



Astria Therapeutics Presents Additional Data Supporting STAR-0215 Profile as a Long-Acting Preventative Therapy for Hereditary Angioedema at the 2023 American Academy of Allergy, Asthma, and Immunology Annual Meeting

February 24, 2023

-- Additional Phase 1a Clinical Data Shows STAR-0215 Has Estimated Half-Life of up to 117 Days, Supporting Potential for Dosing Once Every Three Months or Less Frequently --

-- STAR-0215 Differentiated Plasma Kallikrein Binding is Consistent with High Specificity --

BOSTON--(BUSINESS WIRE)--Feb. 24, 2023-- [Astria Therapeutics, Inc.](#) (Nasdaq:ATXS), a biopharmaceutical company developing STAR-0215 for the treatment of hereditary angioedema and focused on life-changing therapies for rare and niche allergic and immunological diseases, presented new STAR-0215 data in two poster presentations at the American Academy of Allergy, Asthma, and Immunology Annual Meeting in San Antonio, Texas that demonstrate early proof-of-concept for STAR-0215's profile as a long-acting preventative therapy for HAE.

In a poster titled, "Initial Results from a Phase 1a Single Ascending Dose Clinical Trial of STAR-0215, an Investigational Long-Acting Monoclonal Antibody Plasma Kallikrein Inhibitor for Hereditary Angioedema (HAE), in Healthy Subjects Followed for at Least 3 Months," Chris Morabito, M.D., Chief Medical Officer at Astria Therapeutics, shared clinical data including unblinded safety data that showed that STAR-0215 was well-tolerated, with no serious adverse events or discontinuations due to an adverse event. Additionally, there were no clinically significant changes in laboratory assessments, and there were no treatment-emergent anti-drug antibodies (ADAs) detected. STAR-0215 demonstrated dose-dependent pharmacokinetics (PK), with an estimated half-life of up to 117 days. At Day 84, mean concentrations remained above the threshold for potential efficacy after a single 300 mg subcutaneous dose. Suppression of cleaved high molecular weight kininogen (cHMWK) to levels consistent with robust plasma kallikrein inhibition was achieved through Day 84 in both Western Blot and Chromogenic assays. These results demonstrate early proof of concept for STAR-0215 as a potential long-acting therapy for HAE, and additional cohorts have been added to the Phase 1a trial to assess the potential for once every six-months administration, with preliminary results expected in the fourth quarter of 2023.

A second poster titled, "Structure of STAR-0215 Bound to Active Plasma Kallikrein Reveals a Novel Mechanism of Enzyme Inhibition" was presented by Nikolaos Biris, Ph.D., Director of Assay Development at Astria Therapeutics, where STAR-0215 was shown to bind allosterically to a site that is unique to plasma kallikrein. This allosteric binding of STAR-0215 blocks the formation of the active site of plasma kallikrein to potentially inhibit its activity and gives rise to the high selectivity for plasma kallikrein compared with prekallikrein and related serine proteases. These findings, together with the additional Phase 1a clinical data that established long half-life in healthy subjects, support that STAR-0215 is a potential best-in-class therapy for the prevention of HAE attacks.

STAR-0215 is a monoclonal antibody inhibitor of plasma kallikrein in development for the treatment of HAE. Initial results from a Phase 1a trial in healthy subjects support STAR-0215's target profile: a long-acting preventative therapy, best-in-class PK profile, and dosing once every three months or less frequently. The Phase 1b/2 ALPHA-STAR trial evaluating STAR-0215 in people living with HAE is ongoing, with initial results from single and multiple dose cohorts expected in mid-2024.

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 clinical 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 of Astria Therapeutics, Inc. ("Astria," the "Company," "we," "our" or "us") within the meaning of applicable securities laws and regulations, including statements with respect to: expectations regarding the potential significance of the preliminary results from the Phase 1a STAR-0215 trial and the anticipated nature and timing of receipt of the data from the additional cohorts in such trial; expectations regarding the timing and nature of the anticipated proof of concept results from the ALPHA-STAR Phase 1b/2 clinical trial of STAR-0215; the potential attributes and differentiated profile of STAR-0215 as a treatment for HAE, including its potential best-in-class pharmacokinetic profile, potential dosing frequency, clinical benefit and those suggested by the preliminary results from the STAR-0215 Phase 1a trial and its mechanism of action; the potential commercial opportunity for STAR-0215 in HAE; the need for effective treatments for HAE; the potential for six-month dosing of STAR-0215; and the Company's goal to meet the unmet needs of patients with rare and niche allergic and immunological diseases. We use words such as "aims," "anticipate," "believe," "estimate," "expect," "goals," "hope," "intend," "may," "opportunity," "plan," "predict," "project," "target," "potential," "would," "vision," "can," "could," "should," "continue," and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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, 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, that the preliminary results from the Phase 1a trial may not be indicative of the final results, that the results of early stage clinical studies, such as the preliminary results from the Phase 1a trial, may not be replicated in later stage clinical studies, including the ALPHA-STAR trial, the risk that we may not be able to enroll sufficient patients in our clinical trials or cohorts thereof on a timely basis, and the risk that any of our clinical trials or cohorts thereof 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 STAR-0215 and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and drug product for STAR-0215 and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulation for STAR-0215 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 STAR-0215 and any other future product candidates; our potential dependence on collaboration partners; competition with respect to STAR-0215 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 and the anticipated position and attributes of STAR-0215 in HAE based on its clinical data to date, pre-clinical profile, pharmacokinetic modeling and other data; 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, 2021, and in other filings that we may make with the Securities and Exchange Commission ("SEC"), including the Current Report on Form 8-K that we filed with the SEC on December 15, 2022. These forward-looking statements should not be relied upon as representing our view as of any date subsequent to the date of this press release, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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