Astria Therapeutics Announces Exclusive Worldwide License Agreement with Ichnos Sciences for OX40 Portfolio

October 11, 2023

-- Differentiated Preclinical Lead Candidate STAR-0310 to be Developed as a Potential Best-in-Class Long-Acting Treatment for Atopic Dermatitis –

-- Conference Call and Webcast to be Held on October 12, 2023 at 8:30am ET --

BOSTON--(BUSINESS WIRE)--Oct. 11, 2023-- Astria Therapeutics, Inc. (NASDAQ:ATXS), a biopharmaceutical company focused on developing life-changing therapies for allergic and immunological diseases, today announced that it has entered into a worldwide exclusive license agreement with Ichnos Sciences for an OX40 portfolio to be developed for the potential treatment of atopic dermatitis (AD) and potentially for other allergic and immunological diseases. Astria plans to develop the lead candidate, called STAR-0310, a monoclonal antibody OX40 antagonist that incorporates YTE half-life extension technology, for the treatment of AD. Astria believes STAR-0310, a preclinical-stage program, has the potential to have the best-in-class profile in AD with high affinity, reduced treatment burden with infrequent dosing, and favorably differentiated safety and tolerability. OX40 inhibition is a clinically validated mechanism for the treatment of AD. Astria also sees an opportunity with STAR-0310 for potential expansion into additional indications.

“We are very proud to add such a strong program to our company that supports our vision of strategic growth for the future,” said Jill C. Milne, Ph.D., Chief Executive Officer at Astria Therapeutics. “We are building a pipeline of potential first-choice products that can improve the health and outcomes for allergy and immunology patients. We believe STAR-0310 is a perfect complement to STAR-0215. The initial results from the Phase 1a trial support investigating STAR-0215 in hereditary angioedema (HAE) patients and also suggest that there could be an opportunity to dose STAR-0215 every three or six months. Additionally, the Phase 1b/2 trial in HAE patients is on-track and enrolling the third and final cohort, with initial proof-of-concept results expected mid-2024. We expect to initiate a pivotal Phase 3 trial in Q1 2025, assuming positive Phase 1b/2 results. We believe our pipeline has the potential to deliver significant benefit to patients with validated mechanisms and potential best-in-class profiles.”

“Our team worked hard to find a product that was the right fit for Astria’s mission, vision, goals, and plans for the future, and we believe we have found such a program with STAR-0310,” said Andrea Matthews, Chief Business Officer at Astria Therapeutics. “With our team’s expertise in antibody development, our understanding of the market, and our commitment to improving outcomes for patients, we are confident that we can become a leader in the development of first-choice allergy and immunology therapies.”

Ichnos Sciences developed a portfolio of monoclonal antibody antagonists of OX40, including STAR-0310 and telazorlimab, which Astria has exclusively in-licensed worldwide in all fields. STAR-0310 was developed by applying YTE half-life extension technology to an affinity-matured version of telazorlimab. By targeting OX40, STAR-0310 is designed to address a wide range of T cells involved in the heterogenous AD pathology, providing the potential for better efficacy and a broader addressable patient population. In addition, STAR-0310 has been engineered to minimize T cell depletion. As a potential long-acting OX40 inhibitor, STAR-0310 aims to address the need for a safe, effective, and infrequently administered AD treatment.

Astria expects to submit an Investigational New Drug (IND) application for STAR-0310 by year-end 2024 and, if the IND is cleared, plans to initiate a Phase 1a clinical trial in healthy subjects in the first quarter of 2025. Astria anticipates reporting initial results from the trial in the third quarter of 2025. Astria anticipates these initial results will be an important milestone for the program and that these initial results have the potential to establish early proof of concept of STAR-0310, including potentially demonstrating long half-life, initial PD, and safety and tolerability. Pending positive results from the Phase 1a clinical trial, Astria plans to initiate a Phase 1b clinical trial in patients with AD shortly thereafter, with initial results anticipated in second quarter of 2026, the goals of which are to demonstrate proof of concept of STAR-0310, initial efficacy in AD as well as show differentiation on safety and tolerability. Based on the inclusion of the YTE modification, Astria believes STAR-0310 has the potential to be dosed once every two to three months.

About the License:

Under the terms of the license agreement, Astria will pay Ichnos a one-time upfront license fee of $15 million. Astria is also obligated to pay Ichnos up to $305 million in milestones, of which up to $20 million are clinical development milestones in up to three indications and $285 million are related to regulatory approval and commercial sales milestones for all licensed products in up to three indications. In addition, Ichnos will be eligible to receive tiered mid-single digit to low-double digit royalties based on Astria’s and any of its affiliates’ or sublicensees’ annual net sales of the licensed products, subject to reduction in specified circumstances.

Webcast Information:

Astria Therapeutics will host a live webcast and conference call on October 12, 2023, at 8:30am ET to discuss the OX40 program STAR-0310. Interested parties may join the webcast via the Investors section of the Astria website, www.astriatx.com, or with the following link: https://lifescievents.com/event/astria/

Please connect to the webcast several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be required. The webcast will be archived for 90 days.

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 immunological diseases. Our lead program, STAR-0215, is a monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema. 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 Twitter and Instagram @AstriaTx and on Facebook and LinkedIn.

Cautionary Note Regarding 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 regarding adding additional cohorts, and the timing of the results therefrom, to our Phase 1a clinical trial of STAR-0215, and the timing of availability of final results from such trial; our expectations regarding the potential significance of the preliminary results from the Phase 1a STAR-0215 clinical trial and the anticipated nature and timing of receipt of additional data from such trial; our expectations regarding the timing, nature, goals and results of our Phase 1b/2 clinical trial of STAR-0215 and that favorable results from such trial could allow us to move directly into a Phase 3 pivotal trial of STAR-0215 as a potential treatment for HAE; our expectations about the design and anticipated timing of a Phase 3 pivotal clinical trial for STAR-0215 as a potential treatment for HAE, assuming positive data from the Phase 1b/2 trial; the potential therapeutic benefits and potential attributes of STAR-0310 as a treatment for atopic dermatitis, or AD; expectations regarding the timing of regulatory filings for STAR-0310; expectations regarding the timing of initiation and planned design of clinical trials for STAR-0310; the expectations regarding the timing and nature of anticipated data for planned trials of STAR-0310; our goals and vision for STAR-0310; the potential commercial opportunity for STAR-0310 in AD and the likelihood that it can effectively compete in AD, assuming it is approved; the size of the AD market and the need for treatments for AD and the 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,” “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 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, 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 preclinical studies may not be replicated in clinical trials, that the preliminary results from clinical trials, including the Phase 1a clinical trial may not be indicative of the final results, that the results of early stage clinical trials, such as the preliminary results from the Phase 1a clinical trial, may not be replicated in later stage clinical trials, including the ALPHA-STAR 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 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, STAR-0310, and any other future development candidates; our ability to manufacture sufficient quantities of drug substance and drug product for STAR-0215, STAR-0310, and any other future product candidates on a cost-effective and timely basis, and to develop dosages and formulation for STAR-0215, 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 STAR-0215, STAR-0310, and any other future product candidates; our potential dependence on collaboration partners; competition with respect to STAR-0215, 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 hereditary angioedema (HAE), the ability of STAR-0215 to compete in HAE and the anticipated position and attributes of STAR-0215 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; 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, 2022 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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Investor Relations and Media:
Elizabeth Higgins
investors@astriatx.com

Source: Astria Therapeutics, Inc.