Astria Therapeutics Announces FDA Clearance of IND Application for STAR-0310, a Monoclonal Antibody OX40 Antagonist for the Treatment of Atopic Dermatitis

December 10, 2024

-- Phase 1a Trial of STAR-0310 in Healthy Volunteers Expected to Initiate in Q1 2025 --

-- Early Proof-of-Concept Results Expected in Q3 2025 --

BOSTON--(BUSINESS WIRE)--Dec. 10, 2024-- Astria Therapeutics, Inc. (Nasdaq:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunologic diseases, today announced the U.S. Food and Drug Administration (FDA) clearance of its Investigational New Drug (IND) application for STAR-0310, a monoclonal antibody OX40 antagonist, the company is developing as a potential treatment for atopic dermatitis (AD) and potentially other indications. A Phase 1a trial of STAR-0310 in healthy subjects is expected to initiate in the first quarter of 2025, with early proof-of-concept results expected in the third quarter of 2025. Further, the company anticipates proof-of-concept results in atopic dermatitis patients in the second quarter of 2026.

“We are pleased with the FDA’s acceptance of our IND application for STAR-0310 and the progress it represents for the program,” said Chris Morabito, M.D., Chief Medical Officer at Astria Therapeutics. “We are very excited about the potential for the OX40 mechanism. With the goal of creating the overall best OX40 program, we intentionally have designed STAR-0310 to capitalize on the learnings of OX40 receptor and OX40 ligand programs. STAR-0310's high affinity and high potency in conjunction with low ADCC has the potential to enable a wider therapeutic window, and additionally, STAR-0310 has the potential to be dosed as infrequently as every six months due to its long half-life and potential for disease modification.”

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.

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 about the potential for STAR-0310 to be the best overall OX40 program and the potential therapeutic benefits and potential attributes of STAR-0310 as a treatment for AD; expectations regarding the timing of initiation of a Phase 1a trial for STAR-0310 and the timing of receipt of early proof-of-concept results from such trial; expectations regarding the timing of early proof-of-concept results for STAR-0310 in AD; the potential for STAR-0310 in other indications; and the goal of bringing life changing therapies to patients and families affected by allergic and immunological diseases and to become a leading allergy and immunology company. 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 the following 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; 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, including of navenibart and STAR-0310, may not be replicated in clinical trials, that the preliminary 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 navenibart Phase 1a clinical trial and the initial results from the ALPHA-STAR trial, may not be replicated in later stage clinical trials, including additional and final results from the ALPHA-STAR trial or the planned navenibart 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 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 navenibart, STAR-0310, and any other future development candidates, and devices for such product candidates; our ability to manufacture sufficient quantities of drug substance and drug product for navenibart, STAR-0310, and any other future product candidates, and devices for such product candidates, on a cost-effective and timely basis, and to develop dosages and formulation 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 therefore; 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 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 with respect to the ability of STAR-0310 to compete in AD, the anticipated position and attributes of STAR-0310 in AD based on its preclinical profile, and the ability to develop STAR-0310 for additional indications; 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.

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

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