UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **December 15, 2022**

Astria Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-37467**	**26-3687168**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

75 State Street, Suite 1400 **Boston, Massachusetts** (Address of Principal Executive Offices)	**02109** (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 (*see* General Instruction A.2. below):

☐ 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 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 December 15, 2022, Astria Therapeutics, Inc. (the "Company," "we" or "us") issued a press release announcing preliminary results from its Phase 1a clinical trial evaluating the safety, pharmacokinetics, and pharmacodynamics of STAR-0215. A copy of the press release is furnished hereto as Exhibit 99.1.

In connection with the announcement, the Company will host a call and webcast on December 15, 2022 at 8:30 a.m. ET. Call details are contained in the press release referenced above. Accompanying slides may be accessed through the "Investors" section of the Company's website at www.astriatx.com. A copy of these slides is furnished hereto as Exhibit 99.2.

The information furnished under this Item 7.01, including Exhibits 99.1 and 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 Exhibits 99.1 and 99.2, shall not be deemed incorporated by reference into any other filing with the U.S. 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 8.01. Other Events.

In connection with the announcement of the preliminary results from the Company's Phase 1a clinical trial, the Company is announcing the following updated overview of the Company's business and summary of recent developments.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics. Our mission is to bring hope with life-changing therapies to patients and families that are affected by rare and niche allergic and immunological diseases. Our lead product candidate is STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema ("HAE"), a rare, debilitating and potentially life-threatening disease. STAR-0215 has the potential to be the most patient-friendly chronic treatment option for HAE, based on the preclinical and clinical data generated to date and the existing HAE treatment landscape.

The treatment options for patients with HAE have improved, however, there is remaining unmet medical need and the global market for HAE therapy is strong and growing. We estimate that the global HAE therapy market was approximately $2.3 billion in 2021 and that it has the potential to grow to $4.5 billion by 2027 due to earlier diagnosis of patients, an increase in patients taking preventative treatments and geographic expansion for currently available therapies. Our vision for STAR-0215 is to develop a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE with dosing once every three months or longer. Targeted plasma kallikrein inhibition can prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling. In an *in vitro* preclinical study, we observed that STAR-0215 is at least as potent as lanadelumab, a plasma kallikrein inhibitor that has been approved by the U.S. Food and Drug Administration (the "FDA"), for the treatment of HAE, in inhibiting the generation of bradykinin. In an *in vivo* preclinical study in non-human primates, we observed that STAR-0215 has a half-life that is approximately three time longer than lanadelumab. We submitted an Investigational New Drug application ("IND") for STAR-0215 in June 2022 and the FDA cleared the IND for STAR-0215 in July 2022. We initiated a Phase 1a clinical trial for STAR-0215 in August 2022. The Phase 1a randomized, double blind, placebo controlled single ascending dose clinical trial is evaluating the safety, pharmacokinetics ("PK") and pharmacodynamics ("PD") of STAR-0215 at a single U.S. center. We have enrolled 25 healthy subjects who have received a single dose of STAR-0215 or placebo in three cohorts of 100mg, 300mg, and 600mg administered subcutaneously, with subjects in each cohort randomized 3:1 to receive active drug vs. placebo. Subjects in the trial are being followed for safety, PK and PD for a total of up to 224 days.

Recent Developments

On December 15, 2022, we reported preliminary data from our Phase 1a clinical trial of STAR-0215. The preliminary data were based on a data cut-off date of December 5, 2022 and include safety data with respect to all enrolled subjects for 84 days following administration and PK and PD data with respect to the subjects enrolled in the 100mg and 300mg cohorts for 84 days following administration and 56 days following administration for the subjects enrolled in the 600mg cohort.

Key findings as of the data cut-off date include:

- STAR-0215 was well-tolerated at all dose levels. The most common treatment-related adverse event was mild (Grade 1) self-resolving injection site reaction, which most commonly was site redness. There were no clinically relevant changes in liver enzymes or coagulation parameters, serious adverse events or discontinuations.
- Administration of STAR-0215 resulted in rapid and sustained achievement of drug levels consistent with levels associated with clinical benefit, with the observed concentrations of STAR-0215 being proportional to dose levels.
- PK and PD results in the 300mg and 600mg cohorts were consistent with levels associated with clinical benefit for up to three months.
- The estimated half-life of STAR-0215 was up to 110 days, which supports dosing once every 3 months or potentially less frequently.
- Modeling of the PK results suggests that an initial 600mg dose of STAR-0215 followed by 300mg doses every three months thereafter would potentially be capable of maintaining drug concentration levels above the threshold associated with clinical benefit.
- PD results showed rapid and robust target engagement with plasma kallikrein inhibition through at least three months following a single dose of STAR-0215. Administration of STAR-0215 resulted in statistically significant reductions in factor XIIa-activated cleaved high molecular weight kininogen ("cHMKW") through 84 days in the 300mg cohort and through the latest measurement date in the 600mg cohort, which was day 56, with levels of inhibition of cHMKW consistent with levels shown to prevent HAE attacks.

Based on these preliminary data, we plan to initiate a Phase 1b/2 proof of concept trial called ALPHA-STAR, or Astria Long-Acting Prophylaxis for Hereditary Angiodema: STAR-0215, in participants with HAE in the first quarter of 2023. This Phase 1b/2 trial will be a global, multi-center, open-label, single and multiple dose proof-of-concept clinical trial in people with HAE and will evaluate safety, tolerability, HAE attack rate, PK, PD and quality of life in patients. Each qualifying participant will receive at least one dose of STAR-0215 and may be eligible to roll into a long-term open label trial. With the ALPHA-STAR clinical trial, we aim to demonstrate durable activity compatible with robust clinical benefit in people living with HAE and to use the results to inform dose selection for a Phase 3 pivotal trial. We expect to report initial results from the single and multiple dose cohorts in mid-2024.

The preliminary data from the Phase 1a trial also suggest that there could be an opportunity to dose STAR-0215 less frequently than every three months. As a result, we plan to evaluate the potential for 6-month dosing with additional healthy subject cohorts in the Phase 1a trial starting in the first quarter of 2023 with initial results expected in the fourth quarter of 2023.

In addition, the Company is supplementing the risk factors previously disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "2021 Form 10-K") with the following risk factor. This risk factor should be read in conjunction with the risk factors included in the 2021 Form 10-K.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

Item 9.01. Exhibits.

