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 13, 2025

Astria Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37467**	**26-3687168**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
22 Boston Wharf Road 10th Floor Boston, Massachusetts		**02110**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (617) 349-1971

(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, $0.001 par value per share	ATXS	The Nasdaq Stock Market LLC

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 13, 2025, Astria Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing its planned design of the ALPHA-ORBIT Phase 3 clinical trial of navenibart in people with hereditary angioedema. On January 13, 2025, the Company also published on its website an updated corporate presentation (the "Corporate Presentation"). Copies of the Press Release and Corporate Presentation are furnished herewith as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release, dated January 13, 2025
99.2	Corporate Presentation, dated January 13, 2025
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.

ASTRIA THERAPEUTICS, INC.

Date: January 13, 2025

By: /s/ Ben Harshbarger
Ben Harshbarger
Chief Legal Officer

Exhibit 99.1

Astria Therapeutics Announces Design of ALPHA-ORBIT Pivotal Phase 3 Trial of Navenibart in HAE

-- Single Pivotal Trial Designed to Demonstrate Efficacy and Safety of Every 3- and Every 6-Month Administration in a 6-Month Treatment Period --

-- Pioneering Patient-Centric Dosing Flexibility in HAE with Potential Market-Leading First-Choice Profile --

-- Phase 3 Initiation On-Track, Expected in Q1 2025 --

-- Strong Financial Position, Funded Through Expected Top-Line Phase 3 Results --

BOSTON, Mass., January 13, 2025 – Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunologic diseases, today announced its planned design of the ALPHA-ORBIT Phase 3 clinical trial of navenibart in people with hereditary angioedema (HAE), which will include both every 3- (Q3M) and every 6-month (Q6M) treatment arms with the primary analysis at 6 months. Global start-up activities are underway, and ALPHA-ORBIT is expected to initiate in Q1 2025, with top-line results anticipated in early 2027.

“We are thrilled to announce our planned Phase 3 design, which reflects feedback from regulators and is intended to support global registration for both Q3M and Q6M administration,” said Jill C. Milne, Ph.D., Chief Executive Officer at Astria. “With navenibart, we are pioneering patient-centric dosing flexibility in HAE with the goal of maximizing attack rate reduction with a compellingly low burden of treatment. Assuming approval, we believe navenibart will become the market-leading, first-choice therapy for HAE.”

“Our Phase 3 program was designed in collaboration with the patient community and physicians, is based on input from global regulatory authorities, and addresses the importance of providing options to patients for a disease that’s highly variable,” said Christopher Morabito, M.D., Chief Medical Officer at Astria. “Phase 3 preparations are underway, with trial initiation on-track and expected for this quarter. We are driven by the goal of bringing a potentially life-changing therapy to patients with HAE.”

ALPHA-ORBIT is designed as a global, randomized, double-blind, placebo-controlled Phase 3 pivotal clinical trial to evaluate the efficacy and safety of navenibart over a 6-month treatment period in up to 145 patients with Type 1 or Type 2 HAE. Patients will be randomized to receive one of three navenibart dose arms: 1) an initial 600 mg dose and followed by 300 mg Q3M, 2) 600 mg Q6M, and 3) 600 mg Q3M, or placebo. The dose arms support the potential to provide patient-centric dosing flexibility to people with HAE. The primary endpoint is time-normalized monthly HAE attacks at 6 months, and a key secondary endpoint includes the proportion of participants who are attack-free at 6 months. After 6 months, patients may be eligible to enter a long-term extension trial, in which all patients will be treated with navenibart (open-label) and which will include an open-label, patient-centric flexible dosing period. The navenibart Phase 3 program will consist of the ALPHA-ORBIT Phase 3 trial and the long-term extension trial, which are designed to support registration globally. The Phase 3 program was designed with input from the European Medicines Agency and the Company’s end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) held in December 2024.

Planned doses for the Phase 3 ALPHA-ORBIT program were selected based on positive final top-line results from target enrollment in the Phase 1b/2 ALPHA-STAR trial of navenibart, announced in December 2024, which showed rapid onset of robust and durable efficacy, favorable safety and tolerability, and pharmacokinetics and pharmacodynamics consistent with sustained plasma kallikrein inhibition for both Q3M and Q6M administration. Final results included reduction in mean monthly attack rate of 90-95% and up to a 67% attack-free rate over 6 months. The Company will present these data at an upcoming scientific conference.

Additional details regarding the Company's planned Phase 3 program and other business updates are contained in the Company's Corporate Presentation, which is available on the "Events and Presentations" page of the "For Investors" section of the Company's website.

About Astria Therapeutics:

Astria Therapeutics is a biopharmaceutical company, and our mission is to bring life-changing therapies to patients and families affected by allergic and immunologic diseases. Our lead program, navenibart (STAR-0215), is a monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema. Our second program, STAR-0310, is a monoclonal antibody OX40 antagonist in preclinical development for the treatment of atopic dermatitis. Learn more about our company on our website, www.astriatx.com, or follow us on Instagram @AstriaTx and on Facebook and LinkedIn.

About Navenibart:

Navenibart is a monoclonal antibody inhibitor of plasma kallikrein in development for the treatment of HAE. Our goal with navenibart is to provide rapid and sustained HAE attack prevention with a validated mechanism and trusted modality administered every 3 and 6 months. We aim to empower people with HAE to live life without limitations from their disease.

Forward Looking Statements:

This press release contains forward-looking statements within the meaning of applicable securities laws and regulations including, but not limited to, statements regarding: the expected design, timing of initiation and receipt of topline results from the ALPHA-ORBIT trial; the goals and objectives of the ALPHA-ORBIT trial and the long-term extension trial, including that they would support registration of Q3M and Q6M administration, and potentially accelerate the availability of Q6M administration; our expectations for the dosing regimens of navenibart and the efficacy data of navenibart in the ALPHA-ORBIT trial; the potential therapeutic benefits of navenibart as a treatment for HAE; the potential attributes and profile of navenibart as a treatment for HAE, including our expectation that it will be the market-leading, first choice and a potentially life-changing treatment for patients with HAE; our overall vision and goals for the navenibart program; expectations about being funded through top-line Phase 3 results; and our corporate strategy and vision, including our mission to bring life-changing therapies to patients and families affected by allergic and immunologic 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 and 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 studies and clinical trials of 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 results from the ALPHA-STAR Phase 1b/2 clinical trial, may not be replicated in later stage clinical trials, such as the ALPHA-ORBIT trial and the open-label extension trial, 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, including ALPHA-ORBIT, may not commence, continue or be completed on our anticipated timelines, or at all; decisions made by, and feedback received from, the FDA and other regulatory authorities on our clinical trial design, including for ALPHA-ORBIT, and on our regulatory and clinical trial submissions, including receipt of FDA minutes from our December 2024 end of Phase 2 meeting, and other feedback from potential clinical trial sites, including investigational review boards at such sites, and other review bodies with respect to navenibart, STAR-0310, and any other future development candidates, decisions that we make about the design of clinical trials in response to regulatory feedback, including the design of the ALPHA-ORBIT trial and the long-term extension trial; our ability to manufacture sufficient quantities of drug substance and drug product for navenibart, STAR-0310, and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulations for navenibart, STAR-0310, and any other future product candidates that are patient-friendly and competitive; our ability to develop sufficient data to enable the use of planned devices with navenibart, STAR-0310 and any other future product candidates at commercial launch or otherwise as planned; 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 navenibart, STAR-0310 and any other future product candidates; our potential dependence on collaboration partners; competition with respect to navenibart, 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 navenibart to compete in HAE and the anticipated position and attributes of navenibart 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.

Neither Astria, nor its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Astria's views as of any date subsequent to the date hereof.

###

Astria Contact:
Investor Relations and Media:
Elizabeth Higgins
investors@astriatx.com

