Astria Therapeutics Receives FDA Orphan Drug Designation for Navenibart (STAR-0215) for the Treatment of Hereditary Angioedema

September 30, 2024

BOSTON--(BUSINESS WIRE)--Sep. 30, 2024-- Astria Therapeutics, Inc. (Nasdaq:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunologic diseases, today announced that navenibart (STAR-0215) has been granted Orphan Drug Designation for the treatment of hereditary angioedema (HAE) by the U.S. Food and Drug Administration (FDA). Navenibart is a monoclonal antibody inhibitor of plasma kallikrein designed to provide long-acting attack prevention for HAE. Initial results from the Phase 1b/2 ALPHA-STAR clinical trial of navenibart have demonstrated a favorable safety and tolerability profile and a reduction of monthly attack rates by 90-96% when dosed once or twice over six months.

“Receiving orphan drug designation for navenibart is an important affirmation of our belief that there is a significant unmet need for people living with HAE,” said Jill C. Milne, Ph.D., Chief Executive Officer. “We believe navenibart has the potential to be the market-leading HAE treatment because of its trusted mechanism and modality, efficacy observed to date, and low treatment burden with infrequent dosing, and think that navenibart could change the way that people live with their HAE. We expect to share additional results from the ALPHA-STAR trial in Q4 and to progress navenibart into a Phase 3 trial initiating in the first quarter of 2025.”

The FDA’s Orphan Drug Designation program grants orphan status to medicines intended for the safe and effective prevention, diagnosis, or treatment of rare diseases or disorders that affect fewer than 200,000 people in the United States. Orphan status provides sponsors with development and commercial incentives for designated compounds and medicines.

About Navenibart (STAR-0215):

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. The FDA has granted navenibart Orphan Drug and Fast Track Designations. For more information on navenibart, please visit www.astriatx.com.

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 X 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: our expectations about the potential significance of the initial results from the Phase 1b/2 ALPHA-STAR clinical trial of navenibart; the expected timing of the release of additional data from the ALPHA-STAR trial; the expected timing of initiation of the planned navenibart Phase 3 trial and the receipt of topline results from such trial, subject to regulatory feedback; the potential for navenibart in the HAE market, including the potential to be the market leading treatment, the potential therapeutic benefits of navenibart as a treatment for HAE, the administration timing of navenibart, and our overall vision and goals for the navenibart program; the potential unmet medical need for HAE; and the goal of bringing life changing therapies to patients and families affected by allergic and immunologic 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 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 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 and the anticipated position and attributes of STAR-0310 in AD based on its preclinical profile; 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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