Exhibits

Number	Description
99.1	Press Release, dated December 15, 2022
99.2	Company Presentation, dated December 15, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of applicable securities laws and regulations, including statements with respect to: expectations regarding the potential significance of the preliminary results from the Phase 1a STAR-0215 trial, the plans to add additional cohorts to the trial and the anticipated nature and timing of receipt of the data from such additional cohorts; expectations regarding the timing of initiation, design and timing and nature of the anticipated proof of concept results from the planned Phase 1b/2 clinical trial of STAR-0215; the longer term development plans for STAR-0215; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, including its potential best-in-class pharmacokinetic profile, potential dosing frequency, clinical benefit and those suggested by the preliminary results from the STAR-0215 Phase 1a trial, preclinical and pharmacokinetic modeling data; the potential commercial opportunity for STAR-0215 in HAE; the need for effective treatments for HAE; the potential for six-month dosing of STAR-0215; and the Company's goal to meet the unmet needs of patients with rare and niche allergic and immunological diseases. We use words such as "aims," "anticipate," "believe," "estimate," "expect," "goals," "hope," "intend," "may," "opportunity," "plan," "predict," "project," "target," "potential," "would," "vision," "can," "could," "should," "continue," and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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, including the COVID-19 pandemic; 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 pre-clinical studies may not be replicated in clinical studies, that the preliminary results from the Phase 1a trial may not be indicative of the final results, that the results of early stage clinical studies may not be replicated in later stage clinical studies, 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 and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and drug product for STAR-0215 and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulation for STAR-0215 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 therefore; our ability to obtain, maintain and enforce intellectual property rights for STAR-0215 and any other future product candidates; our potential dependence on collaboration partners; competition with respect to STAR-0215 or any of our other future product candidates; the risk that survey results and market research may not be accurate predictors of the commercial landscape for HAE and the anticipated position and attributes of STAR-0215 in HAE based on its clinical data to date, pre-clinical profile, pharmacokinetic modeling and other data; 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, 2021, and in other filings that we may make with the Securities and Exchange Commission. These forward-looking statements should not be relied upon as representing our view as of any date subsequent to the date of this Current Report on Form 8-K, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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: December 15, 2022

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

Exhibit 99.1

Astria Therapeutics Announces Positive Preliminary Results from the Phase 1a Clinical Trial of STAR-0215 in Healthy Subjects

-- Shown Early Proof of Concept of STAR-0215's Profile as a Long-Acting Plasma Kallikrein Inhibitor with Estimated Half-Life of Up to 110 Days --

-- Plans to Initiate ALPHA-STAR Phase 1b/2 Trial in Hereditary Angioedema Patients in Q1 2023 --

-- Results to be discussed in a Webcast Today at 8:30am ET --

BOSTON, Mass., December 15, 2022 – Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company developing STAR-0215 for the treatment of hereditary angioedema (HAE), today announced positive preliminary results from the Phase 1a clinical trial of STAR-0215 in healthy subjects establishing early proof of concept of STAR-0215 as a potential long-acting preventative treatment for HAE. STAR-0215 was well-tolerated at all doses studied. The results showed rapid and sustained drug levels consistent with clinical benefit and sustained target engagement with plasma kallikrein inhibition for at least three months, supporting the potential for STAR-0215 to be dosed once every three months or less frequently. Astria plans to initiate the ALPHA-STAR Phase 1b/2 trial in HAE patients in Q1 2023.

"These results mark a significant milestone for STAR-0215 and Astria. We are excited that STAR-0215 has shown early proof of concept for its target profile: of being a long-acting preventative therapy for HAE, with a best-in-class PK profile, and dosing once every 3 months or less frequently," said Jill C. Milne, Ph.D., Chief Executive Officer at Astria. "We aim to change the way those affected by HAE live with their disease and see these preliminary results as a critical step bringing us closer to improving patients' lives. We are looking forward to bringing STAR-0215 to patients in the ALPHA-STAR trial early next year."

"Patients want treatment options that can normalize their lives. I am pleased to see STAR-0215 moving forward in clinical development to patients," said William Lumry, M.D., Founder and Medical Director of the AARA Research Center. "We understand the need from the HAE community for an effective treatment with less burdensome dosing administration and are excited to see that potential in STAR-0215."

STAR-0215 is a monoclonal antibody inhibitor of plasma kallikrein designed to provide long-acting, effective HAE attack prevention. The Phase 1a randomized, double-blind, placebo-controlled single ascending dose trial of STAR-0215 evaluated the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of STAR-0215 at a single U.S. center. Twenty-five healthy adult subjects each received a single subcutaneous administration of one of three dose levels of 100mg, 300mg, or 600mg of STAR-0215 or placebo, and subjects are being followed for safety, PK, and PD for a total of 224 days. Preliminary data includes safety through 84 days for all three cohorts, PK and PD for the 100 mg and 300 mg cohorts through 84 days and PK and PD through 56 days for the 600 mg cohort.

Blinded safety results showed that STAR-0215 was well-tolerated at all dose levels. The most common treatment-related adverse event was mild (Grade 1), self-resolving injection site reaction, which most commonly was site redness. There were no clinically relevant changes in liver enzymes or coagulation parameters, serious adverse events or discontinuations. In the 300 and 600 mg dose groups, PK and PD results were consistent with clinical benefit up to three months, with an estimated half-life of STAR-0215 up to 110 days. Rapid and sustained drug levels consistent with clinical benefit support the potential for dosing STAR-0215 once every three months or less frequently. PD results showed rapid and robust target engagement with plasma kallikrein inhibition through at least three months with a single dose of STAR-0215. The levels of inhibition, 40 to 60% decrease in FXIIa-activated cleaved high molecular weight kininogen, are consistent with the levels shown to prevent attacks in people living with HAE.

The results support advancing STAR-0215 to a Phase 1b/2 trial, ALPHA-STAR, expected to initiate in Q1 2023. This global, multi-center, open-label, single and multiple dose proof-of-concept clinical trial in people with HAE, will evaluate safety, tolerability, HAE attack rate, PK, PD, and quality of life in patients. Initial results are expected from the single and multiple dose cohorts in mid-2024. The results from the Phase 1a trial also suggest that there could be an opportunity to dose STAR-0215 less frequently. Astria plans to evaluate the potential for 6-month dosing with additional healthy subject cohorts in the Phase 1a trial starting in Q1 2023 with initial results expected in Q4 2023.

Webcast Information:
Interested parties may join the webcast via the Investors section of the Astria website, www.astriatx.com or with the following link: https://edge.media-server.com/mmc/p/rchg8tau.

Please connect to the webcast several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be required. The webcast will be archived for 90 days.

About Astria Therapeutics:
Astria Therapeutics is a biopharmaceutical company, and our mission is to bring life-changing therapies to patients and families affected by rare and niche allergic and immunological diseases. Our lead program, STAR-0215, is a monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema.