Corporate Presentati

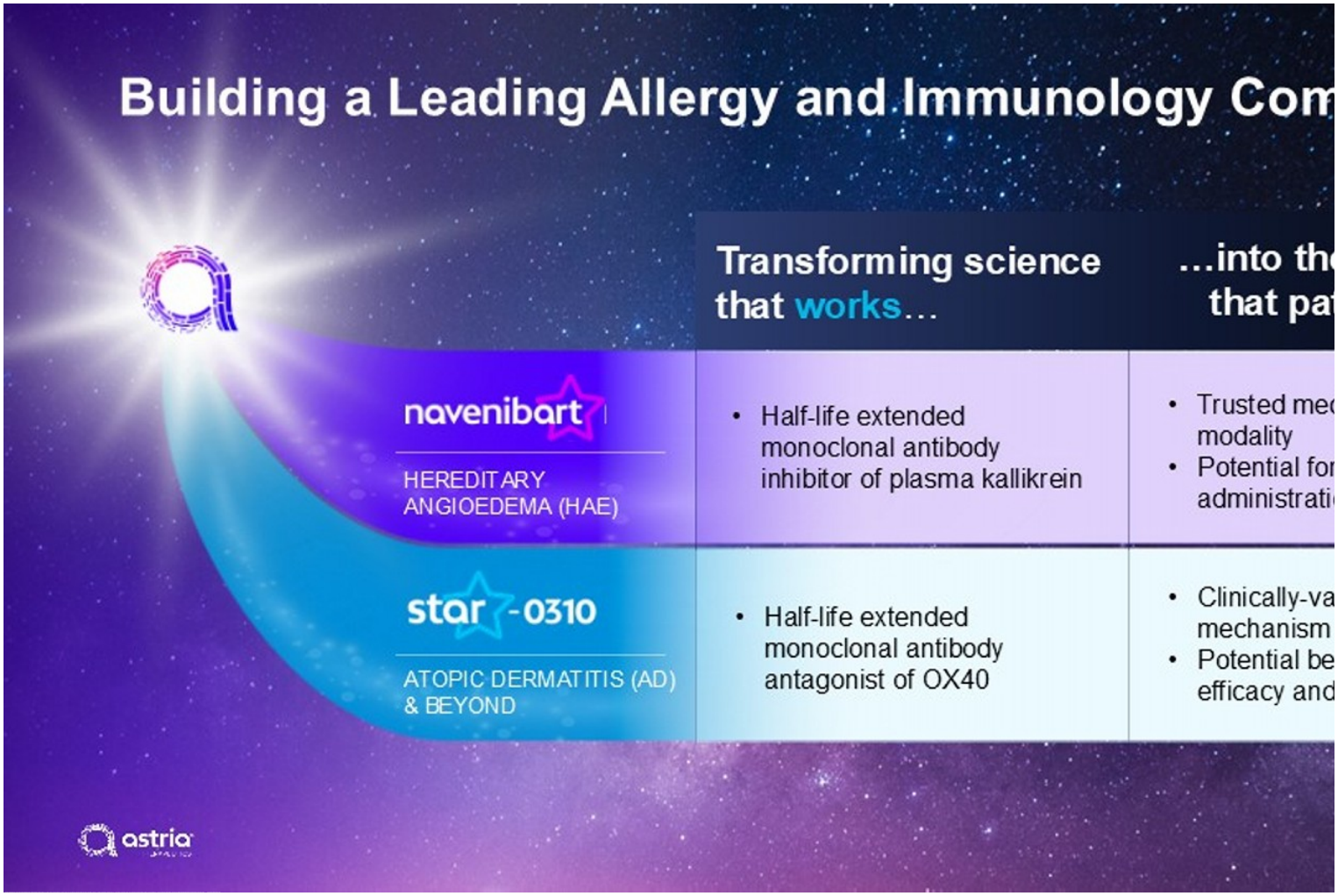
January 2025

FLS

This presentation contains forward-looking statements within the meaning of applicable securities laws and regulations including, but not limited to, statements regarding: the expected design, timing of initiatio the ALPHA-ORBIT trial; the goals and objectives of the ALPHA-ORBIT trial and the long-term extension trial, including that they would support registration of Q3M and Q6M administration, and potentially acce administration; our expectations for the dosing regimens of navenibart and the efficacy data of navenibart in the ALPHA-ORBIT trial; the potential therapeutic benefits of navenibart as a treatment for HAE; the navenibart as a treatment for HAE, including our expectation that it will be the market-leading, first choice and a potentially life-changing treatment for patients with HAE; our overall vision and goals for the nav being funded through top-line Phase 3 results and our cash runway; and our corporate strategy and vision, including our mission to bring life-changing therapies to patients and families affected by allergic and 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," 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 regarding the future of its business, future plans and strategies, future financial performance, results of pre-clinical studies and clinical trials of Astria's product candidates and other future conditions. Actual res 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 advers 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 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 results from the ALP may not be replicated in later stage clinical trials, such as the ALPHA-ORBIT trial and the open-label extension trial, the risk that we may not be able to enroll sufficient patients in our clinical trials on a timely ba clinical trials, including ALPHA-ORBIT, may not commence, continue or be completed on our anticipated timelines, or at all; decisions made by, and feedback received from, the FDA and other regulatory auth including for ALPHA-ORBIT, and on our regulatory and clinical trial submissions, including receipt of FDA minutes from our December 2024 end of Phase 2 meeting, and other feedback from potential clinical t review boards at such sites, and other review bodies with respect to navenibart, STAR-0310, and any other future development candidates, decisions that we make about the design of clinical trials in response the design of the ALPHA-ORBIT trial and the long-term extension trial; our ability to manufacture sufficient quantities of drug substance and drug product for navenibart, STAR-0310, and any other future produ and timely basis, and to develop dosages and formulations for navenibart, STAR-0310, and any other future product candidates that are patient-friendly and competitive; our ability to develop sufficient data to with navenibart, STAR-0310 and any other future product candidates at commercial launch or otherwise as planned; our ability to develop biomarker and other assays, along with the testing protocols therefor, enforce intellectual property rights for navenibart, STAR-0310 and any other future product candidates; our potential dependence on collaboration partners; competition with respect to navenibart, STAR-0310, 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 navenibart to compete in HAE and the anticipated navenibart 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 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 necess 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 gen 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 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 investors and potential investors should not place undue reliance on Astria's forward-looking statements.

Neither Astria, nor its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, forward-looking statements should not be relied upon as representing Astria's views as of any date subsequent to the date hereof.

astria THERAPEUTICS


Building a Leading Allergy and Immunology Com
Transforming science that works…
…into th
that pa
navenibart
HEREDITARY ANGIOEDEMA (HAE)
• Half-life extended monoclonal antibody inhibitor of plasma kallikrein
• Trusted mec
modality
• Potential for
administrati
star-0310
ATOPIC DERMATITIS (AD) & BEYOND
• Half-life extended monoclonal antibody antagonist of OX40
• Clinically-va
mechanism
• Potential be
efficacy and
astria

Astria's Pipeline Has Multiple Potential Near-Te Catalysts

PROGRAM	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	RECENT & EXPECTED MILEST
NAVENIBART (STAR-0215) *Anti-plasma kallikrein half-life extended mAb*				Hereditary Angioedema		✓ **Q4 2024:** Final results from Phase1b/2 A STAR trial ◆ **Q1 2025:** Phase 3 trial initiation ◆ **Mid-2025:** Initial results from ALPHA-SOL ◆ **Early 2027:** Phase 3 ALPHA-ORBIT top-lin results
STAR-0310 *Anti-OX40 half-life extended mAb*				Atopic Dermatitis Undisclosed Indications		✓ **Year-End 2024:** IND submission ◆ **Q1 2025:** Phase 1a initiation ◆ **Q3 2025:** Phase 1a results

astria THERAPEUTICS

Developing the Potential Market-Leading HAE Trea
Navenibart Phase 3 Program

ALPHA ORBIT

- Single 6-month pivotal Phase 3 trial and long-term extension designed wit Q3M and Q6M administration
- Pioneering expected patient-centric dosing flexibility in HAE with potentia leading first-choice profile
- Expected to initiate this quarter, with top-line results expected in early 202

1. As of 12/31/2024

Navenibart Designed for Best Patient Experier

Navenibart Vision

SCIENCE THAT WORKS:	THERAPY THAT PATIENTS WANT:
• Monoclonal antibody inhibitor of plasma kallikrein	• Trusted mechanism and modality with esta
• High affinity and potency with fast onset	• Rapid, effective prevention against HAE att
• YTE modification for extended half-life	• Infrequent administration expected every 3
• Citrate-free, high-concentration formulation	• Well-tolerated, pain-free, autoinjector-enab

astria

HAE: Significant Opportunity to Improve Lives

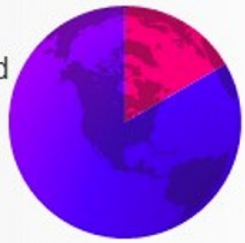
PREVALENCE

1 in 50,000 - 80,000 people worldwide (<8k US, <15k EU) [1,2,3,4]

COMMERCIAL OPPORTUNITY

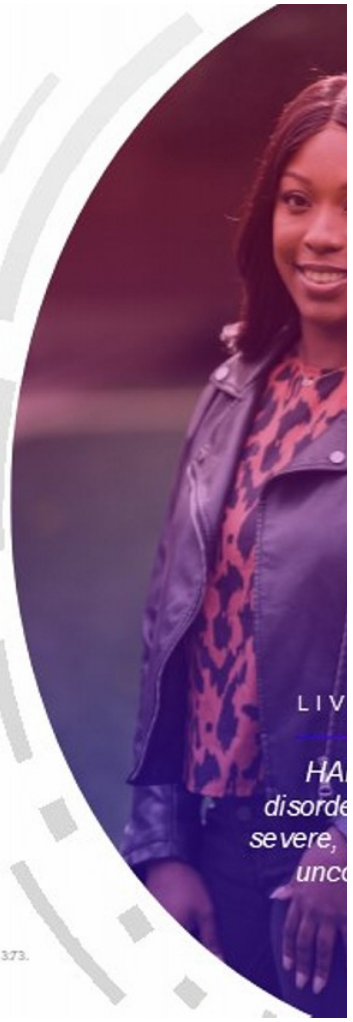
2023 HAE Market[5]
$2.8B

2030 Estimated HAE Market[5,6]
$5.4B



HAE Treatment
- Preventative
- On-Demand

Market growth driven by:
- Patients being diagnosed earlier
- More patients taking preventative treatments
- Geographic expansion for currently available therapies



astria THERAPEUTICS

1. Kanepa A, Narbas I, Rots D, Gailite L, Farkas H, Kurjane N. National survey on clinical and genetic characteristics of patients with hereditary angioedema in Latvia. Allergy Asthma Clin Immunol. 2023;19(1):28.
2. Busse, P.J. et al. JACI. 2021; 132-150.
3. Lumry, W.R. Front Med. 2018; 5, 22.
4. Aygören-Pürsün, E. et al. Orphanet J Rare Dis. 2018; 13:73.
5. EvaluatePharma
6. Astria company research and analysis

ALPHA ORBIT Phase 3 Trial Strategy

- Our goal is to revolutionize the way that patients manage their HAE
- Phase 3 designed to evaluate both Q3M and Q6M regimens with the goal o providing options for patients that, if approved, would ultimately create fle how patients manage their disease
- Planned Phase 3 dose selection determined from cumulative program data
- Phase 3 program was designed with input from the EMA and end of Phase meeting with the FDA held in December 2024

astria THERAPEUTICS

A Single, Global Phase 3 Pivotal Trial Designed to Assess Effi
Safety for Both Q3M and Q6M Administration of Navenibart

6-Month Primary Analysis

Population: Adolescents and adults
Types 1 and 2

Primary Endpoint at 6 months:
- Number of time-normalized investig
  HAE attacks in the 6-month treatme

