



Astria Therapeutics Receives Fast Track Designation for STAR-0215 for the Treatment of Hereditary Angioedema

July 20, 2023

-- On Track for Proof-of-Concept Results in HAE Patients in Mid-2024 --

-- Results To-Date Support STAR-0215 Administration Once Every Three or Six Months for Robust Suppression of HAE Attacks --

BOSTON--(BUSINESS WIRE)--Jul. 20, 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 that the STAR-0215 development program has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of Hereditary Angioedema (HAE), a rare genetic disorder that causes severe unpredictable attacks of swelling throughout the body. STAR-0215 is currently being evaluated in the ALPHA-STAR clinical trial in people with HAE, with initial proof-of-concept results expected in mid-2024.

"Receiving Fast Track designation for STAR-0215 is an important milestone that underscores the need for HAE therapies that can normalize the lives of people living with HAE with dosing every three or six months," said Jill C. Milne, Ph.D., Chief Executive Officer at Astria Therapeutics. "We look forward to more frequent communication with the FDA as we work to reduce both the disease and treatment burden for the HAE community."

The FDA Fast Track process is designed to expedite the development and review of therapies to treat serious or life-threatening conditions and that demonstrate the potential to address unmet needs. Companies that receive Fast Track designation for a product candidate are able to submit New Drug Applications (NDA) for such candidate on a rolling basis, potentially expediting the FDA review process, and benefit from more frequent communication with the FDA to discuss all aspects of clinical development. In addition, drugs that receive Fast Track designation may be eligible for a priority review if certain criteria are met.

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.

About STAR-0215:

STAR-0215 is a monoclonal antibody inhibitor of plasma kallikrein in development for the treatment of HAE. Our vision is for STAR-0215 to be the first-choice preventative treatment for people with HAE dosed once every three or six months and to make substantial progress towards normalizing their lives. The Phase 1b/2 ALPHA-STAR trial evaluating STAR-0215 in HAE patients is ongoing, with proof-of-concept results expected in mid-2024.

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: expectations regarding the timing and nature of the anticipated proof of concept results from the ALPHA-STAR Phase 1b/2 clinical trial; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, and our vision for STAR-0215 as a treatment for HAE; the need for effective treatments for HAE; the potential for three and six-month administration of STAR-0215; the potential benefits of STAR-0215's receipt of Fast Track designation; and our 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: 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 and initial unblinded 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 FDA 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; the risk that we do not realize some or all of the potential benefits of STAR-0215's Fast Track designation; 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 the clinical results to date, survey results 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 its clinical data to date, pre-clinical profile, mechanistic and other modeling,

market research, patient feedback 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, 2022 and in other filings that we make with the Securities and Exchange Commission ("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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