



Astria Therapeutics Announces Positive Initial Proof-of-Concept Results from the ALPHA-STAR Phase 1b/2 Trial of STAR-0215 for HAE

March 25, 2024

-- STAR-0215 Dosed Once or Twice Over 6 Months Reduced Monthly Attack Rates by 90-96%, Supporting Chronic Dosing 2 or 4 Times Per Year --

-- 92-100% Decrease in Moderate or Severe Attacks and 91-95% Reduction in Attacks Requiring Rescue Medications with STAR-0215 --

-- Very Well-Tolerated with No Serious Adverse Events and No Discontinuations --

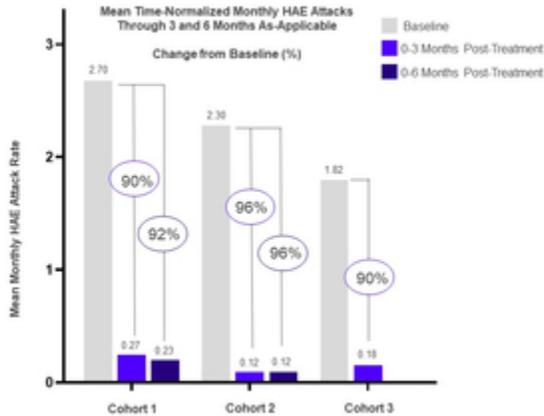
-- Phase 3 Initiation on Track for Q1 2025, with Top-Line Results Expected by Year End 2026 --

-- Current Cash Expected to Fund Company into Mid-2027 --

-- Conference Call Today at 8:30am ET --

BOSTON, Mass.--(BUSINESS WIRE)--Mar. 25, 2024-- [Astria Therapeutics, Inc.](https://www.businesswire.com/news/home/20240325940590/en/) (NASDAQ:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunological diseases, today announced positive initial proof-of-concept results from the ALPHA-STAR Phase 1b/2 clinical trial evaluating STAR-0215, a monoclonal antibody inhibitor of plasma kallikrein, in hereditary angioedema (HAE) patients. Initial results demonstrate a favorable safety and tolerability profile, mean monthly attack rate reduction of 90-96% for up to 6 months of follow up, and support both three- (Q3M) and six-month (Q6M) dosing regimens. Based on the positive results, Astria plans to advance STAR-0215 to Phase 3 development with trial initiation expected in Q1 2025 and top-line results expected by year-end 2026.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20240325940590/en/>



"We are thrilled with these initial results from ALPHA-STAR and believe that STAR-0215 can be a transformative therapy for patients that greatly reduces their disease and treatment burdens," said Christopher Morabito, M.D., Chief Medical Officer at Astria Therapeutics. "These results give us conviction that we will be able to deliver STAR-0215 once every three and six months, and we look forward to progressing this program into Phase 3 as quickly as possible."

"The initial results of the ALPHA-STAR trial represent a very exciting step forward in the HAE treatment landscape," said Marcus Maurer, M.D., Executive Director of the Institute of Allergology at Charite – Universitätsmedizin Berlin. "STAR-0215 has the potential to help patients manage their disease with a mechanism and modality that they trust, but with a substantially improved dosing regimen and the ability to administer without pain. Based

(Photo: Business Wire)

on this profile, STAR-0215 has the potential to normalize the lives of people living with HAE."

"Thanks to the enthusiasm for STAR-0215, the ALPHA-STAR trial enrolled ahead of schedule, enabling us to report these data earlier than originally scheduled," said Jill C. Milne, Ph.D., Chief Executive Officer. "We believe STAR-0215 has the potential to be the first-choice HAE treatment and I am thankful for the HAE community and the Astria team for helping us to achieve today's important milestone."

ALPHA-STAR is a dose-ranging proof-of-concept trial in adults with HAE Type 1 or 2 designed to assess safety, tolerability, efficacy, pharmacokinetics (PK), pharmacodynamics (PD), and quality of life in patients receiving single and multiple doses of STAR-0215 delivered subcutaneously to prevent attacks in HAE. Target enrollment of 16 patients has been achieved and all doses have been administered. All cohorts began with an eight-week run-in period to measure baseline HAE attacks and safety, efficacy, PK, and PD are assessed through 6-months (Day 168) after the last dose received. The initial efficacy and safety data-cut was as of March 13, 2024.

Cohort 1 evaluated a 450 mg dose and all four patients have completed 6 months of follow-up. Efficacy observations compared to baseline through 6 months of follow-up were as follows:

- 92% reduction in monthly attack rate
- 96% reduction in moderate and severe attacks

- 91% reduction in acute rescue medication use
- 50% of patients were attack-free through 3 months of follow-up

Cohort 2 evaluated a 600 mg dose followed by a 300 mg dose three months later, on Day 84. The Company plans to evaluate this dosing regimen in Phase 3. All six patients have completed 3 months of follow up and three patients have completed 6 months of follow-up. Efficacy observations compared to baseline through 6 months of follow-up were as follows:

- 96% reduction in monthly attack rate
- 98% reduction in moderate and severe attacks
- 94% reduction in acute rescue medication use
- 67% of patients were attack-free
- 100% of patients were attack-free in the first month after dosing, demonstrating rapid onset of action

Cohort 3 received a 600 mg dose followed by a 600 mg dose one month later, on Day 28. Four of six patients have completed 3 months of follow-up. Efficacy observations compared to baseline through 3 months of follow-up were as follows:

- 90% reduction in monthly attack rate
- 100% reduction in moderate and severe attacks
- 95% reduction in acute rescue medication use
- 50% of patients were attack-free

Preliminary PK and PD data are consistent with Phase 1a data in healthy subjects and consistent with observed efficacy.