Forward Looking Statements

This press release contains forward-looking statements of Astria Therapeutics, Inc. (“Astria,” the “Company,” “we”, “our” or “us”) within the meaning of applicable securities laws and regulations, including statements with respect to: expectations regarding the potential significance of the preliminary results from the Phase 1a STAR-0215 trial, the plans to add additional cohorts to the trial and the anticipated nature and timing of receipt of the data from such additional cohorts; expectations regarding the timing of initiation, design and timing and nature of the anticipated proof of concept results from the planned Phase 1b/2 clinical trial of STAR-0215; the longer term development plans for STAR-0215; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, including its potential best-in-class pharmacokinetic profile, potential dosing frequency, clinical benefit and those suggested by the preliminary results from the STAR-0215 Phase 1a trial, preclinical and pharmacokinetic modeling data; the potential commercial opportunity for STAR-0215 in HAE; the need for effective treatments for HAE; the potential for six-month dosing of STAR-0215; and the Company’s goal to meet the unmet needs of patients with rare and niche allergic and immunological diseases. We use words such as "aims," “anticipate,” “believe,” “estimate,” “expect," "goals," “hope,” “intend,” “may,” "opportunity," “plan,” “predict,” “project,” “target,” “potential,” “would,” "vision," “can,” “could,” “should,” “continue,” and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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, including the COVID-19 pandemic; 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 pre-clinical studies may not be replicated in clinical studies, that the preliminary results from the Phase 1a trial may not be indicative of the final results, that the results of early stage clinical studies may not be replicated in later stage clinical studies, 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 and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and drug product for STAR-0215 and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulation for STAR-0215 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 therefore; our ability to obtain, maintain and enforce intellectual property rights for STAR-0215 and any other future product candidates; our potential dependence on collaboration partners; competition with respect to STAR-0215 or any of our other future product candidates; the risk that survey results and market research may not be accurate predictors of the commercial landscape for HAE and the anticipated position and attributes of STAR-0215 in HAE based on its clinical data to date, pre-clinical profile, pharmacokinetic modeling and other data; 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, 2021, and in other filings that we may make with the Securities and Exchange Commission. These forward-looking statements should not be relied upon as representing our view as of any date subsequent to the date of this press release, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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Exhibit 99.2

Astria STAR-0215 Ph
Trial Preliminary Res

December 2022

Forward Looking Statements

This presentation and various remarks we make during this presentation contain forward-looking statements of Astria Therapeutics, Inc. ("Astria," the "Company," "we", "our" or "us") within the meanin regulations, including statements with respect to: the Company's projected cash runway; expectations regarding the nature, timing and potential significance of the preliminary results from the Phase 1a additional cohorts to the trial and the anticipated nature and timing of receipt of the data from such additional cohorts; expectations regarding the timing of initiation, design and timing and nature of the a from the planned Phase 1b/2 clinical trial of STAR-0215; the longer term development plans for STAR-0215; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, pharmacokinetic profile, potential dosing frequency, clinical benefit and those suggested by the preliminary results from the STAR-0215 Phase 1a trial, preclinical and pharmacokinetic modeling data; th for STAR-0215 in HAE, including its potential to be a best-in-class and most patient friendly treatment option for HAE; the need for effective treatments for HAE; the size and anticipated growth of the protection of patents directed at STAR-0215; potential every six-month dosing for STAR-0215; and the Company's goal to meet the unmet needs of patients with rare and niche allergic and immur pipeline. We use words such as "aims," "anticipate," "believe," "estimate," "expect," "goals," "hope," "intend," "may," "opportunity," "plan," "predict," "project," "target," "potential," "would," "vision," "can, other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially fro 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 competitive factors, including the COVID-19 pandemic; risks inherent in pharmaceutical research and development, such as: adverse results in our drug discovery, preclinical and clinical development a pre-clinical studies may not be replicated in clinical studies, that the preliminary results from the Phase 1a trial may be change once the final results are received and analyzed, that the results of earl replicated in later stage clinical studies, 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, co at all; decisions made by, and feedback received from, the U.S. FDA ("FDA") and other regulatory authorities on our regulatory and clinical trial submissions and other feedback from potential clinical review boards at such sites, and other review bodies with respect to STAR-0215 and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and dru other future product candidates on a cost-effective and timely basis, and to develop dosages and formulation for STAR-0215 and any other future product candidates that are patient-friendly and biomarker and other assays, along with the testing protocols therefore; our ability to obtain, maintain and enforce intellectual property rights for STAR-0215 and any other future product candida collaboration partners; competition with respect to STAR-0215 or any of our other future product candidates; the risk that survey results and market research may not be accurate predictors of the comr anticipated position and attributes of STAR-0215 in HAE based on its clinical data to date, pre-clinical profile, pharmacokinetic modeling and other data; our ability to manage our cash usage and 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 recogn 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 31, 2021, and in other filings that we may make with the Securities and Exchange Commission ("SEC"). These forward-looking statements should not be relied upon as representing our view as of any presentation, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This presentation contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assum cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we o high degree of uncertainty and risk.

astria
THERAPEUTICS

Executive Summary

STAR-0215 has shown early proof of concept for its target profile: long-acting preventati for HAE, best-in-class PK profile, and dosing once every 3 months or less frequen

Positive preliminary results from Phase 1a trial in healthy subjects

- Well-tolerated and favorable safety profile
- Rapid and sustained drug levels with estimated half-life up to 110 days
- Target engagement with durable plasma kallikrein inhibition for at least 3 months

Near-term clinical development plans

- Initiating Phase 1b/2 ALPHA-STAR trial in HAE patients, expected in Q1 2023
  - Initial proof of concept results in HAE patients expected in mid-2024
- Planning to evaluate potential for 6-month dosing in Phase 1a healthy subject trial expecte commence in Q1 2023, with initial results expected in Q4 2023

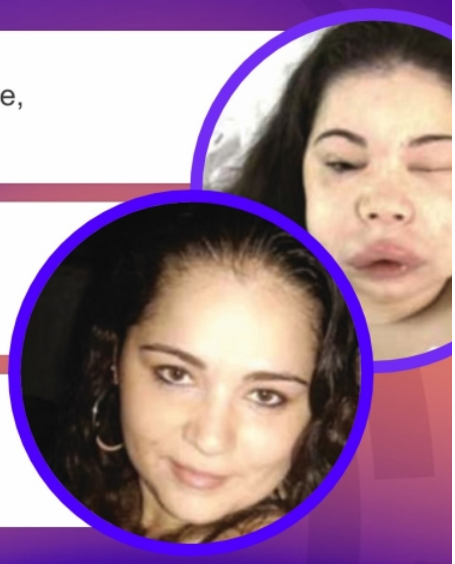
astria THERAPEUTICS

Hereditary Angioedema (HAE): A Rare, Disfiguring, and Potentially Life-Threatening Dis

Rare genetic disorder charactered by severe, unpredictable, sometimes **life-threatening** swelling[1]

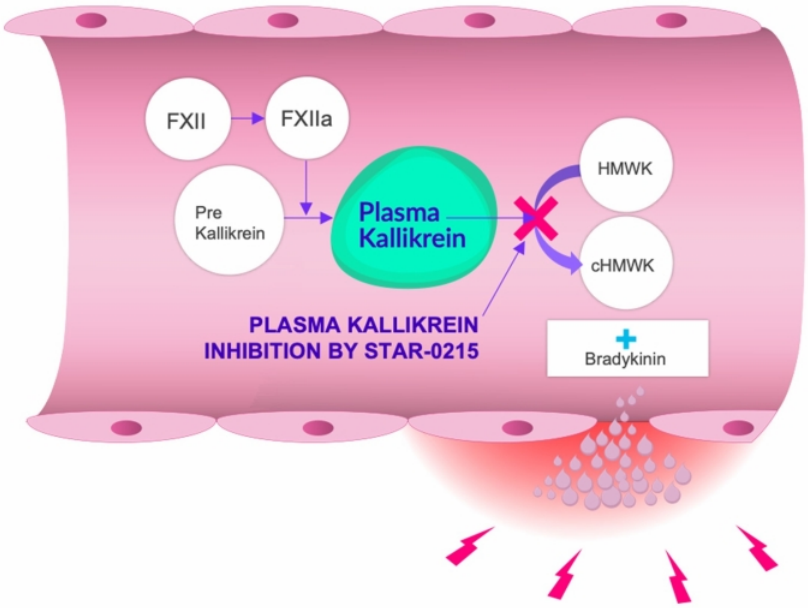
Affects **<8,000 in the U.S. and <15,000 in Europe,**[2, 3, 4] average age of onset is 11 years old[5]

