALPHA-STAR in Cohorts 2 and 3 for a total of up to 28 patients



Initial safety and efficacy data from Q3M and Q6M dosing expected mid-2025

# STAR-0215 Phase 3 Plans

# Positive Proof-of-Concept Data Support Advancing STAR-0215 to Phase 3 for Q3M and Q6M Dosing



**Strategy: take fastest path to market and establish position**



**Q3M dosing:  
fastest path to  
market**



**Q6M dosing: rapid  
label expansion to  
maximize reduction  
in treatment burden**



# On Track to Initiate Q3M Phase 3 as a Potential Single Registrational Trial in Q1 2025

## Planned Trial Design:

- HAE Types 1 and 2, age  $\geq$  12 years old
- Global enrollment
- N~100 participants
- 6-month treatment period
- Primary Endpoint:
  - Time-normalized monthly HAE attacks
- Key Secondary Endpoint:
  - % Attack-free at 6 months
- Dose Selection:
  - Expected regimen is 600 mg SC loading dose then 300 mg SC Q3M,
- Top-line results expected by YE 2026

## Expected Phase 3 Q3M Regimen supported by current data:

600 mg SC loading dose then 300 mg SC

- 96% reduction in monthly attack rate
- 98-100% reduction in moderate/severe attacks
- 94% reduction in use of rescue medications
- 100% of patients in this cohort were attack-free in first month
- 67% of patients attack-free through 6 months
- Well-tolerated and favorable safety to date



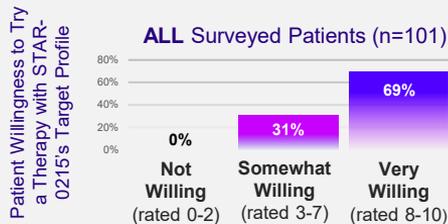
# **Building a Leading Allergy & Immunology Company**

# Market Research Suggests STAR-0215's Target Profile Would Be Highly Compelling Across Stakeholders

## Patients

U.S. patients (n=101)<sup>1</sup> were **highly interested** in trying a product with the Q3M profile and lanadelumab-like efficacy, including patients currently treated with:

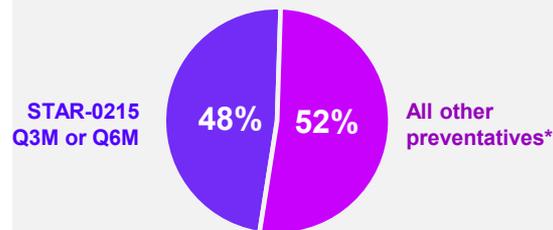
- Injectable preventative medicines, including once-monthly
- Oral preventative medicines
- On-demand medication only



## Physicians

**93-97%** of U.S. HAE-treating physicians (n=60)<sup>2</sup> are likely to prescribe a product with STAR-0215's profile.

On average, physicians anticipate prescribing a product with these profiles to nearly **HALF** of their future patients.



## Payers

**100%** of US payers interviewed (n=7)<sup>3</sup> felt that a therapy with the profile of STAR-0215 should be covered and available to patients.

Payers would expect pressure from both patients and physicians to have access to a therapy like STAR-0215 that would reduce dosing frequency significantly.

1. Astria proprietary blinded quantitative market research study (2022) with 101 HAE patients recruited by HAEA patient organization. Patients were screened for those currently taking preventative HAE therapy or having at least 1 attack every 3 months.

2. Company quantitative Market Research (Aug 2023) with 92 U.S. HAE patients and caregivers of adolescents and 60 U.S. HAE treatment providers.

3. Qualitative Market Research (Jun 2023) with 7 U.S. Payers (National and Regional Health Plan Medical Directors and PBMs) Conducted by TKG Access.