Secondary Endpoints at 6 months[1]:
- Proportion of participants attack-fre
- Number of moderate/severe HAE at
- Number of attacks that require on-d
  treatment

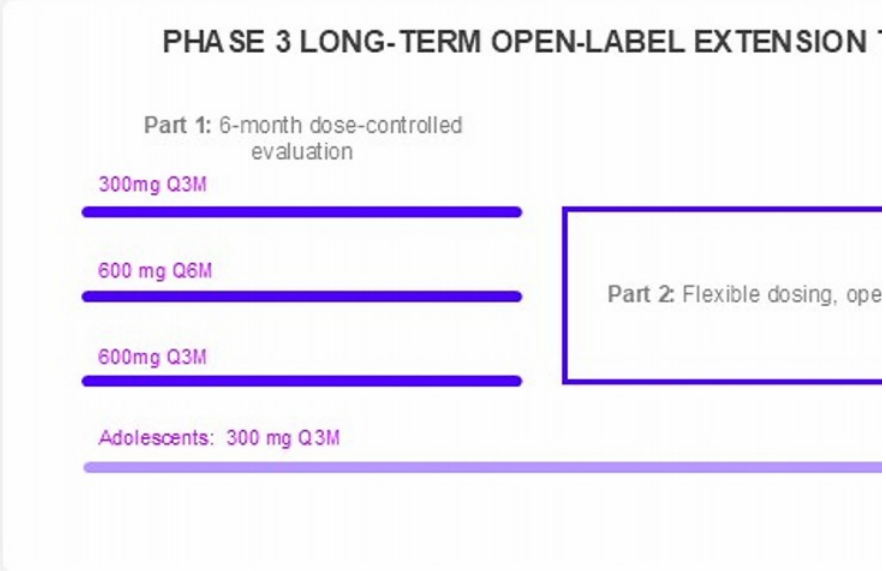
All dose regimens expected to meet
efficacy of current market-leading p

astria THERAPEUTICS

1. Selected secondary endpoints shown.
R = randomization
2. Banerji et al (2018), JAMA 3. TAKHZYRO US Prescribing Information (Feb 2023) 4.Astria QSP analysis

Long-Term Extension Trial to Support Naveniba Registration and Profile in HAE

- ALPHA-ORBIT participants on drug may be eligible to continue on the same dose regimen through Part 1
- Placebo patients enter 600 mg Q3M arm
- Primary objective: assess long-term safety and tolerability of navenibart



astria THERAPEUTICS

Path to ALPHA-ORBIT Success

navenibart

NAVENIBART'S PROFILE

- Trusted mechanism and modality
- Strong proof-of-concept and safety profile to-date
- Q3M and Q6M administration
- Low risk for administration pain

OUR COLLABORATION WITH HAE COMMUNITY

- ALPHA-ORBIT designed with input from patients and physicians from around the world
- Design reflects feedback from FDA and CHMP

alpha-star

OUR HISTORY OF STRONG EXECUTION

- Phase 1b/2 enrolled faster than anticipated
- Expanded enrollment has allowed additional site experience that lays foundation for Phase 3

ALPH

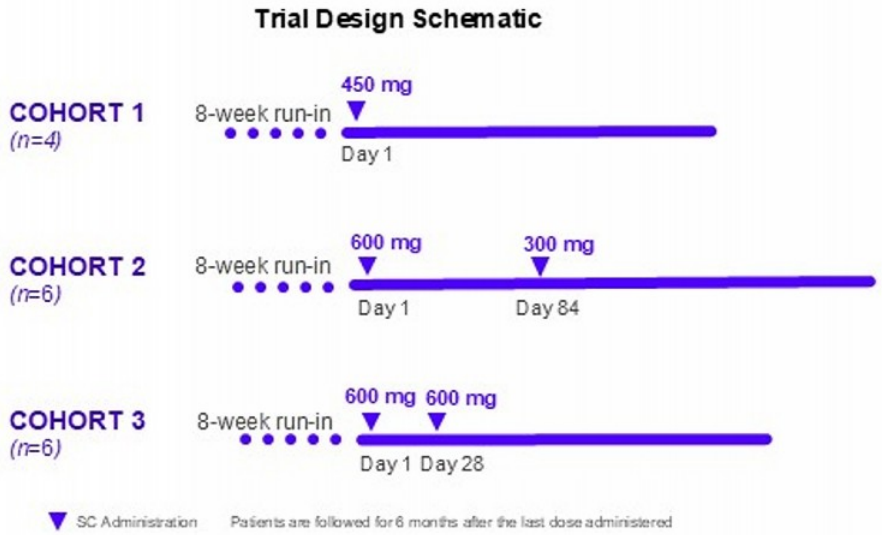
OUR COM TO OPER EXCELLE

- Wide foc trial
- Robust p outreach
- Site recr activities

astria THERAPEUTICS

alpha-star+

ALPHA-STAR Informed Q3M and Q6M Dosin



- ALPHA-STAR Phase 1b/2 is a dose-r of-concept trial in adults with HAE
- Target enrollment (n=16) has been ac complete follow-up
- Topline results demonstrated potentia effectiveness of Q3M and Q6M dosin
- These data to be presented at upcom conference

astria THERAPEUTICS

SC = subcutaneous. Run-in period is at least 8 weeks (56 days) to measure baseline HAE attacks.
Final data from target enrollment patients (n=16)

alpha-star+

ALPHA-STAR Phase 1b/2 Results Established Pr
Concept and Path for Potential Phase 3 Succe

ALPHA-STAR Phase 1b/2 6-Months Results Summary

Navenibart Summary

- **91-95%** Attack Rate Reduction
- **25-67%** Attack-Free Rate
- **95-96%** Reduction in Moderate and Severe Attack Rate
- **91-94%** Reduction in Attacks Requiring Rescue Medication
- **0%** Injection Site Pain

6-Month Phase 3 Results Summaries

	Attack Rate Reduction	Attack-Free Rate	Reduction in Moderate and Severe Attack Rate	Reduction in Attacks Requiring Rescue Medication	Injection Site Pain
Lanadelumab[2,3] 300 mg Q2W	87%	44%	83%	87%	52%
Berotralstat[4,5,6] 150 mg QD	44%	8%	40%	49%	N.A.
Garadacimab[7] 200 mg Q4W	87%	72%	90%	88%	N.R.
Donidalorsen[8] 80mg Q4W	81%	53%	89%	92%	N.R.

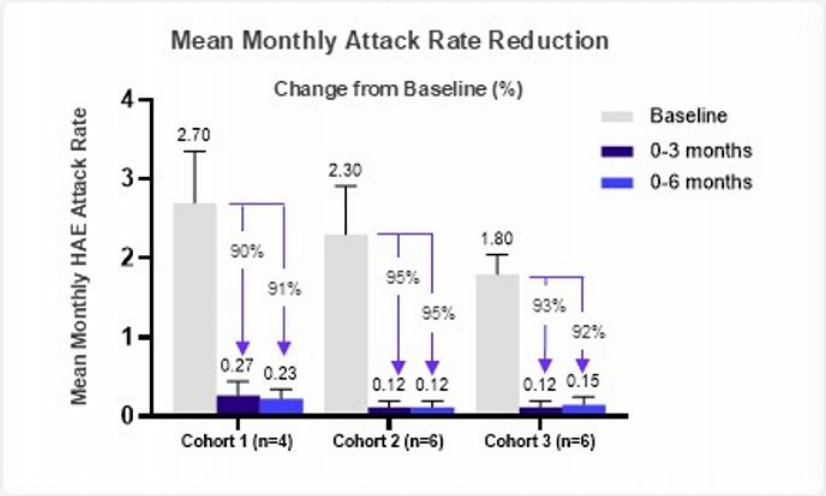
astria THERAPEUTICS

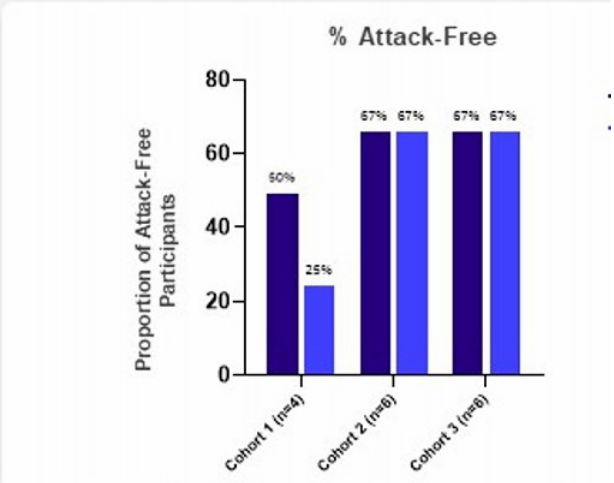
Navenibart efficacy endpoints are mean change from baseline. Final data from target enrollment patients (n=16). Results from lanadelumab, berotralstat, garadacimab, and donidalorsen are from separate, Phase 3, placebo-contro adults and adolescents with Type 1 or 2 HAE. Data from most efficacious dose regimens shown. The comparison presented between navenibart and the lanadelumab, berotralstat, garadacimab, and donidalorsen data represent c comparisons and does not involve data from a head-to-head clinical trial. For lanadelumab, berotralstat, garadacimab, and donidalorsen, endpoints are changes from placebo. N.A. = Not applicable; N.R. = Not reported.