Standard of care has evolved to both **on-demand** and **preventative treatments** with room for improvement



1. Zuraw BL. N Engl J Med. 2008;359:1027-36.
2. Busse, P.J. et al. N Engl J Med. 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. Bork K, et al. Am J Med. 2006;119;267-274.
6. Images obtained by haeimages.com

Plasma Kallikrein is an Established Target in H



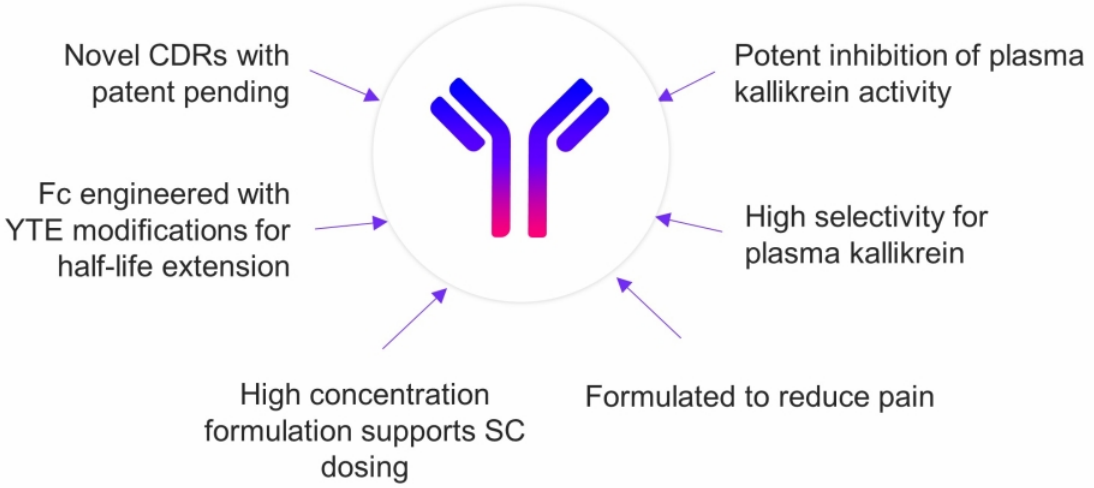
- In HAE, missing C1 inhibitor allows pla kallikrein to process HMWK, which ge cleaved HMWK (cHMWK) and release bradykinin
- Bradykinin binds to receptors allowing leak through blood vessel walls and ca edema/pain

STAR-0215 inhibits plasma kallikrei the absence of C1 inhibitor, reducir bradykinin production and preventi and pain

HMWK = high molecular weight kininogen
cHMWK = cleaved high molecular weight kininogen
FXII = Factor XII
FXIIa = activated Factor XII

STAR-0215: Designed to Normalize Life with H

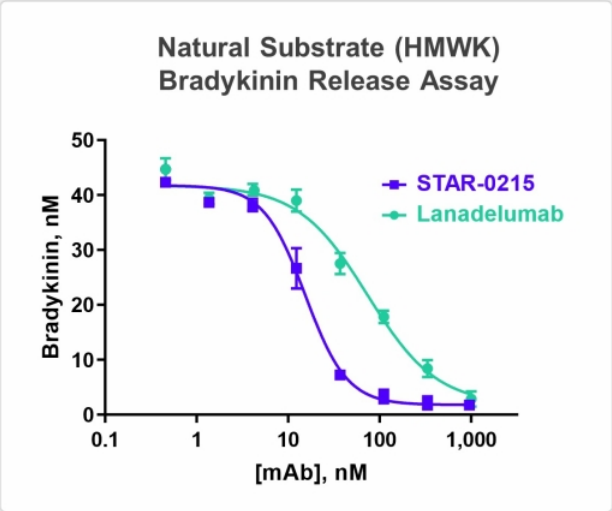
Key Features of STAR-0215

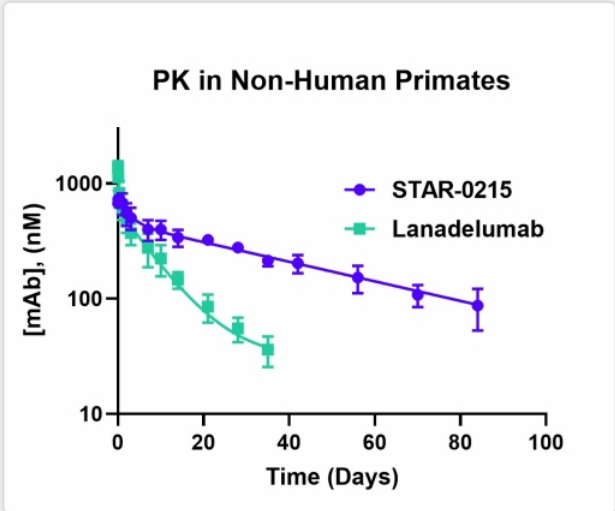


Astria wholly owns an international patent application directed to STAR-0215 with potential patent term into 2042, excludi potential patent term extension.[1]

1. If this application is nationalized in PCT member states ex-U.S., the term of any resulting patents would also be to 2042, exclusive of any available term extensions.

STAR-0215 Shows Long Half-Life and High Poter Preclinical Studies





- STAR-0215 kallikrein a potently as
- STAR-0215 three times lanadeluma primates

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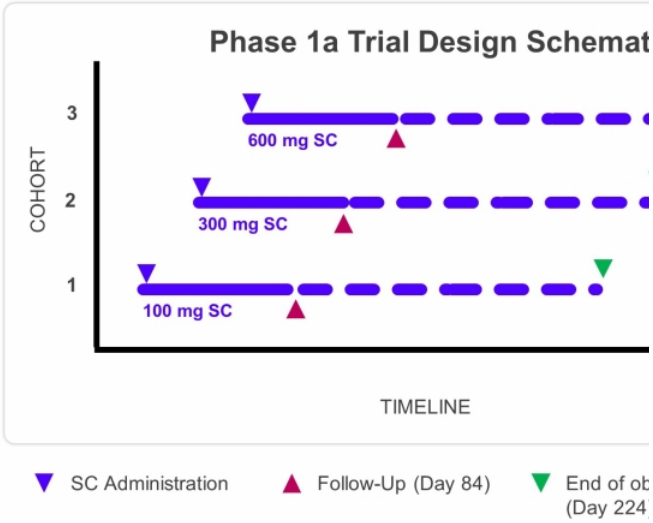
STAR-0215 Phase 1a Trial