STAR-0215 was generally well-tolerated with no serious treatment-emergent adverse events (TEAEs) and no discontinuations. There were two treatment-related TEAEs (both mild), one of which was a case of dizziness and the other a transient injection site reaction (rash). There were no injection site reactions of pain.

After completion of the ALPHA-STAR trial, patients have the opportunity to continue to receive STAR-0215 every three or six months in the long-term open label ALPHA-SOLAR trial. Initial safety and efficacy data from Q3M and Q6M dosing in the ALPHA-SOLAR trial are expected mid-2025.

The observed efficacy, PK, PD, and safety and tolerability profile of STAR-0215 support advancement of STAR-0215 into Phase 3 development. To progress STAR-0215 to market as quickly as possible, the Company plans to focus the Phase 3 program on Q3M dosing initially, immediately followed by a second trial to support label expansion to Q6M. Pending regulatory feedback, the Company expects to start a pivotal Q3M Phase 3 trial in Q1 2025, with top-line results expected by year-end 2026.

The Company expects that its current cash, cash equivalents, and short-term investments of \$246.5 million as of December 31, 2023, plus \$137.1 million from financing activity in the first quarter of 2024, will be sufficient to fund the Company into mid-2027 including all STAR-0215 program activities through the completion of a planned Q3M Phase 3 pivotal trial as well as advancing the Company's STAR-0310 OX40 program through IND submission and early proof-of-concept results from a Phase 1a trial.

Webcast Information

The Company will host a webcast today at 8:30am ET. Interested parties may join the webcast via the Investors section of the Astria website, www.astriatx.com or with following the link <https://lifescievents.com/event/astriatx/>. 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 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. 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 X and Instagram @AstriaTx and on Facebook and LinkedIn.

About STAR-0215:

STAR-0215 is a monoclonal antibody inhibitor of plasma kallikrein in development for the treatment of HAE. Our goal with STAR-0215 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 living with HAE to live life without limitations from their disease. Pending regulatory feedback, we expect to initiate a pivotal Q3M Phase 3 trial in Q1 of 2025 with top-line results expected by year-end 2026.

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: our expectations regarding the potential significance of the initial results from the Phase 1b/2 ALPHA-STAR clinical trial of STAR-0215, and that the results from such trial will allow us to move directly into a Phase 3 trial of STAR-0215 as a potential treatment for hereditary angioedema (HAE); the expected timing of initiation and design of the planned Phase 3 trials of STAR-0215; the potential therapeutic benefits of STAR-0215 as a treatment for HAE; the potential market impact of STAR-0215 as a treatment for HAE and our vision and goals for the STAR-0215 program; expectations regarding the timing of initiation and planned design of clinical trials for STAR-0310 in AD; expectations regarding the timing and nature of anticipated data from planned trials of STAR-0310; our anticipated cash runway; and our corporate strategy and vision, including the goal to meet the unmet needs of patients with rare and niche allergic and immunological diseases. The use of words such as, but not limited to, "anticipate," "believe," "continue," "could," "estimate," "expect," "goals," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would," or "vision," and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Astria's current beliefs, expectations and assumptions regarding the

future of its business, future plans and strategies, future financial performance, results of pre-clinical and clinical results of the Astria's product candidates and other future conditions. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks and uncertainties related to: changes in applicable laws or regulations; the possibility that we may be adversely affected by other economic, business, and/or competitive factors; risks inherent in pharmaceutical research and development, such as: adverse results in our drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies may not be replicated in clinical trials, that the preliminary, initial or interim results from clinical trials may not be indicative of the final results, that the results of early stage clinical trials, such as the initial results from the ALPHA-STAR Phase 1b/2 clinical trial, may not be replicated in later stage clinical trials, the risk that we may not be able to enroll sufficient patients in our clinical trials on a timely basis, and the risk that any of our clinical trials may not commence, continue or be completed on time, or at all; decisions made by, and feedback received from, the U.S. Food and Drug Administration and other regulatory authorities on our regulatory and clinical trial submissions and other feedback from potential clinical trial sites, including investigational review boards at such sites, and other review bodies with respect to STAR-0215, STAR-0310, and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and drug product for STAR-0215, STAR-0310, and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulations for STAR-0215, STAR-0310, and any other future product candidates that are patient-friendly and competitive; our ability to develop biomarker and other assays, along with the testing protocols therefor; our ability to obtain, maintain and enforce intellectual property rights for STAR-0215, STAR-0310 and any other future product candidates; our potential dependence on collaboration partners; competition with respect to STAR-0215, STAR-0310, or any of our other future product candidates; the risk that survey results, modeling data and market research may not be accurate predictors of the commercial landscape for HAE, the ability of STAR-0215 to compete in HAE and the anticipated position and attributes of STAR-0215 in HAE based on clinical data to date, its preclinical profile, pharmacokinetic modeling, market research and other data; risks that any of our clinical trials of STAR-0310 may not commence, continue or be completed on time, or at all; risks that results of preclinical studies of STAR-0310 will not be replicated in clinical trials; our ability to manage our cash usage and the possibility of unexpected cash expenditures; our ability to obtain necessary financing to conduct our planned activities and to manage unplanned cash requirements; the risks and uncertainties related to our ability to recognize the benefits of any additional acquisitions, licenses or similar transactions; and general economic and market conditions; as well as the risks and uncertainties discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the period ended December 31, 2023 and in other filings that we may make with the Securities and Exchange Commission. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Astria may not actually achieve the forecasts or expectations disclosed in our forward-looking statements, and investors and potential investors should not place undue reliance on Astria's forward-looking statements.

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.

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