\*Queried versus currently available therapies

# Opportunity for STAR-0215 to Lead the Market for HAE Treatments

**star**  
-0215

**Potential to become market leader in HAE**

Expected Global HAE Market  
\$4.5B by 2027<sup>1,2</sup>

## STAR-0215 Market Share Expected to Come from:

Patients taking injectable preventative treatments



Patients taking oral preventative treatments

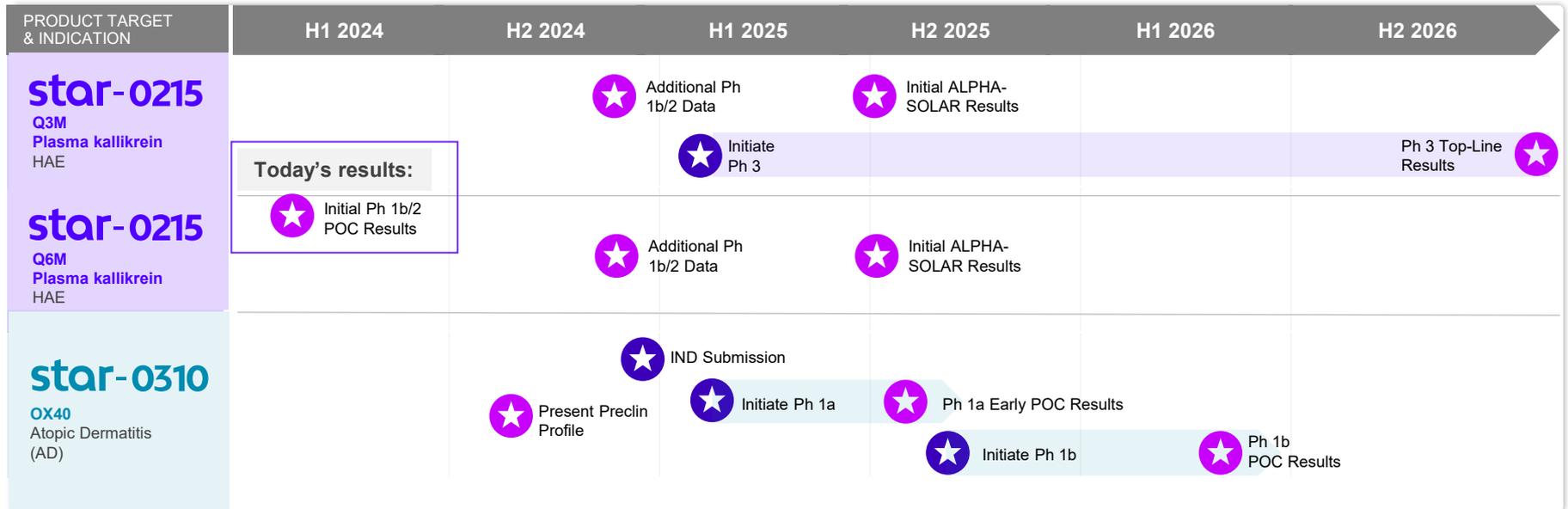


Patients taking only on-demand treatments



# Building Leading Allergy & Immunology Company

## Upcoming Expected Program Milestones



# ATXS: Strong Financial Foundation

- **Cash and equivalents of \$246.5M as of 12/31/23, plus \$137.1M from Q1 2024 financing activity, funds the Company into mid-2027 and is expected to enable:**
  - Top-line results for STAR-0215 Q3M Phase 3 (expected by YE 2026)
  - Completion of BLA-enabling STAR-0215 development and manufacturing
  - Development of pre-filled syringe and autoinjector
  - Pre-launch activities for STAR-0215
  - STAR-0310 IND
  - STAR-0310 early proof-of-concept results from Phase 1a trial

- **Equity summary:**

	Common	Preferred Stock as Common Equivalents	Pre-Funded Warrants	Total Issued and Outstanding Common & Common Equivalents
Outstanding as of 12/31/2023	41,034,797	5,184,591	1,571,093	47,790,481
Subsequent Equity Issuances	13,868,264	-	-	13,868,264
Outstanding as of 2/29/24	54,903,061	5,184,591	1,571,093	61,658,745

# Our Goal is to Change the Way Patients Live with HAE



Opportunity for STAR-0215 to become the **market-leading HAE product** with Q3M and Q6M dosing



Initial proof-of-concept results support the potential for **STAR-0215 to be the first-choice HAE treatment**



Phase 3 strategy to bring STAR-0215 to market as quickly as possible

- **Phase 3** expected to initiate in Q1 2025 with **top-line results expected by YE 2026**



**Patient-driven drug development** in close collaboration with advocacy community



**Enrollment ongoing** for long-term open-label ALPHA-SOLAR to provide ALPHA-STAR patients with continued access to STAR-0215

- Initial safety and efficacy **data from Q3M and Q6M dosing in ALPHA-SOLAR trial expected mid-2025**



Patient-focused device strategy: plan to **launch with both autoinjector and pre-filled syringe**



Novel composition of matter **IP<sup>1</sup> through 2042+**



“

*Not having to think about taking a medication except for 2 or 4 times per year would be incredible. The opportunity to be able to forget about my HAE is something I never thought could happen.* ”

**—Kim, Type 2 HAE, Texas, USA**

Despite experiencing her first attack at age 8, Kim did not receive a formal diagnosis for her **Type II HAE** until 25 years later.

Kim is a dedicated advocate for HAE patients and understands the importance of potential new treatments firsthand.

The background features a gradient from deep blue on the left to a warm orange on the right. Overlaid on this are several concentric, semi-transparent curved lines and small rectangular segments, creating a sense of motion or a stylized globe.

**Q&A**



**astria**  
THERAPEUTICS