- **Randomized, double-blind[1], placebo-controlled**
  - Healthy adult subjects
  - 3 single ascending doses, delivered SC
  - 6 active to 2 placebo randomization
- **Preliminary data include safety (84 days for 3 cohorts), PK and PD (84 days for cohorts 1 and 2; 56 days for cohort 3)**



Preliminary, blinded data, cut-off Dec 5, 2022

1. As of this data cut-off, treatment assignments remain blinded. Presented PK, PD, and safety data are delinked from individual subject identifier.
SC = subcutaneous; PK = pharmacokinetic; PD = pharmacodynamic

Phase 1a Designed to Demonstrate Early Proof of Concept

- Safety and tolerability profile: STAR-0215 has shown a favorab safety profile and has been well-tolerated in healthy subjects
- Pharmacokinetics: Concentrations of STAR-0215 are sustaine at levels consistent with clinical benefit in HAE
- Target engagement: STAR-0215 reduced cHMWK

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Preliminary Results

Phase 1a Baseline Demographics

	100 mg (N = 9)[1]	300 mg (N = 8)	600 mg (N = 8)	Ove
Age, Mean (SD)	39.7 (10.9)	39.5 (7.3)	35.4 (12.5)	38
Female	3 (33.3)	4 (50)	4 (50)	
Black or African American	3 (33.3)	6 (75)	8 (100)	
Weight (kg), mean (SD)	92.33 (11.247)	85.50 (14.296)	78.70 (14.315)	85.7

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1. Cohort 1 includes one subject who did not receive a full dose and is included in this analysis. PK and PD data from this subject will be excluded from the final analysis of this cohort. Results will be finalized after the end of the observation period.

Results Suggest that STAR-0215 is Well-Tolerated and Favorable Safety Profile

3-Month Timepoint Blinded Adverse Event Results

STAR-0215[1]:

- 8 (32%) subjects (STAR-0215 or placebo) had related TEAEs
- No SAEs and all related TEAEs were mild (Grade 1) and resolved. No Grade 2, 3, or 4 TEAEs.
- 6 subjects had ISRs (all mild), most commonly site redness; no reports of pain

Lanadelumab[2]:

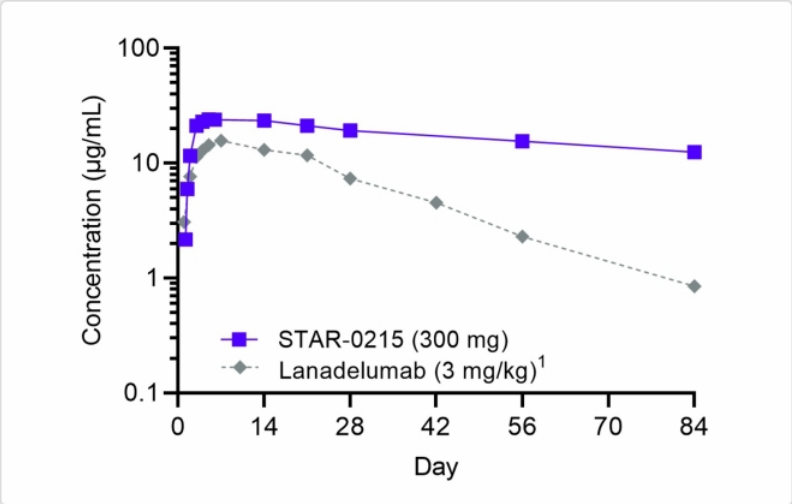
The most common adverse reactions associated with lanadelumab are:

- Injection site reactions, most co pain (52%)
- Upper respiratory tract infection
- Headache (21%)

TEAE= Treatment-emergent adverse event; ISR = injection site reaction; SAE = serious adverse events

1. Other related TEAEs were headache (1 subject) and unexplained weight gain (1 subject), both in Cohort 1 (100 mg). There were no clinically relevant changes in vital signs, ECG paramete
15 Grade 1 (mild) ISRs occurred in 6 subjects, including erythema (site redness), pruritus, swelling and inflammation.
No clinically relevant changes in liver enzymes or coagulation parameters. No deaths, or adverse events leading to study discontinuation.
Results will be finalized after the end of the observation period
2. TAKHZYRO US Prescribing Information, Feb 2022.
The comparison presented between STAR-0215 and lanadelumab represents a cross-trial comparison and does not involve data from a head-to-head clinical trial

Results Show STAR-0215 has a Potential Best-In-C PK Profile



STAR-0215:

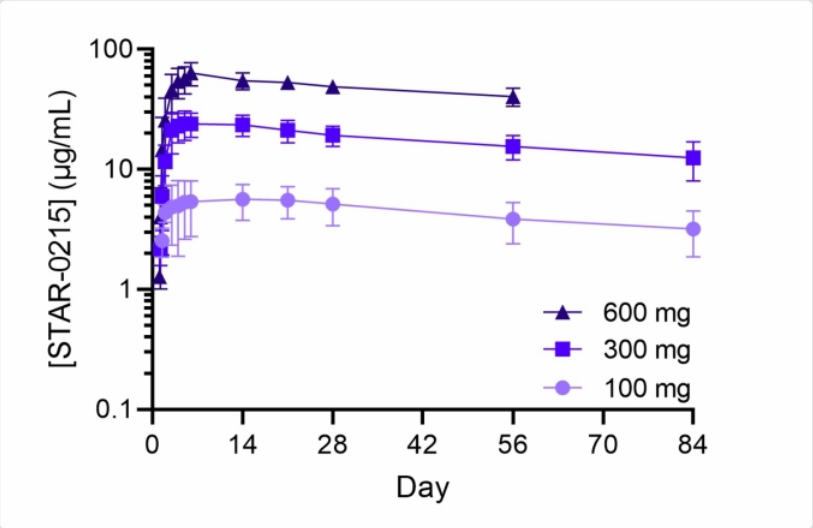
- Estimated half-life is up to 110 longer than lanadelumab
- Rapid achievement of maximu concentration
- Sustained concentrations at le with clinical benefit

Results will be finalized after the end of the observation period

1. Chyung et al 2014. Weight (SD) in this dose cohort = 83.08 (9.459) kg. Mean dose is 249.2 mg SC.

The comparison presented between STAR-0215 and lanadelumab represents a cross-trial comparison and does not involve data from a head-to-head clinical trial.