1. Planned administration for navenibart 2. Banerji et al (2018), JAMA 3. TAKHZYRO US Prescribing Information (Feb 2023) 4. ORLADEYO US Prescribing Information (Oct 2024) 5. Zuraw et al (2021). J. Allergy Clin. Immunol. 6. Multidisciplinary Review and Evaluation, Orladeyo (Oct 2018) 7. Craig et al (2023), The Lancet 8. Riedl et al (2024), NEJM

alpha-star+

Navenibart Demonstrated 6 Months of HAE Att Prevention with 1 or 2 Doses





astria THERAPEUTICS

Final data from target enrollment patients (n=16). Showing %difference between the means in each group (3 months and 6 months) vs the mean run-in (baseline).

alpha-star+

Navenibart Was Well-Tolerated and Demonstrat Favorable Safety Profile

	Cohort 1 (N=4)	Cohort 2 (N=6)	Cohort 3 (N=6)	To
Participants with at least 1 Treatment-Emergent Adverse Event (TEAE)	4	5	6	
TEAEs occurring in ≥ 2 participants				
Nasopharyngitis	1	1	2	
Sinusitis	–	1	1	
Headache	2	–	–	
Participants with at least 1 related TEAE[1]	–	1	2	
Injection site erythema	–	–	1	
Injection site pruritus	–	–	1	
Injection site rash	–	–	1	
Dizziness	–	1	–	

No serious adverse events (SAEs) and no discontinuations due to TEAE

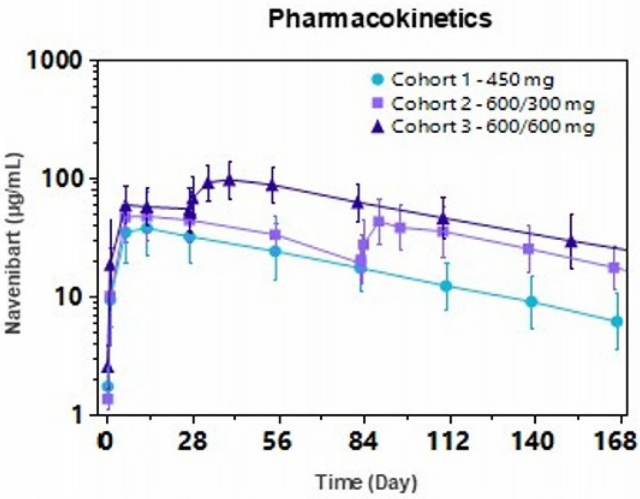
astria THERAPEUTICS

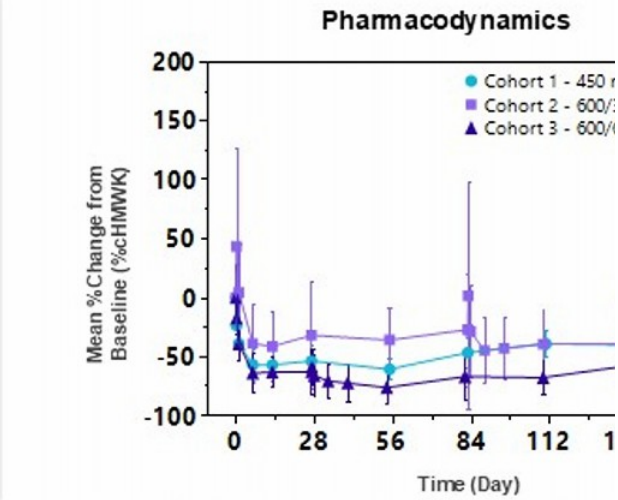
1. One participant experienced mild dizziness occurring 6 days after the first dose in Cohort 2 and lasting < 1 day;
   One participant experienced 2 injection site reactions: injection site erythema and injection site pruritus occurring 1 day after the second dose in Cohort 3 and lasting <1 day;
   One participant experienced injection site rash occurring 5 days after the second dose in Cohort 3 and lasting < 1 day

Final data from target enrollment patients (n=16).

alpha-star+

Results Show that Navenibart PK and PD Are Cons with Rapid and Durable Clinical Benefit





Maximum lanadelumab effect -53.7% [1]

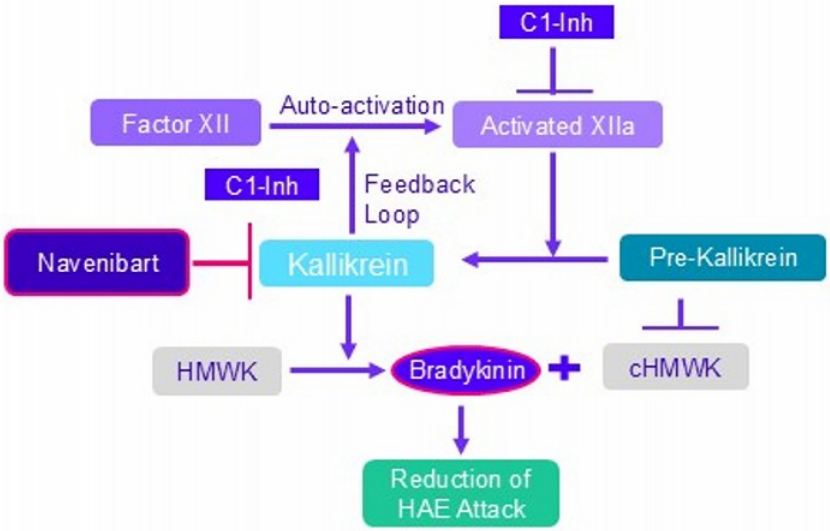
astria THERAPEUTICS

Final data from target enrollment patients (n=16).

1. Wang et al (2020). Lanadelumab FDA Multidisciplinary Review (2017): maximum 53.7% inhibition of formation rate of cHMWK with lanadelumab (exposure-response model).

Navenibart and lanadelumab have not been evaluated in a head to head clinical trial.

Mechanistic QSP Model Informed Phase 3 Dos Selection



Mechanistic Quantitative Syst Pharmacology (QSP) Model

•Validated model in HAE[1]

•Model integrates HAE pathoph accumulated navenibart preclini clinical data including:

- C1-Inh activity
- Baseline attack frequen
- PK characteristics
- PD (cHMWK levels)

•Simulations of various dose re virtual HAE patients informed d

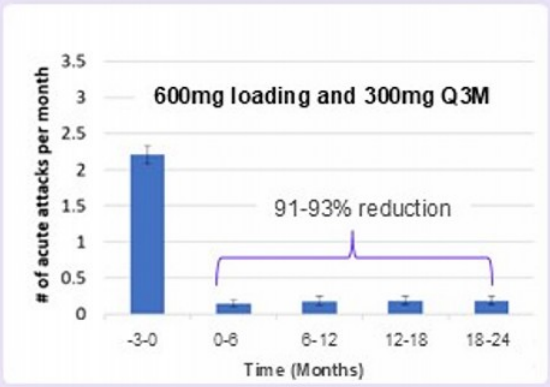
astria THERAPEUTICS

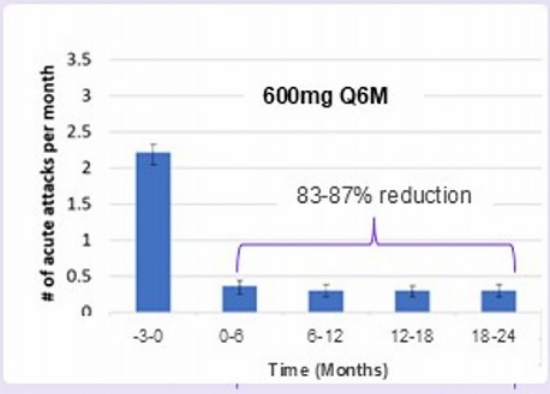
Species: XII = factor XII, XIIa = activated factor XII, C1-Inh = C1-inhibitor, HMWK = high molecular weight kininogen, cHMWK = cleaved HMWK, Kallikrein = plasma kallikrein, PK = pharmacokinetics, PD = pharmacodynamics

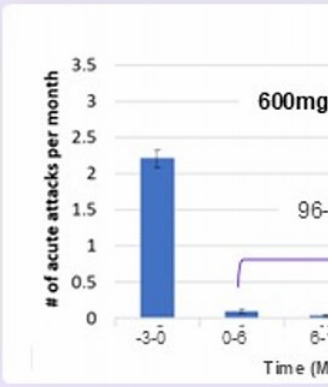
1. Sexton D et al (2024) J Pharmacokinet Pharmacodyn

Navenibart Has the Potential to be the Market-Le
HAE Preventative Therapy

QSP Model-Predicted Change in Time-Normalized Monthly HAE Attack Rate[1]







Phase 3 Results Summaries: 6-Month Time-Normalized Monthly HAE Attack Rate[2,3,4,5,6,7]

Lanadelumab 300 mg Q2W *(70% of use)*[5]	Lanadelumab 300 mg Q4W *(30% of use)*[5]	Berotralstat 150 mg QD	Garadacimab 200 mg Q4W	Donidalorsen 80 mg Q4W	
87%	73%	44%	87%	81%	

1. Mean ± 5 and 95 percentiles from 100 subsets of virtual population with ~100 subjects in each subset. Ranges of mean reductions in 6-month time-normalized monthly HAE attack rates through 24 months are shown. Navenibart QS based on the ALPHA-STAR target enrollment attack rates and are mean change from baseline. Results from lanadelumab, berotralstat, garadacimab, and donidalorsen are from separate, Phase 3, placebo-controlled trials in adults a with Type 1 or 2 HAE. Data from most efficacious dose regimens shown. The comparison presented between navenibart and the lanadelumab, berotralstat, garadacimab, and donidalorsen data represent cross-trial comparisons and data from a head-to-head clinical trial. For lanadelumab, berotralstat, garadacimab, and donidalorsen, endpoints are changes from placebo. 2. Banerji et al (2018), JAMA 3. TAKHZYRO US Prescribing Information (Feb 2023) 4. ORL Prescribing Information (Oct 2024) 5. Zuraw et al (2021), J. Allergy Clin. Immunol. 6. Craig et al (2023), The Lancet 7. Riedl et al (2024), NEJM. QSP = Quantitative Systems Pharmacology 8. Watt et al. AAAAI (Feb 2024).

