Astria Therapeutics Announces Positive Final Results from Target Enrollment in the ALPHA-STAR Phase 1b/2 Trial of Navenibart for HAE

December 11, 2024

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

-- 90-95% Mean Monthly Attack Rate Reduction Supporting Chronic Dosing 2 or 4 Times Per Year --

-- 67% Attack-Free Rate Over 6 Months in Cohorts 2 and 3 --

-- Favorable Safety and Well-Tolerated Profile --

-- Phase 3 Initiation on Track for Q1 2025 --

BOSTON--(BUSINESS WIRE)--Dec. 11, 2024-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunologic diseases, today announced positive final results from the target enrollment group of 16 patients in the ALPHA-STAR Phase 1b/2 clinical trial evaluating navenibart (STAR-0215), a monoclonal antibody inhibitor of plasma kallikrein, in hereditary angioedema (HAE) patients. These final results demonstrated reduction in the mean monthly attack rate of 90-95% at 6 months, favorable safety and tolerability profile, and support both every three- (Q3M) and every six-month (Q6M) dosing regimens. The results underscore the potential of navenibart's profile to be the market-leading therapy for HAE. Astria is advancing navenibart to Phase 3 development with trial initiation expected in Q1 2025.

"The results from the ALPHA-STAR Phase 1b/2 trial affirm our belief in navenibart's profile and its potential to be a life-changing, market-leading preventative treatment for HAE patients," said Christopher Morabito, M.D., Chief Medical Officer at Astria Therapeutics. "After one or two doses over six months, patients experienced rapid onset of robust and durable efficacy, favorable safety and tolerability, and PK and PD that are consistent with sustained plasma kallikrein inhibition and Q3M and Q6M administration. These results are highly consistent with the interim results we reported in March. We look forward to presenting these data at an upcoming scientific conference and expect to initiate Phase 3 development in Q1, pending completion of discussions with global regulators."

"These results from the ALPHA-STAR trial are exciting for the future of the HAE treatment landscape," said Dr. Aleena Banerji, Clinical Director MGH Allergy and Clinical Immunology Unit. "We understand from people living with HAE that the disease and treatment burden can weigh heavily on their physical and mental health. I am optimistic that a therapy with infrequent dosing, a well-tolerated profile, and a trusted mechanism and modality could alleviate the burden for patients."

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 navenibart in three cohorts delivered subcutaneously to prevent attacks in HAE. 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. Among the target enrollment (n=16), 88% had Type 1 HAE, the average age was 46 years, and 56% were female.

Cohort 1 evaluated a 450 mg dose (n=4). Results show that, on average, over 6 months:

- 91% reduction in monthly attack rate
- 96% reduction in moderate and severe attacks
- 94% reduction in acute rescue medication use
- 50% of patients were attack-free through 3 months of follow-up, and 25% were attack-free through 6 months of follow-up

Cohort 2 evaluated a 600 mg dose followed by a 300 mg dose three months later (n=6). Results show that, on average, over 6 months:

- 95% reduction in monthly attack rate
- 95% reduction in moderate and severe attacks
- 94% reduction in acute rescue medication use
- 67% of patients were attack-free

Cohort 3 evaluated a 600 mg dose followed by a 600 mg dose one month later (n=6). Results show that, on average, over 6 months:

- 92% reduction in monthly attack rate
- 96% reduction in moderate and severe attacks
- 91% reduction in acute rescue medication use
- 67% of patients were attack-free

PK and PD were consistent with previously reported results and demonstrated rapid and sustained target plasma kallikrein inhibition consistent with effective and safe Q3M and Q6M administration.

Navenibart was generally well-tolerated with no serious treatment-emergent adverse events (TEAEs) and no discontinuations. There were four non-severe and quickly resolved treatment-related TEAEs: one case of dizziness, a transient injection site reaction (rash), an injection site erythema, and an injection site pruritus. There were no injection site reactions of pain.

The results shared above are available in the Company's corporate presentation in the investor section of www.astriatx.com. The Company expects to present these data at an upcoming scientific conference.

All 16 patients have enrolled into ALPHA-SOLAR, a long-term open-label trial. Initial safety and efficacy data from Q3M and Q6M dosing in the ALPHA-SOLAR trial are expected mid-2025.

Pending regulatory feedback, the Company plans to initiate the Phase 3 program in Q1 2025 and expects topline results by year-end 2026.

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 living 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: our expectations regarding the potential significance of the results from the navenibart Phase 1b/2 ALPHA-STAR clinical trial; our expectations about the timing of release of initial data from the ALPHA-SOLAR trial; the expected timing of initiation and receipt of topline results from the planned navenibart Phase 3 program; the goals and objectives of the planned navenibart Phase 3 program; the potential therapeutic benefits of navenibart as a treatment for HAE; the potential attributes and profile of navenibart as a treatment for HAE, including its potential to be a life-changing, market leading preventative treatment for HAE, and our overall vision and goals for the navenibart program; and our corporate strategy and vision, including our mission is 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 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 results from the ALPHA-STAR Phase 1b/2 clinical trial, may not be replicated in later stage clinical trials, such as the planned Phase 3 development program, 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 navenibart, STAR-0310, and any other future development candidates; 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 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20241211638946/en/

Astria:

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

Source: Astria Therapeutics, Inc.