Results Show Rapid and Sustained STAR-021 Concentrations After Single Subcutaneous Dos



STAR-0215:

- Concentrations are prop dose
- Long elimination phase with YTE-modification
- Estimated half-life of up

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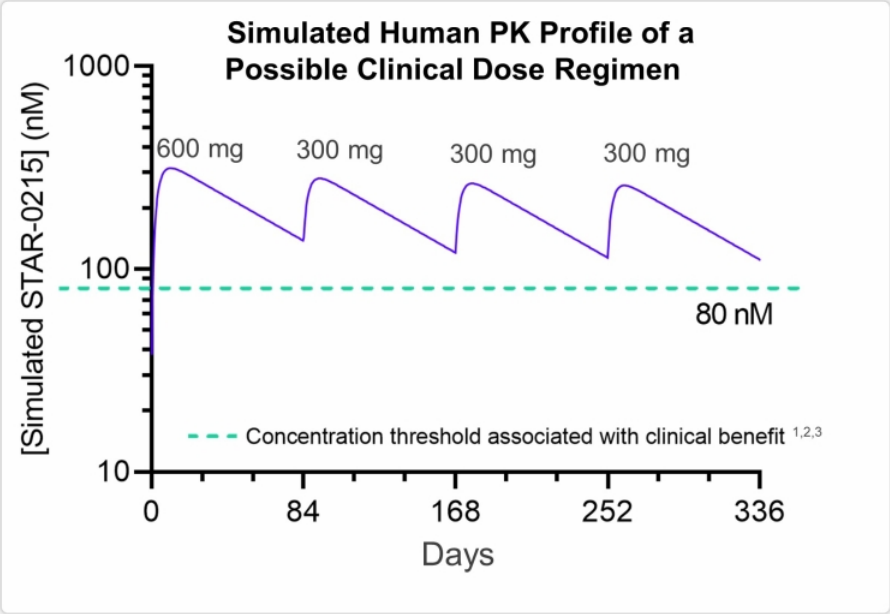
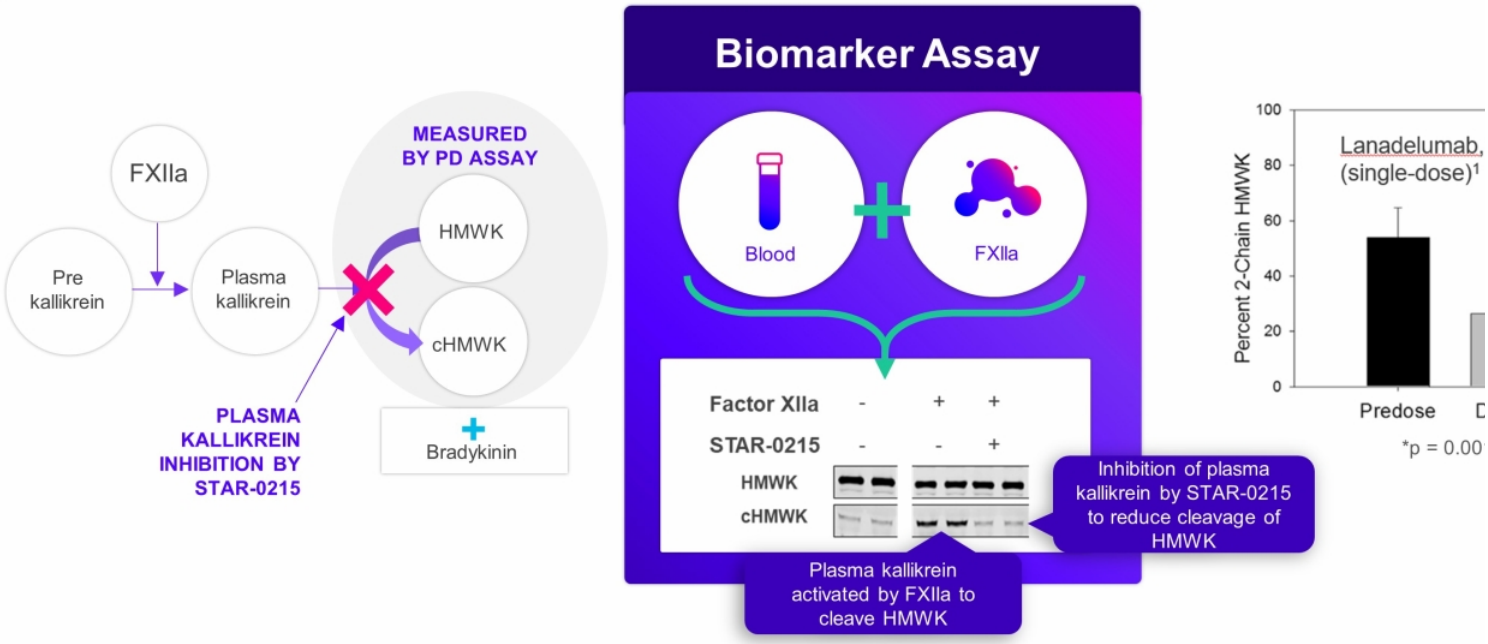
Mean (SD) concentrations over time
Results will be finalized after the end of the observation period

Modeling Supports Potential for Clinical Benefit Infrequent Dosing



1. Kaufman 1991 June 15. Blood 77(12): 2660-2667
2. Wang et al. Clin Transl Sci. 2020 Nov, 13(6): 1208-1216. doi 10-1111/cts. 12806 Epub 2020 May 26.
3. Ecallantide EMA Assessment Report. 2011 June 23. EMA/CHMP/476618/2011

Target Engagement is Assessed by Change in F Activated cHMWK

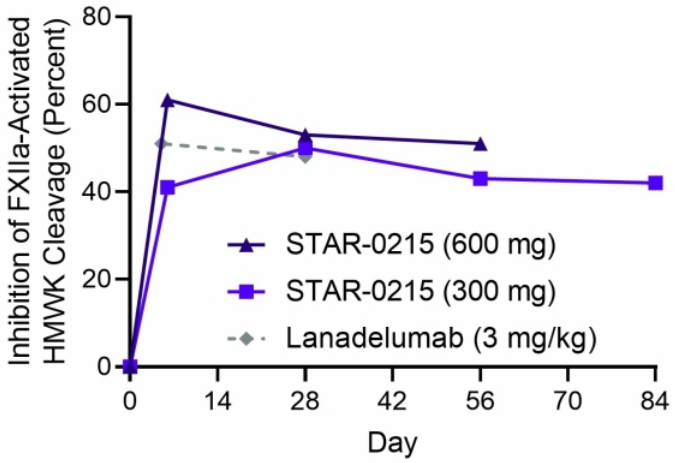


HMWK = high molecular weight kininogen
cHMWK = cleaved high molecular weight kininogen

FXIIa = activated Factor XII

1. Chyung et al, 2014
HV = healthy volunteer

Results Show STAR-0215 Achieves Sustained Inh of Plasma Kallikrein



- Levels of inhibition a 60% decreases in F cHMWK) are consis levels shown to pre patients[1]
- Single dose of 300 significant durable i plasma kallikrein ob through 3 months

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No significant changes at any timepoints with placebo or 100 mg STAR-0215
Results will be finalized after the end of the observation period
1. Wang et al. Clin Transl Sci. 2020 Nov, 13(6): 1208-1216. doi 10-1111/cts. 12806 Epub 2020 May 26.
The comparison presented between STAR-0215 and lanadelumab represents a cross-trial comparison and does not involve data from a head-to-head clinical trial