Navenibart Dosing Flexibility Has the Potential to Transform the Treatment of HAE

Patients and physicians increasingly recognize flexible dosing as most appropriate care.

For example, VABYSMO (faricimab-svoa) revolutionized the wet AMD and DME markets with dosing flexibility ($3.2B USD in sales as of 9/30/2024[1])

TAKHZYRO (lanadelumab), the current HAE market-leading product ($1.0B USD in sales as of 9/30/2024[2,3,4]) is dosed every 2 weeks with the potential to extend the dosing interval to every 4 weeks

Navenibart Phase 3 program is designed to enable dosing flexibility

Navenibart has potential to deliver efficacy at or better than TAKHZYRO with the ability for patients and clinicians to decide what works best for them with dosing every 3 or 6 months

astria THERAPEUTICS

1. Roche. YTD September 2024 sales (2024).
2. Takeda Pharmaceutical Co. Takeda Quarterly Financial Report For the Quarter Ended March 31, 2024. (2024).
3. Takeda Pharmaceutical Co. Takeda Quarterly Financial Report For the Quarter Ended June 30, 2024. (2024).
4. Takeda Pharmaceutical Co. Takeda Quarterly Financial Report For the Quarter Ended September 30, 2024. (2024).

Advancing Navenibart to Become the Potential M
Leading Treatment for HAE

Growing HAE Market Expected to be $5.4B by 2030

+

Compelling Navenibart Clinical Profile that Supports Potential Q3M and Q6M Administration

+

Pioneering Potential Patient-Centric Dosing Flexibility

+

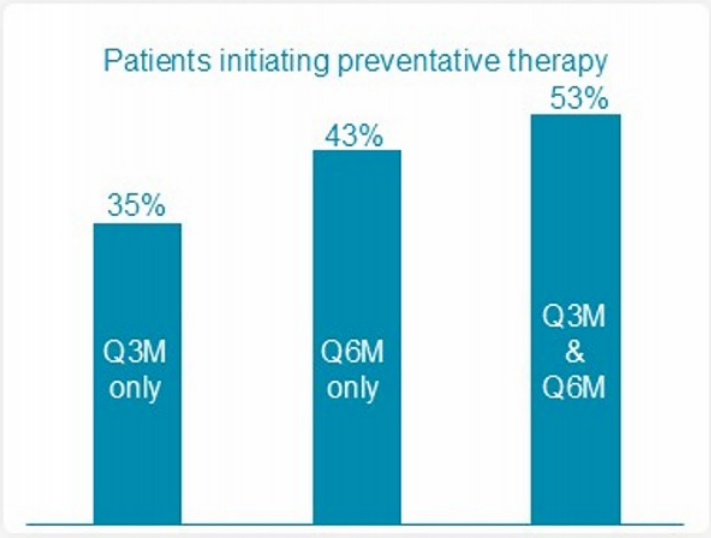
Buildi
Expec
Patien
From
Switch
New S

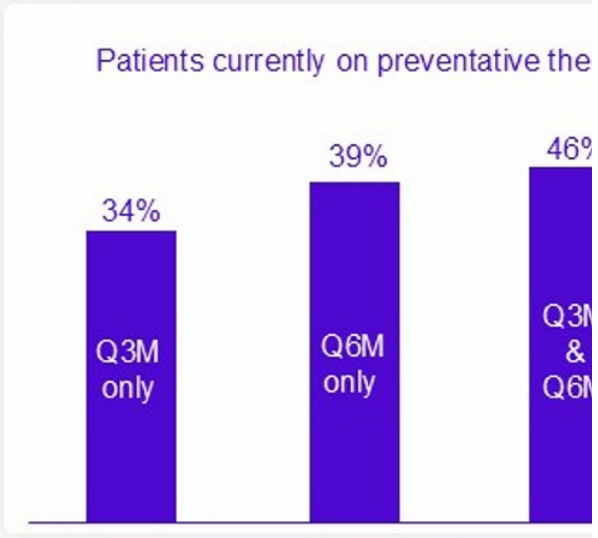
Our goal with navenibart is to revolutionize the treatment of

astria THERAPEUTICS

Providing Patients Both Q3M and Q6M Options Would Individual Choice and Address the Needs of a Broader P

HCP-Anticipated Patient Share

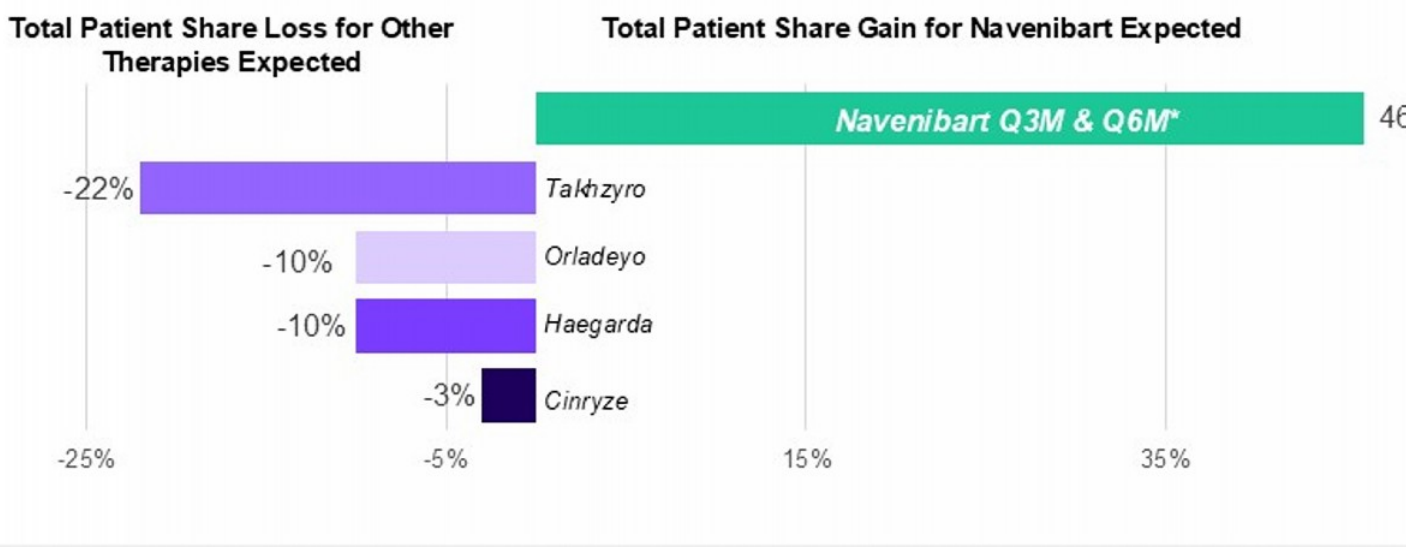




astria THERAPEUTICS

TRINITY Primary Market Research, July – August 2024; Quantitative Research with N=50 U.S. HAE Treaters; Shares reported with respect to currently available treatments
*Blinded profile shared of a monoclonal antibody inhibitor of plasma kallikrein, with efficacy comparable to TAKHZYRO, low risk of injection pain, and with dosing regimen of every 3 months and/or every 6 months.

Navenibart Expected to Draw Switches from Ot Current Therapies

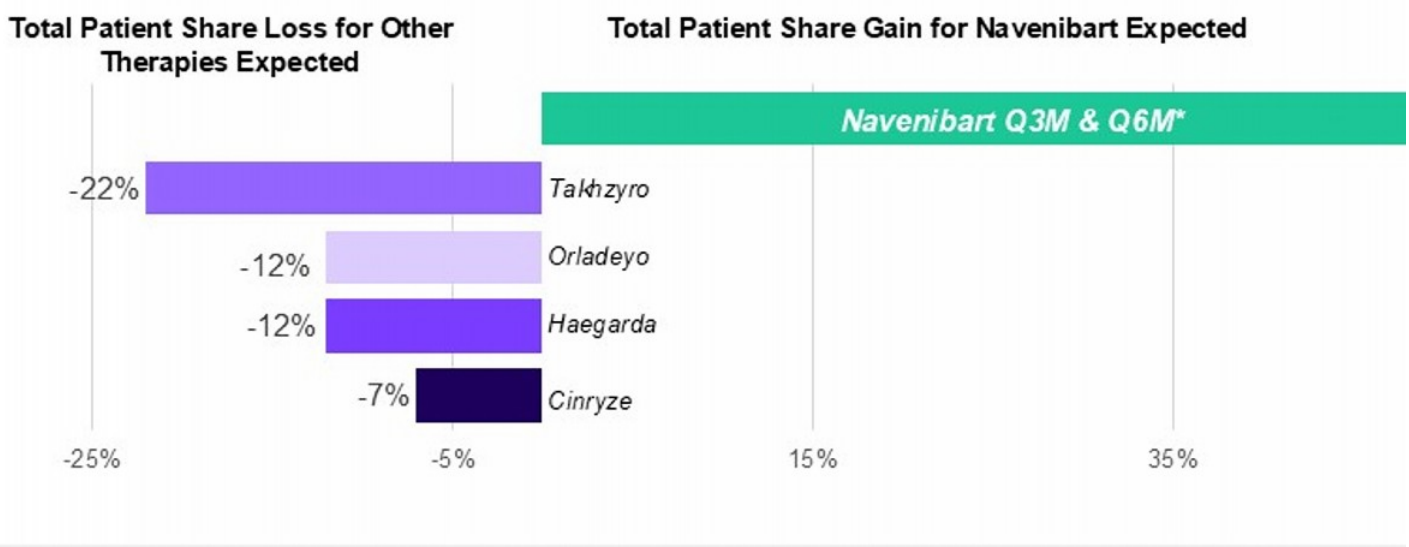


astria THERAPEUTICS

TRINITY Primary Market Research, July – August 2024; Quantitative Research with N=50 U.S. HAE Treaters; Shares reported with respect to currently available treatments

