Astria Therapeutics Presents New Preclinical Data Showing the Differentiated Profile of STAR-0215, in Development to Treat Hereditary Angioedema

November 5, 2021

-- STAR-0215 Demonstrates High Potency to Inhibit Plasma Kallikrein Preclinically --

-- Preclinical Data Show STAR-0215's Extended Plasma Half-Life, Predicting Long Duration of Action --

BOSTON--(BUSINESS WIRE)--Nov. 5, 2021-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company developing STAR-0215 for the treatment of hereditary angioedema (HAE), today presented new preclinical data that included demonstration of the high potency of STAR-0215 to bind to and inhibit plasma kallikrein on a site different than lanadelumab and introduction of YTE technology to extend half-life. The poster entitled "STAR-0215 is a Long-Acting Monoclonal Antibody Plasma Kallikrein Inhibitor for the Potential Treatment of HAE" was presented at the 2021 American College of Allergy, Asthma and Immunology Annual Scientific Meeting in New Orleans, Louisiana.

"These preclinical data support the potential of STAR-0215 to provide long-acting, effective prevention of HAE attacks, with dosing once every three months or longer," said Andy Nichols, Ph.D., Chief Scientific Officer at Astria Therapeutics. "These data show that STAR-0215 binds to plasma kallikrein with high affinity and inhibits its activity more potently than lanadelumab, a plasma kallikrein inhibitor on the market for the treatment of HAE. Combined with the long plasma half-life from the YTE modifications and high potency, we believe that STAR-0215 has a differentiated profile that has the potential to be the most patient-friendly preventative treatment option for HAE."

HAE is a rare genetic disorder characterized by severe, recurrent, unpredictable, painful, and sometimes life-threatening swelling in the face, limbs, abdomen, and airway. Plasma kallikrein binding affinity and plasma half-life are key drivers of efficacy for the prevention of HAE attacks. The data presented today show that STAR-0215 binds to plasma kallikrein *in vitro* with high affinity, about ten-fold more potently than lanadelumab, a monoclonal antibody plasma kallikrein inhibitor. In addition, in competition binding experiments, STAR-0215 was shown to bind to a different site on plasma kallikrein than lanadelumab. YTE modifications in STAR-0215 are designed to enable a longer duration of action. In cynomolgus monkeys dosed with STAR-0215, the enhanced FcRn binding enabled by the YTE modifications translated to a more than three-fold increase in plasma half-life to about 34 days with STAR-0215 compared to an antibody without the YTE modifications. The plasma half-life of STAR-0215 in cynomolgus monkeys was also more than three-fold longer than that of lanadelumab, supporting the potential for less frequent dosing.

STAR-0215's potency was also tested using a physiologically relevant assay. STAR-0215 potently inhibited the release of bradykinin from high molecular weight kininogen, with an IC90 about 10-fold more potent than the IC90 achieved by lanadelumab in the same assay. IC90 corresponds to the concentration required to inhibit 90% of enzymatic activity, which is thought to be the level of plasma kallikrein inhibition required to prevent HAE attacks. Pharmacokinetic/pharmacodynamic modeling showed that STAR-0215 is predicted to prevent HAE attacks for a substantially longer period than lanadelumab. Based on these data, STAR-0215 has the potential to be administered once every three months or longer to effectively prevent HAE attacks.

STAR-0215 is in preclinical development to treat HAE, and is a monoclonal antibody inhibitor of plasma kallikrein, designed to provide long-acting, effective HAE attack prevention. The company's goal is to provide the most patient-friendly preventative treatment option for people living with HAE. The company expects to file an Investigational New Drug application for STAR-0215 in mid-2022 and plans to initiate a Phase 1 clinical trial with initial results anticipated by year end 2022.

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 Company's expectations regarding the timing for the filing of an IND and commencement of a Phase 1 clinical trial for STAR-0215, the timing of the initial results from such trial; the potential attributes and differentiated profile of STAR-0215 as a potential treatment for HAE; and the Company's mission to bring life changing therapies to patients and families affected by 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 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; the Company's ability to obtain, maintain and enforce intellectual property rights for

STAR-0215 and any other future product candidates; competition; 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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