Results Show Early Proof of Concept of STAR-0 Achieved

- Safety and tolerability profile: STAR-0215 has shown a favora safety profile and has been well-tolerated in healthy subjects
- Pharmacokinetics: Estimated half-life is up to 110 days, keeping concentrations of STAR-0215 sustained at levels consistent with clinical benefit in HAE for at least 3 months aft single dose
- Target engagement: STAR-0215 reduced FXIIA-activated cHMWK through at least 3 months to levels associated with clinical benefit in HAE

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Future Plans

alpha-star Trial

Expect to Initiate Q1 2023, Initial Results Anticipated Mid-2024

DESIGN

- Phase 1b/2
- HAE patients, multiple sites, global
- Single and multiple dose SC cohorts
- Each qualifying participant will receive at least one dose of STAR-0215
- Each participant may roll into a long-term open label trial

PROOF OF CONCEPT (POC)

- **Aim to:**
  - Demonstrate durable activity compatible with robust clinica benefit in people living with H
  - Inform the dose selection for pivotal Phase 3 trial

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ALPHA-STAR: A Phase 1b/2 Single and Multiple Dose Study to Assess the Safety, Tolerability, Clinical Activity, Pharmacokinetics, Pharmacodynamics, and Immunogenicity of STAR-0215 in Participants with Hereditary Angioedema.

Proposed ALPHA-STAR Trial Design

Open-Label Single and Multiple Dose Phase 1b/2 POC Clinical Trial in HAE

PROOF OF CONCEPT ENDPOINTS:

PRIMARY:	Safety and Tolerability
SECONDARY:	Change from baseline in HAE attacks, PK, and PD
EXPLORATORY:	Angioedema Quality of Life Patient Reported Outcome Assessment

Doses may change based on emerging data

Planned Phase 2 Long-Term Op
(LTOL)

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1. This cohort is expected to commence after a safety assessment of Cohort 1

ALPHA-STAR Optimizing Trial Conduct

Multifactor Approach for Operational Success

- Trial designed with feedback from patients and trialists
- Trial awareness and recruitment via partnerships with advocacy and clinical groups across patient, partner and caregiver communities
- LTOL trial may provide continued access to STAR-0215

- No placebo group
- Frequent remote contact and for support and engagement
- Personalized assistance for

- Global; multiple site on regions with effic processes
- Selection of countri for trial's eligibility c

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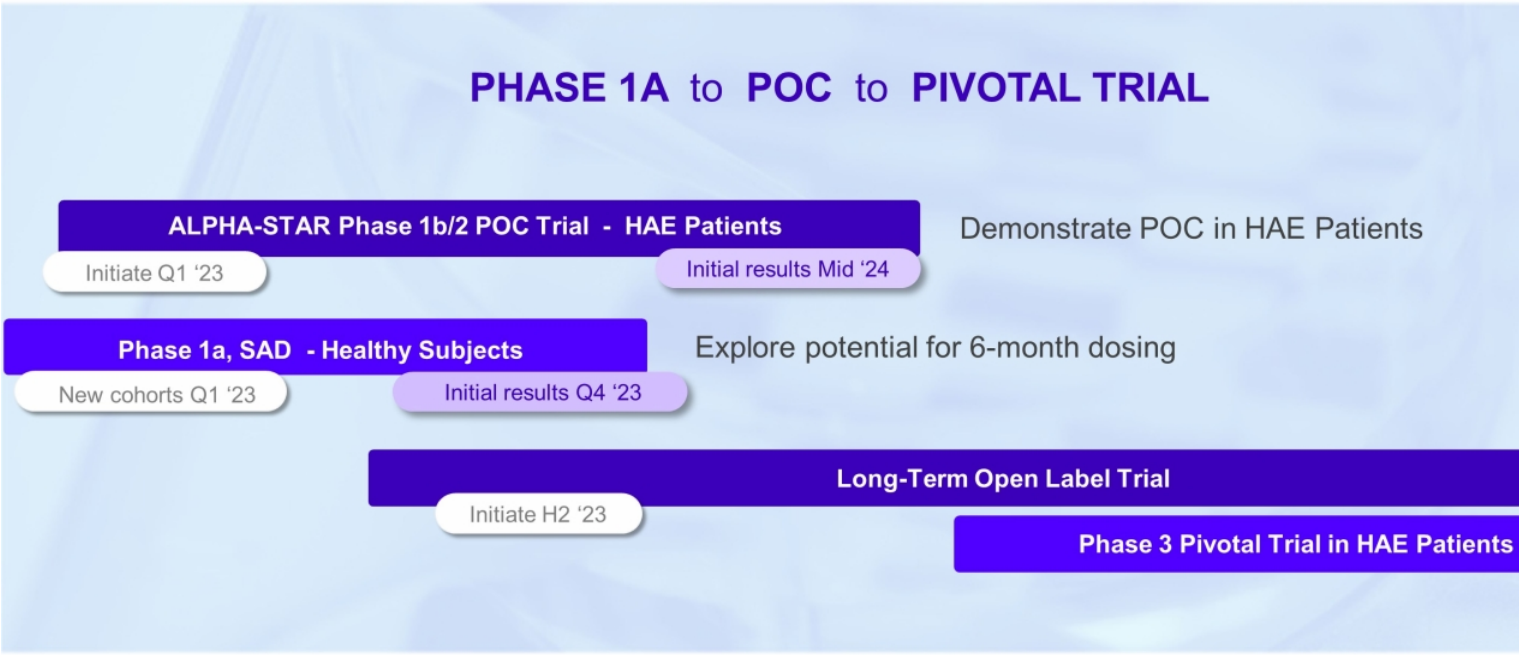
Overview of the Expected Clinical Development



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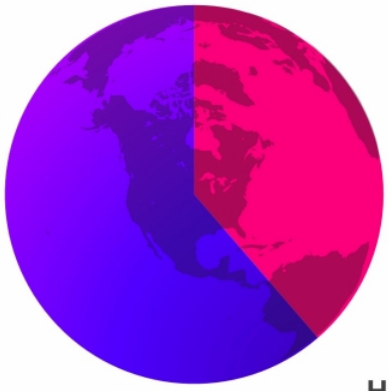
HAE Market Insights

Global HAE Treatment Market is Substantial and G

The HAE market is expected to nearly double by 2027[1,2], driven by:

- Patients being diagnosed earlier[3]
- More patients taking preventative treatments[4]
- Geographic expansion for currently available therapies[5]

2021 HAE Market[1]



$2.3B

2027 Estimated HAE

$4.5B

HAE Treatment

- Preventative
- On-Demand

1. Company-reported sales (Takeda, CSL Behring, Pharming, BioCryst)
2. Analyst consensus forecasts compiled by Clarivate's Cortellis, Astria company research and analysis.
3. Zanichelli A. Clin Transl Allergy. 2018: doi: 10.1186/s13601-018-0229-4
4. Astria company research and analysis
5. Company-reported expectations (Takeda, CSL Behring, BioCryst)

Approved and Late-Stage Preventative HAE Treatm

Approved Therapies

Product	Mechanism of Action	Administration	Mean Attack Reduction*	% o
CINRYZE	Plasma derived C1-INH	2x/week	52%	
HAEGARDA	Plasma derived C1-INH	2x/week	88%	
TAKHZYRO *(lanadelumab)*	Plasma kallikrein inhibitor	1-2x/month	73-87%	
ORLADEYO *(berotralstat)*	Plasma kallikrein inhibitor	1x/day	30-44%	

Late-Stage Development Programs

Program	Mechanism of Action	Administration	Development Phase
garadacimab	Factor XIIa inhibitor	1x/month	3
donidalorsen	Prekallikrein inhibitor	1x/1-2 months	3

There remains a need for an effective, infrequent treatment that can help normalize the lives of people

*Efficacy quoted as reduction in mean attack rate vs placebo; data from respective products' Prescribing Information[1,2,3,7].