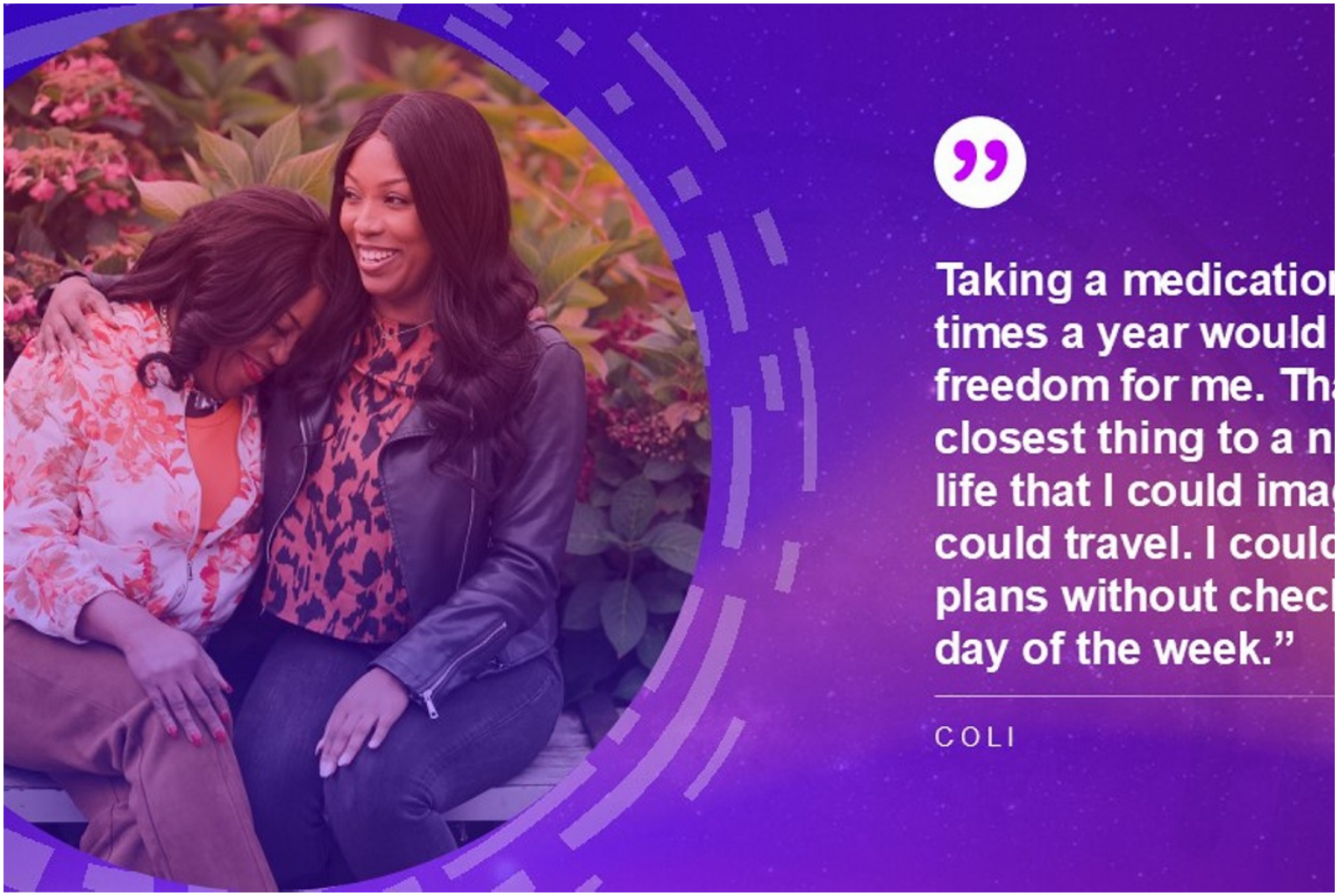
*Blinded profile shared of a monoclonal antibody inhibitor of plasma kallikrein, with efficacy comparable to market-leader TAKHZYRO, low risk of injection pain, and with dosing regimens of every 3 months and/or every 6 months.

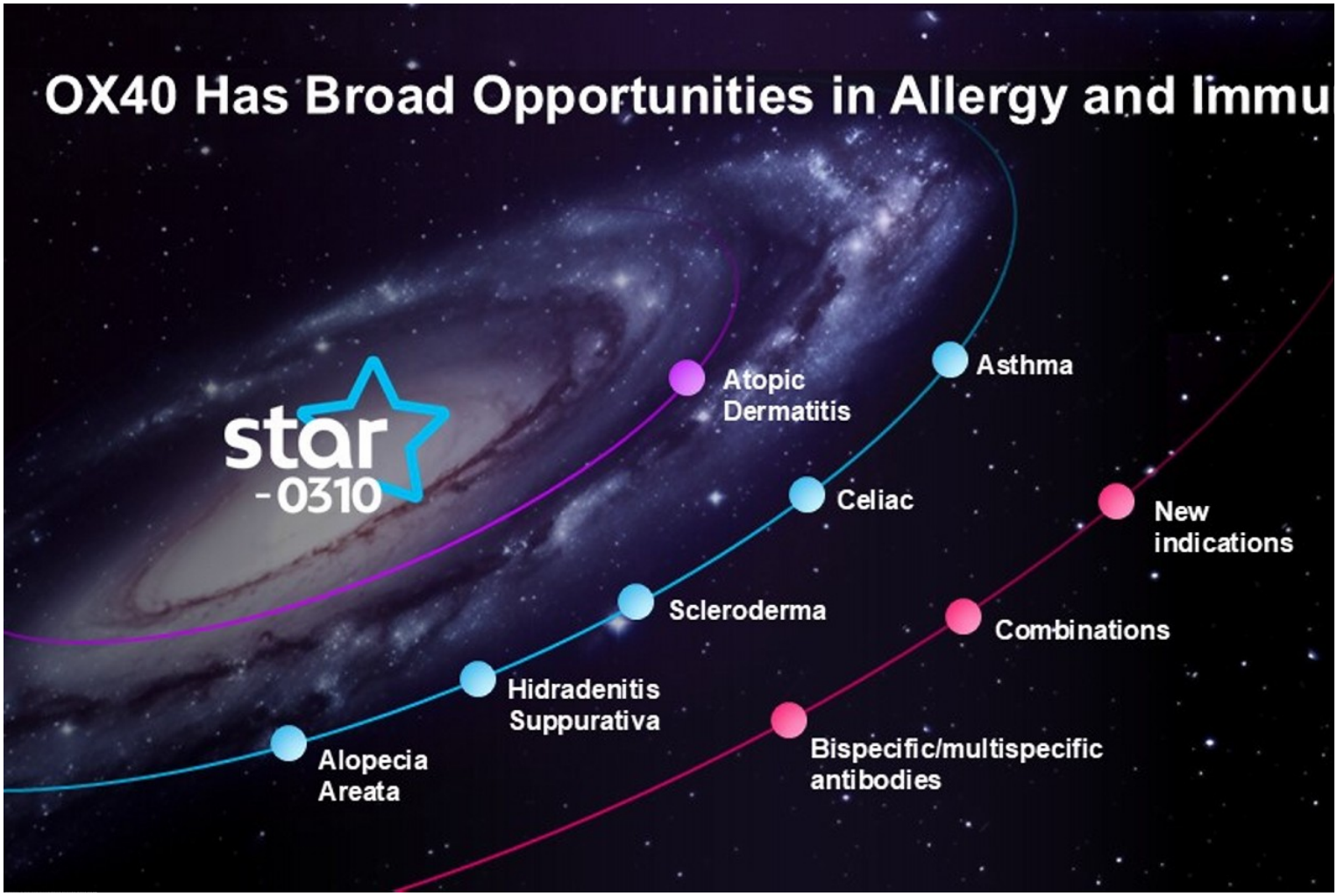
Navenibart Expected to Draw Patients From Ne Initiating Preventative Therapies



TRINITY Primary Market Research, July – August 2024; Quantitative Research with N=50 U.S. HAE Treaters; Shares reported with respect to currently available treatments

*Blinded profile shared of a monoclonal antibody inhibitor of plasma kallikrein, with efficacy comparable to market-leader TAKHZYRO, low risk of injection pain, and with dosing regimens of every 3 months and/or every 6 months.


