Astria Therapeutics Initiates ALPHA-STAR Phase 1b/2 Clinical Trial of STAR-0215 in People with HAE

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-- Initial Proof-of-Concept Results Anticipated in Mid-2024 --

BOSTON--(BUSINESS WIRE)--Feb. 8, 2023-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company developing STAR-0215 for the treatment of hereditary angioedema (HAE) and focused on life-changing therapies for rare and niche allergic and immunological diseases, today announced the initiation of the ALPHA-STAR Phase 1b/2 clinical trial of STAR-0215 in people living with HAE. Initial proof-of-concept results in HAE patients from single and multiple dose cohorts are expected in mid-2024.

“Our vision for STAR-0215 is to develop a long-acting, safe, and effective preventative therapy that normalizes the lives of people living with HAE,” said Chris Morabito, M.D., Chief Medical Officer at Astria Therapeutics. “After seeing promising Phase 1a clinical results at the end of last year, we are proud to be taking the next step forward by evaluating STAR-0215 in HAE patients in our proof-of-concept clinical trial. We believe that STAR-0215 has the potential to change the way that people live with their HAE.”

“We are thrilled that STAR-0215 is moving forward in development with a thoughtfully planned clinical trial that takes our patient community into consideration by allowing all qualifying participants to receive STAR-0215,” said Dr. Marcus Maurer, M.D., Professor of Dermatology and Allergy at Charité Universitätsmedizin in Berlin. “The HAE community is looking for treatments that have the potential to be less burdensome on their lives. ALPHA-STAR is designed to efficiently assess the potential of STAR-0215, and I am looking forward to the expected proof-of-concept results mid-next year.”

The ALPHA-STAR trial is a global open-label Phase 1b/2 proof-of-concept trial enrolling patients with HAE types I and II evaluating safety and tolerability, changes in HAE attack rate, pharmacokinetics, pharmacodynamics, and quality-of-life assessments. Following an initial run-in period, qualifying participants will be enrolled in either a single or multiple dose cohort. Data from up to 18 participants will evaluate efficacy and safety, and comparisons will be made against data collected during the run-in period. Initial results from the single and multiple-dose cohorts from the ALPHA-STAR trial are expected in mid-2024, and pending positive results, Astria expects to progress directly to a pivotal trial.

STAR-0215 is a monoclonal antibody inhibitor of plasma kallikrein in development for the treatment of HAE. Preliminary results from a Phase 1a trial in healthy subjects supports STAR-0215’s target profile: a long-acting preventative therapy, best-in-class PK profile, and dosing once every three months or less frequently. Based on results seen to-date, Astria is planning to evaluate the potential for six-month administration of STAR-0215 in additional cohorts in the Phase 1a trial, with preliminary results expected in the fourth quarter of 2023.

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. Learn more about our company on our website, www.astriatx.com, or follow us on Twitter and Instagram @AstriaTx and on Facebook and LinkedIn.

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 and nature of the anticipated proof of concept results from the ALPHA-STAR Phase 1b/2 clinical trial of STAR-0215; the longer term development plans for STAR-0215, including the plan, assuming positive results, to move directly from the ALPHA-STAR trial into a pivotal trial; 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; 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, such as the preliminary results from the Phase 1a trial, may not be replicated in later stage clinical studies, including the ALPHA-STAR 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 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 ("SEC"), including the Current Report on Form 8-K that we filed with the SEC on December 15, 2022. 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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Astria Contacts:

Investor relations:
Andrea Matthews
investors@astriatx.com

Media:
Elizabeth Higgins
media@astriatx.com

Source: Astria Therapeutics, Inc.