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

December 15, 2022

-- 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--(BUSINESS WIRE)--Dec. 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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