Taking a medicatio
times a year would
freedom for me. Th
closest thing to a n
life that I could ima
could travel. I coul
plans without chec
day of the week.”
COLI


OX40 Has Broad Opportunities in Allergy and Immu
star
-0310
Atopic
Dermatitis
Asthma
Celiac
New
indications
Scleroderma
Combinations
Hidradenitis
Suppurativa
Alopecia
Areata
Bispecific/multispecific
antibodies

Atopic Dermatitis: Opportu
Broad Impact on Patients'

PREVALENCE

16 million people in the U.S
About half of those people are
be moderate-to-severe[1]

COMMERCIAL OPPORTUNITY

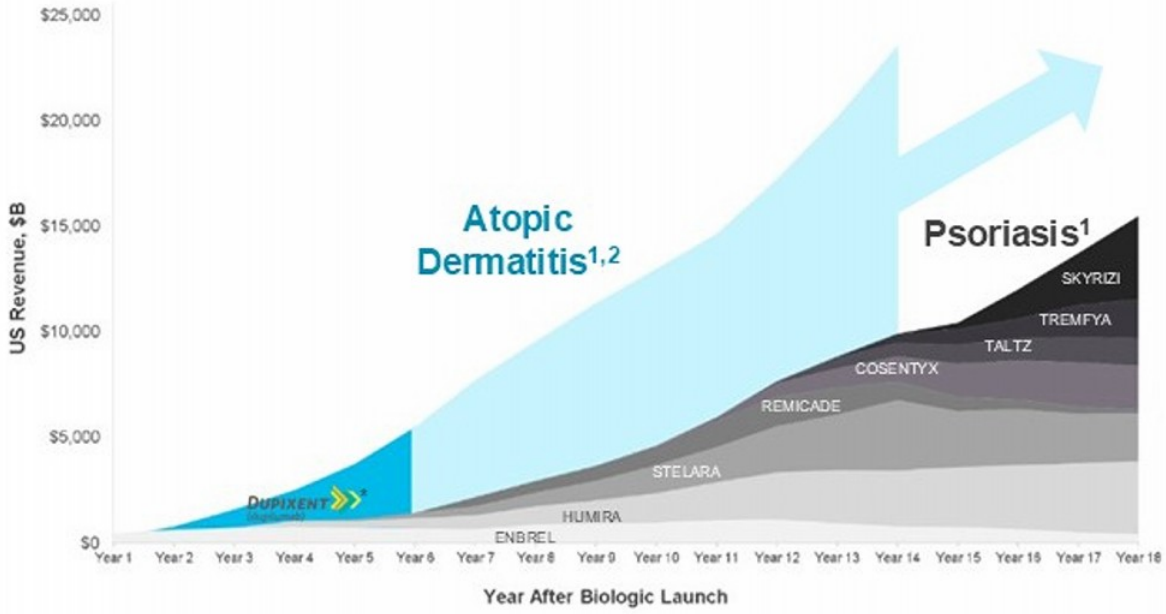
2023 Moderate-to-Severe AD Market
$7B[2]

2030 Moderate-to-Severe AD Market
$26B[2]

Treatment
- Topicals and immunosuppressants
- Advanced treatment*

1. Barbarot S, et al. Allergy. 2018 Jun;73(6):1284-1293. doi: 10.1111/all.13401
2. Decision Resources Group: Atopic Dermatitis Disease Landscape & Forecast, July 2023

Proven Precedence for Market Growth and Evolu
Targeted Dermatology Therapies



US Pre

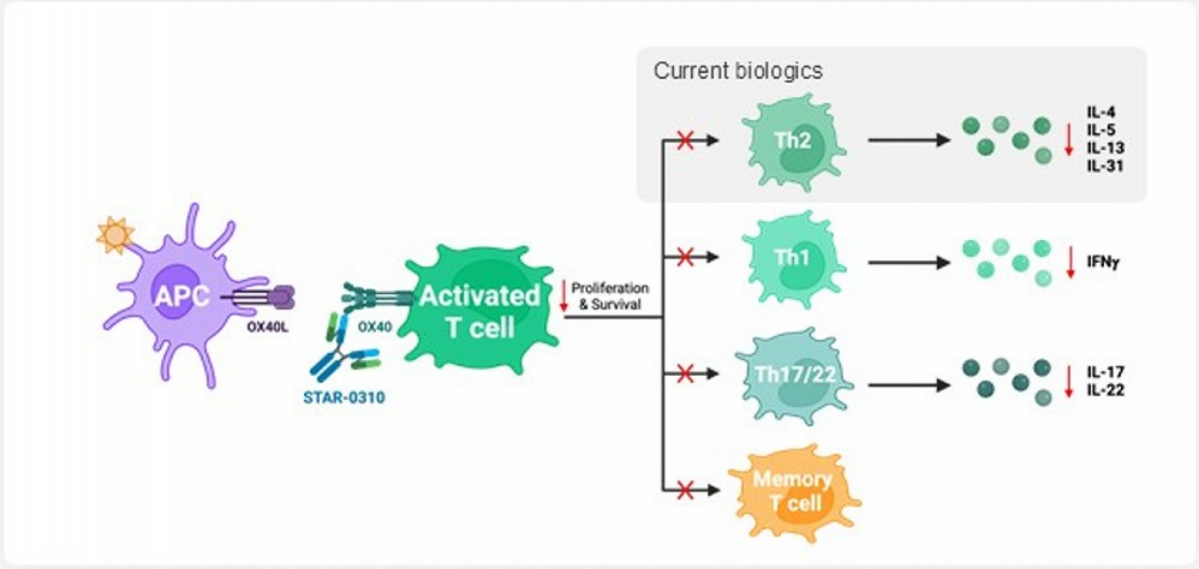
Psc
2

Atopic D

* Includes Cibinqo and Rinvoq.

1. Evaluate Pharma Consensus Sales by Indication in the US
2. Decision Resources Group. Atopic Dermatitis Disease Landscape & Forecast, July 2023
3. Damiani, G. et al. Front Med (Lausanne) 2021 Dec 16;8:743180. doi: 10.3389/fmed.2021.743180
4. Barbarot S, et al. Allergy. 2018 Jun;73(6):1284-1293. doi: 10.1111/all.13401

Targeting OX40 Has Potential for Disease Modific



- AD is driven b
  T cells, includi
  and Th17/22
- Current biolog
  the Th2 pathw
- **Targeting OX**
  cells broadly
  result in high
  clinical respo

astria THERAPEUTICS

STAR-0310 Shows Potential for Differentiation f
Late-Stage OX40/OX40L Programs

Anti-OX40 Monoclonal Antibodies
Precise Targeting of Activated T Cells

Anti-OX40L Mon
Widely Targeting

STAR-0310

- Fully humanized, IgG1
- Full antagonist
- Low ADCC and T cell preserving
- YTE half-life extended
- **STAR-0310 is optimally designed to target the receptor with high affinity, high potency, and long half-life**

Rocatinlimab[2,3,6]

- Fully human, afucosylated, IgG1
- Depletes T cells via enhanced ADCC
- T cell depletion leads to cytokine release (pyrexia and chills) and potential increased risk of infection
- Top-line data from 1st Phase 3 trial shared

Amliteli

- Fully human, IgG4
- OX40L is widely expre
- Binding OX40L may i upper respiratory infe nasopharyngitis, respi vascular AEs
- Positive Phase 2a an
- Ph 3 in AD ongoing

APCs= antigen presenting cells. These include epithelial, endothelial, smooth muscle, mast and B cells. AEs= adverse events

astria THERAPEUTICS

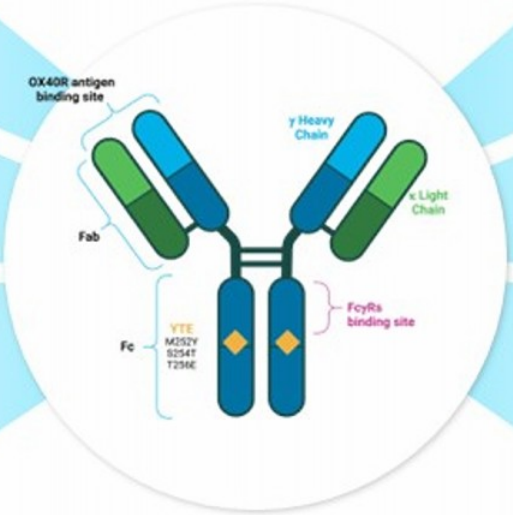
1. Weidinger et al. 2023; Br J Dermatol.
2. Le A, Torres T. 2022; Pharmaceutics. 2022, Dec 8; 14(12):2753
3. Guttman-Yassky et al 2023; Lancet. 2023, Dec 9; 401:204-14
4. Rewerska et al 2023; AAAAI. 2023, Nov 22.
5. Clinicaltrials.gov NCT05131477
6. Clinicaltrials.gov NCT05651711

STAR-0310:
Engineered to Differentiate on Efficacy, Safety, and Treatmen

High Affinity, Next Generation Anti-OX40 antibody

Selective Potency for Activated T-Cells

Potential Best-in-Class Safety Profile Designed for low ADCC and to be T cell preserving



Extended Half-Lif technology

Potential for Low Infrequent SC De

Patent Pending T U.S. provisional pate filed, potential patent

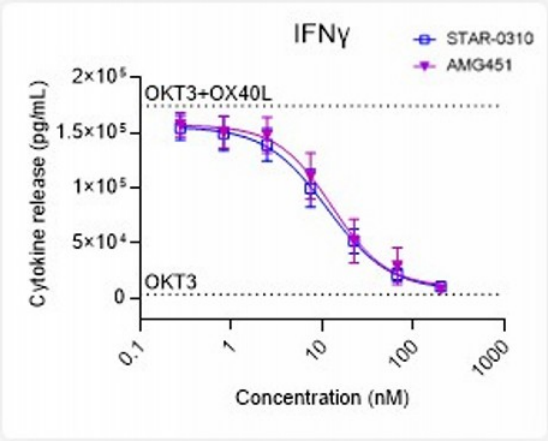
astria THERAPEUTICS

1.Dall'Acqua WF, Kiener PA, Wu H. Properties of human IgG1s engineered for enhanced binding to the neonatal Fc receptor (FcRn). J Biol Chem. 2006 Aug 18;281(33):23514-24.
2.Booth BJ, Ramakrishnan B, Narayan K, Wollacott AM, Babcock GJ, Shriver Z, Viswanathan K. Extending human IgG half-life using structure-guided design. MAbs. 2018 Oct;10(7):1098-1110.
3.U.S. provisional patent application filed October 2023 covering STAR-0310 and its use in AD and other disorders. If converted, nationalized and approved, expect the patent to expire in 2044, excluding potentially applicable patent term extension.

