Astria Therapeutics Announces Design of ALPHA-ORBIT Pivotal Phase 3 Trial of Navenibart in HAE

January 13, 2025

-- Single Pivotal Trial Designed to Demonstrate Efficacy and Safety of Every 3- and Every 6-Month Administration in a 6-Month Treatment Period --

-- Pioneering Patient-Centric Dosing Flexibility in HAE with Potential Market-Leading First-Choice Profile --

-- Phase 3 Initiation On-Track, Expected in Q1 2025 --

-- Strong Financial Position, Funded Through Expected Top-Line Phase 3 Results --

BOSTON--(BUSINESS WIRE)--Jan. 13, 2025-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunologic diseases, today announced its planned design of the ALPHA-ORBIT Phase 3 clinical trial of navenibart in people with hereditary angioedema (HAE), which will include both every 3- (Q3M) and every 6-month (Q6M) treatment arms with the primary analysis at 6 months. Global start-up activities are underway, and ALPHA-ORBIT is expected to initiate in Q1 2025, with top-line results anticipated in early 2027.

“We are thrilled to announce our planned Phase 3 design, which reflects feedback from regulators and is intended to support global registration for both Q3M and Q6M administration,” said Jill C. Milne, Ph.D., Chief Executive Officer at Astria. “With navenibart, we are pioneering patient-centric dosing flexibility in HAE with the goal of maximizing attack rate reduction with a compellingly low burden of treatment. Assuming approval, we believe navenibart will become the market-leading, first-choice therapy for HAE.”

“Our Phase 3 program was designed in collaboration with the patient community and physicians, is based on input from global regulatory authorities, and addresses the importance of providing options to patients for a disease that’s highly variable,” said Christopher Morabito, M.D., Chief Medical Officer at Astria. “Phase 3 preparations are underway, with trial initiation on-track and expected for this quarter. We are driven by the goal of bringing a potentially life-changing therapy to patients with HAE.”

ALPHA-ORBIT is designed as a global, randomized, double-blind, placebo-controlled Phase 3 pivotal clinical trial to evaluate the efficacy and safety of navenibart over a 6-month treatment period in up to 145 patients with Type 1 or Type 2 HAE. Patients will be randomized to receive one of three navenibart dose arms: 1) an initial 600 mg dose and followed by 300 mg Q3M, 2) 600 mg Q6M, and 3) 600 mg Q3M, or placebo. The dose arms support the potential to provide patient-centric dosing flexibility to people with HAE. The primary endpoint is time-normalized monthly HAE attacks at 6 months, and a key secondary endpoint includes the proportion of participants who are attack-free at 6 months. After 6 months, patients may be eligible to enter a long-term extension trial, in which all patients will be treated with navenibart (open-label) and which will include an open-label, patient-centric flexible dosing period. The navenibart Phase 3 program will consist of the ALPHA-ORBIT Phase 3 trial and the long-term extension trial, which are designed to support registration globally. The Phase 3 program was designed with input from the European Medicines Agency and the Company’s end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) held in December 2024.

Planned doses for the Phase 3 ALPHA-ORBIT program were selected based on positive final top-line results from target enrollment in the Phase 1b/2 ALPHA-STAR trial of navenibart, announced in December 2024, which showed rapid onset of robust and durable efficacy, favorable safety and tolerability, and pharmacokinetics and pharmacodynamics consistent with sustained plasma kallikrein inhibition for both Q3M and Q6M administration. Final results included reduction in mean monthly attack rate of 90-95% and up to a 67% attack-free rate over 6 months. The Company will present these data at an upcoming scientific conference.

Additional details regarding the Company’s planned Phase 3 program and other business updates are contained in the Company’s Corporate Presentation, which is available on the “Events and Presentations” page of the “For Investors” section of the Company’s website.

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.

About Navenibart:

Navenibart is a monoclonal antibody inhibitor of plasma kallikrein in development for the treatment of HAE. Our goal with navenibart is to provide rapid and sustained HAE attack prevention with a validated mechanism and trusted modality administered every 3 and 6 months. We aim to empower people with HAE to live life without limitations from their disease.

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 expected design, timing of initiation and receipt of topline results from the ALPHA-ORBIT trial; the goals and objectives of the ALPHA-ORBIT trial and the long-term extension trial, including that they would support registration of Q3M and Q6M administration, and potentially accelerate the availability of Q6M administration; our expectations for the dosing regimens of navenibart and the efficacy data of navenibart in the ALPHA-ORBIT trial; the potential therapeutic benefits of navenibart as a treatment for HAE; the potential attributes and profile of navenibart as a

treatment for HAE, including our expectation that it will be the market-leading, first choice and a potentially life-changing treatment for patients with HAE; our overall vision and goals for the navenibart program; expectations about being funded through top-line Phase 3 results; and our corporate strategy and vision, including our mission to bring life-changing therapies to patients and families affected by allergic and immunologic 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,” “would,” or "vision," and similar words and 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 studies and clinical trials of 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 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; 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 may not be replicated in clinical trials, that the preliminary, initial 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 ALPHA-STAR Phase 1b/2 clinical trial, may not be replicated in later stage clinical trials, such as the ALPHA-ORBIT trial and the open-label extension 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, including ALPHA-ORBIT, may not commence, continue or be completed on our anticipated timelines, or at all; decisions made by, and feedback received from, the FDA and other regulatory authorities on our clinical trial design, including for ALPHA-ORBIT, and on our regulatory and clinical trial submissions, including receipt of FDA minutes from our December 2024 end of Phase 2 meeting, 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, decisions that we make about the design of clinical trials in response to regulatory feedback, including the design of the ALPHA-ORBIT trial and the long-term extension trial; our ability to manufacture sufficient quantities of drug substance and drug product for navenibart, STAR-0310, and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulations for navenibart, STAR-0310, and any other future product candidates that are patient-friendly and competitive; our ability to develop sufficient data to enable the use of planned devices with navenibart, STAR-0310 and any other future product candidates at commercial launch or otherwise as planned; our ability to develop biomarker and other assays, along with the testing protocols therefor; 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, modeling data 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 that any of our clinical trials of STAR-0310 may not commence, continue or be completed on time, or at all; risks that results of preclinical studies of STAR-0310 will not be replicated in clinical trials; 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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