1. CINRYZE Prescribing Information, 2021.
2. HAEGARDA Prescribing Information, 2020.
3. TAKHZYRO Prescribing Information, 2018.
4. Center for Drug Evaluation and Research. NDA/BLA Multidisciplinary Review and Evaluation NDA 214094. Washington DC: CDER (US); 2020.
5. CSL Behring, 2022 Aug 17, Press release. https://www.cslbehring.com/newsroom/2022/positive-top-line-p 3-results-for-garadacimab
6. IONIS 2021 Nov 18, Press Release. https://ir.ionispharma.com/news-releases/news-release-details/ionis- initiates-phase-3-clinical-program-donidalorsen-patients
7. ORLADEYO Prescribing Information 2020.

Interviewed HAE Treatment Providers Were Highly Mo
to Prescribe a Product With STAR-0215's Target Pro

Prescribers Viewed STAR-0215's Target Profile as the Potential Next Generation of HAE T

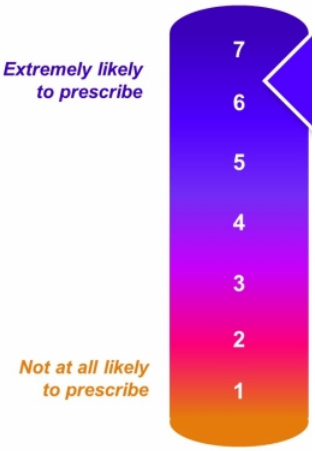
Blinded Product Profile

- A monoclonal antibody inhibitor of plasma kallikrein that helps prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling
- Efficacy on par with current subcutaneous therapies
- Dosing once every 3 months or longer

> *"[if this were available], this would be my first choice. I've looked through all the products [in development], this is the first one which is really exciting. This is a generation leap; anybody who is on medication now either daily, every three days, or every two or four weeks, why wouldn't they want to do this?"*
>
> *— HAE Prescriber 16*

Average **Prescriber** Rating for STAR-0215's Target Product Profile

n = 20 prescribers



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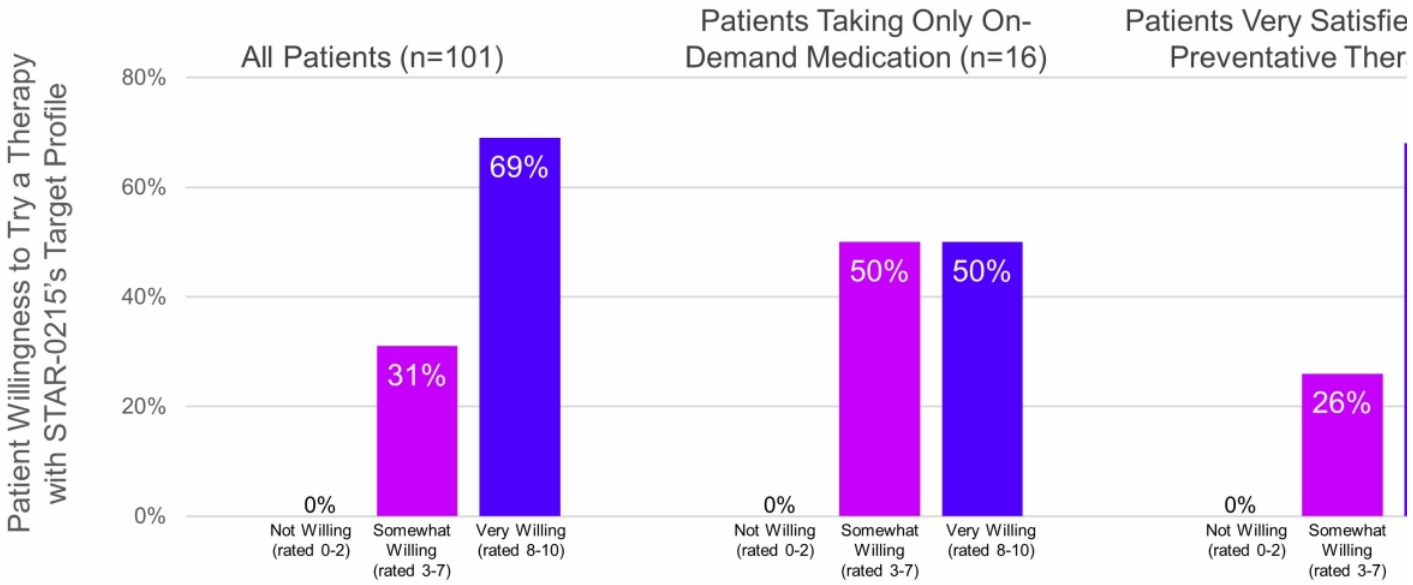
Astria proprietary blinded qualitative market research study (2021) with 20 HAE treatment providers (screened for those treating at least 5 Type 1 & 2 HAE patients per year)

All Surveyed HAE Patients Were Willing to Try a Product STAR-0215's Target Profile



Willingness rated on a scale where "0" indicates "Not at all willing," and "10" indicates "Extremely willing."
Satisfaction with current treatment rated on a scale where "0" indicates "Not at all satisfied," and "10" indicates "Extremely satisfied." Ratings of 8-10 grouped a

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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. Patients were shown a blinded profile of STAR-0215 with attributes shown on previous slide.

Early Proof of Concept for STAR-0215 for HAE
Expected Upcoming Milestones

STAR-0215 has shown early proof of concept for its target profile: long-acting preventative for HAE, best-in-class PK profile, and dosing once every 3 months or less frequently

- Full results from 3-month data set to be presented at a scientific conference in Q1 2023

Progress to HAE patients

- Initiate Phase 1b/2 ALPHA-STAR trial Q1 2023
- Initial proof of concept results in HAE patients in mid-2024

STAR-0215 could potentially be dosed less frequently

Evaluate potential for 6-month dosing

- Initiate additional cohorts in Phase 1a healthy subject trial Q1 2023
- Initial results in Q4 2023

Astria's HAE patient market research indicates high interest in a preventative therapy like STAR-0215

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