



Astria Therapeutics Announces Initiation of Phase 1a Trial of STAR-0215, a Monoclonal Antibody Inhibitor of Plasma Kallikrein for Treatment of Hereditary Angioedema

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-- Preliminary Results from the Phase 1a Trial Anticipated by Year-End --

BOSTON--(BUSINESS WIRE)--Aug. 4, 2022-- [Astria Therapeutics, Inc.](https://www.astriatx.com) (NASDAQ:ATXS), a biopharmaceutical company developing STAR-0215 for hereditary angioedema and focused on life-changing therapies for rare and niche allergic and immunological diseases, today announced initiation of a Phase 1a clinical trial of STAR-0215 in healthy subjects. STAR-0215 is a monoclonal antibody inhibitor of plasma kallikrein designed to provide long-acting, effective attack prevention for hereditary angioedema (HAE), with dosing once every three months or longer. Astria anticipates preliminary results from the Phase 1a trial by year-end. The Phase 1a trial is intended to establish clinical proof of concept for the differentiated profile anticipated for STAR-0215.

"The initiation of the Phase 1a trial of STAR-0215 in healthy subjects is an important milestone for us, as it marks our progression to a clinical-stage company and is a critical next step towards our goal of improving the disease burden for people living with HAE," said Chris Morabito, M.D., Chief Medical Officer at Astria Therapeutics. "We are proud of our progress so far, and the initiation of our first clinical trial in HAE is a representation of our commitment to bringing hope with life-changing therapies to patients affected by rare diseases."

The Phase 1a randomized, double-blind, placebo-controlled single ascending dose trial is evaluating the safety, pharmacokinetics, and pharmacodynamics of STAR-0215 at a single U.S. center. Approximately 24 subjects will receive a single dose of STAR-0215 or placebo in at least three cohorts of 100mg, 300mg, and 600mg administered subcutaneously. The trial will assess safety and tolerability and aims to establish prolonged half-life and demonstrate inhibition of plasma kallikrein activity, which, if favorable, would provide proof of mechanism for STAR-0215 as a potential best-in-class treatment for HAE.

Preclinically, STAR-0215 has been shown to be a long-acting, potent, and selective inhibitor of plasma kallikrein. In a study conducted in cynomolgus monkeys, STAR-0215 showed rapid inhibition of plasma kallikrein after subcutaneous administration, and inhibition of high molecular weight kininogen cleavage was rapid and sustained throughout the entire 84-day dose-free period in the extended portion of the study. These preclinical data support the potential for once every three-month dosing.

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 within the meaning of applicable securities laws and regulations including, but not limited to, statements regarding: the timing and nature of the preliminary from the Phase 1a clinical trial for STAR-0215; the potential attributes, characteristics and differentiated profile of STAR-0215 as a potential treatment for HAE; and the Company's broader 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," or "would" 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 the Company'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 Company'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 the Company 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, the Company's ability to enroll patients in our clinical trials, and the risk that any of the Company's clinical trials may not commence, continue or be completed on time, or at all; decisions made by, or feedback received from, the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and other review bodies with respect to STAR-0215 and any future product candidates; the Company's ability to manufacture and release sufficient quantities of drug substance and drug product on a cost-effective and timely basis; the Company's ability to obtain, maintain and enforce intellectual property rights for STAR-0215 and any other future product candidates; competition with respect to STAR-0215 in HAE or with respect to any other future product candidates; the anticipated position and attributes of STAR-0215 in HAE based on its pre-clinical profile, pharmacokinetic modeling and other data; the Company's ability to manage its cash usage and the possibility of unexpected cash expenditures; the Company's ability to obtain necessary financing to conduct its planned activities and to manage unplanned cash requirements; general economic and market conditions; as well as the risks and uncertainties set forth under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the SEC. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. The Company 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 the Company's forward-looking statements. Neither the Company, 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 the Company's views as of any date subsequent to the date hereof.

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