Astria Therapeutics Announces FDA Clearance of IND Application for STAR-0215, a Monoclonal Antibody Inhibitor of Plasma Kallikrein for Treatment of Hereditary Angioedema

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BOSTON--(BUSINESS WIRE)--Jul. 28, 2022-- Astria Therapeutics, Inc. (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 the U.S. Food and Drug Administration (FDA) clearance of its Investigational New Drug (IND) application for STAR-0215, which the company is developing for the treatment of Hereditary Angioedema (HAE). A Phase 1a trial of STAR-0215 in healthy volunteers is expected to initiate in the coming weeks, with preliminary results anticipated by year-end.

“The acceptance of our IND by the FDA is an important next step in bringing STAR-0215 to the clinic for our planned first-in-human trial,” said Chris Morabito, M.D., Chief Medical Officer at Astria Therapeutics. “We are optimistic that STAR-0215’s differentiated profile, including dosing once every three months or longer, has the potential to change the way that people with HAE live with their disease.”

STAR-0215 is an investigational monoclonal antibody inhibitor of plasma kallikrein designed to provide long-acting, effective attack prevention for HAE with dosing once every 3 months or longer. The company’s goal is to provide the most patient-friendly preventative treatment option for people living with HAE. The Phase 1a trial is planned to be a randomized, double-blind, placebo-controlled trial evaluating STAR-0215 in healthy volunteers. The goals for the trial include assessing safety and tolerability, establishing the prolonged half-life of STAR-0215, and inhibition of plasma kallikrein activity, which, if favorable, would provide proof of mechanism in HAE.

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 preclinical 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 expected commencement, design and goals of a Phase 1a clinical trial for STAR-0215 and the expected timing and nature of the preliminary results from such trial; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE and the potential commercial opportunity for STAR-0215 in HAE; the need for effective treatments 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 sufficient quantities of drug substance and drug product on a cost-effective and timely basis, and that meets release and other relevant standards; 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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