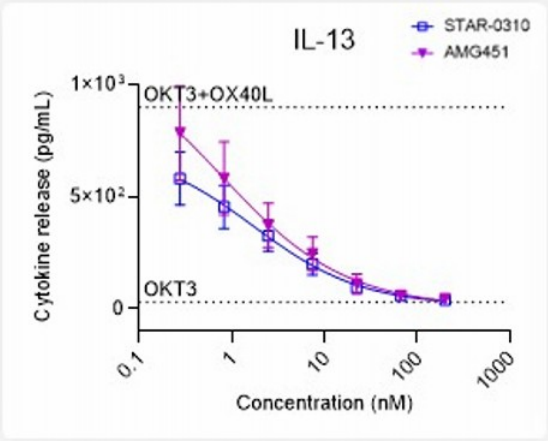
STAR-0310 Has High Potency for OX40

STAR-0310 and Rocatinlimab Have Similar Potency on Effector T (Th)

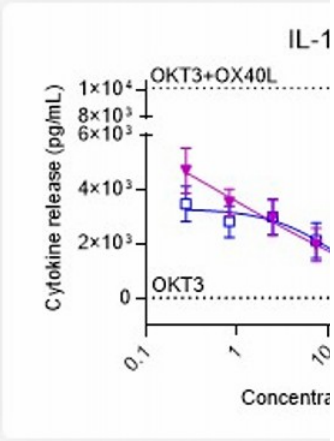
Th1 cytokine



Th2 cytokine



Th17 cytok



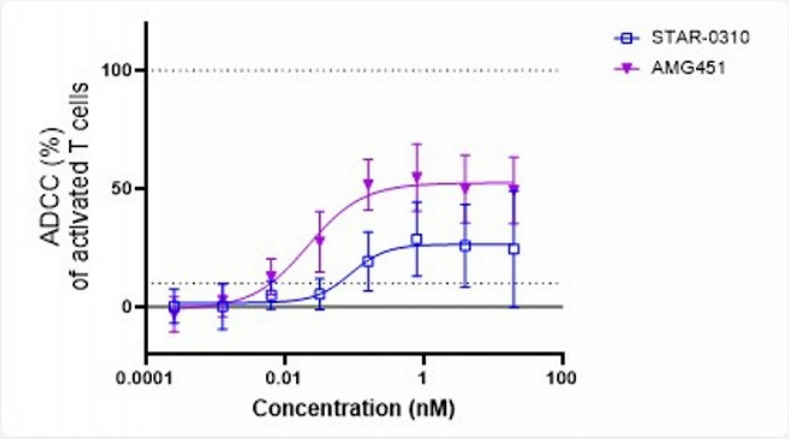
astria THERAPEUTICS

1. Biris, et al. "Development and characterization of STAR-0310: a novel OX40 antagonistic monoclonal antibody. EAACI May 2024.

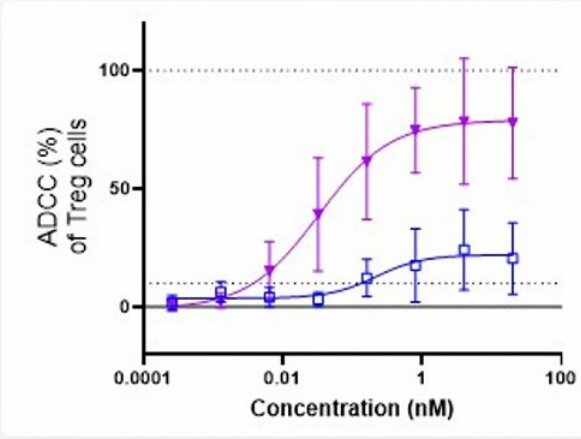
STAR-0310 Is Engineered for Low ADCC

STAR-0310 Has Lower ADCC than Rocatinlimab

ADCC on Activated T Cells



ADCC on Regulatory T Cell

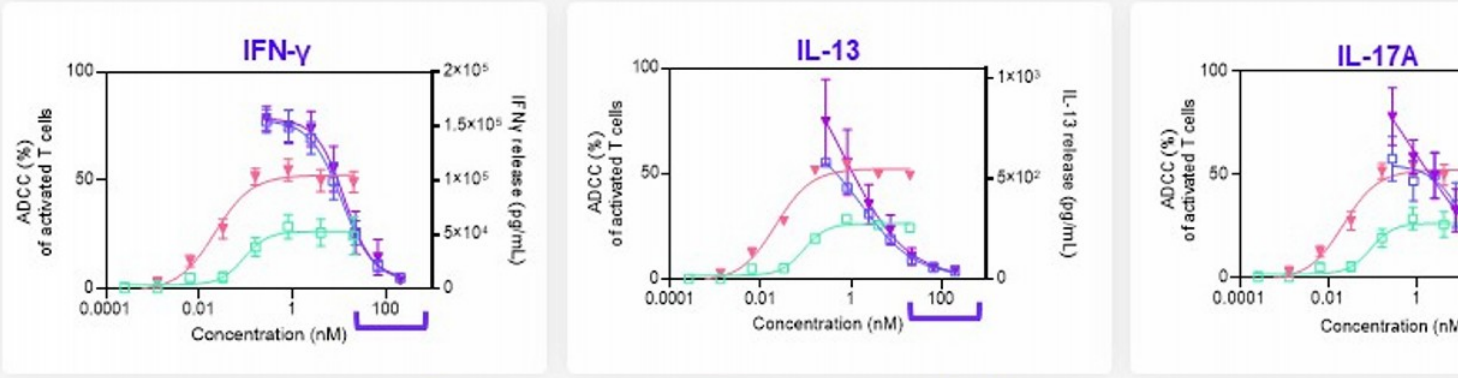


1. Birs, et al. "Development and characterization of STAR-0310: a novel OX40 antagonistic monoclonal antibody. EAACI May 2024.

STAR-0310 Has Potential for Best-in-Class Effic

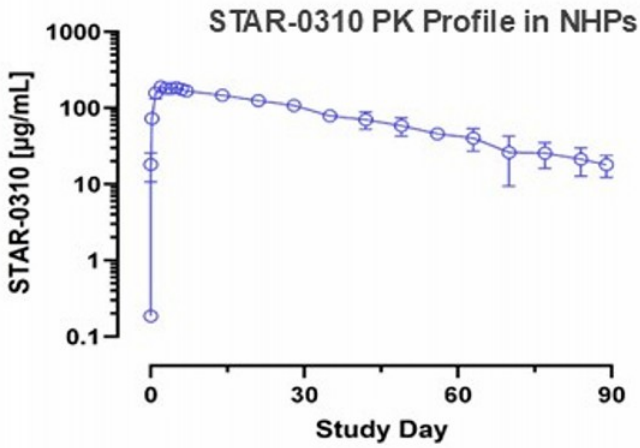
STAR-0310 Has a Potentially Wider Therapeutic Windo

In vitro Activated T Cell ADCC (%) Compared to Potency for Th1, 2, and 17/22 Cytokines



1. Figures represent a cross-experiment comparison
2. Biris, et al. "Development and characterization of STAR-0310, a novel OX40 antagonistic monoclonal antibody. EAACI May 2024.

STAR-0310 Has Potential to be the Least Freque Administered OX40



- **Extended half-life with YTE tec**
  - Estimated mean half-life of 26
    - Average 10-14 days in non-ha extended IgG antibodies
  - Expected 2-5 fold increase in ha humans
- **Potential for administration a infrequently as once every 6 due to long half-life and pote disease modification**

NHP = Nonhuman primate

Single dose in vivo pharmacokinetic data from cynomolgus monkeys dosed with STAR-0310 via subcutaneous (SC, N= 3) route at 20 mg/kg.

Birs, et al. "Development and characterization of STAR-0310: a novel OX40 antagonistic monoclonal antibody. EAACI May 2024.

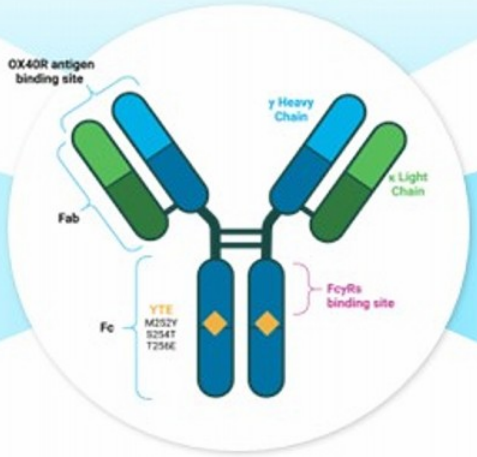
STAR-0310:

Potential First-Choice for Moderate-to-Severe AD

Phase 1a Initiation Anticipated in Q1 2025

Best-in-Class Efficacy

Better Safety and Tolerability



Least Frequ Administered

astria THERAPEUTICS

Recent and Expected Milestones

navenibart

HEREDITARY ANGIOEDEMA

- Q1 2024: Initial POC results from ALPHA-STAR
- Q3 & Q4 2024: Orphan Drug and Orphan Medicinal Product Des
- Q4 2024: Final ALPHA-STAR target enrollment results
- Q1 2025: Initiate Phase 3 trial
- Mid-2025: Long-term treatment results from ALPHA-SOLAR

star-0310

ATOPIC DERMATITIS

- Mid 2024: Present preclinical profile
- YE 2024: IND submission
- Q1 2025: Initiate Phase 1a healthy subject trial
- Q3 2025: Phase 1a results
- Q3 2025: Initiate Phase 1b trial

astria THERAPEUTICS

Strong Financial Foundation

Astria (Nasdaq: ATXS)

- Cash, cash equivalents, and short-term investments as of 12/31/2024 of over $325M
- Cash expected to support current operating plan[1] into mid-2027

Equity Summary

	Common	Preferred Stock as Common Equivalents	Pre-Funded Warrants	Total OS Common Eq
Outstanding as of 9/30/24	56,434,219	5,184,591	1,571,093	63,189,903

1. The Company expects that its cash, cash equivalents and short-term investments as of September 30, 2024 will be sufficient to fund its operations into mid-2027, including all navenibart program activities through the completion of a planned Phase 3 pivotal trial as well as advancing the STAR-0310 CIM40 program through submission of an IND and early proof-of-concept results from a Phase 1a clinical trial.


astria
THERAPEUTICS