aTyr Pharma Provides Regulatory and Clinical Update for Efzofitimod in Pulmonary Sarcoidosis Following FDA Type C Meeting

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Company to continue development of efzofitimod in pulmonary sarcoidosis incorporating FDA feedback.

Company plans to submit IND in June 2026 for new Phase 3 study of efzofitimod in patients with chronic, symptomatic pulmonary sarcoidosis with restrictive lung disease utilizing FVC as primary endpoint and KSQ-Lung as key secondary endpoint.

Management to host conference call and webcast today at 4:30pm ET / 1:30pm PT.

SAN DIEGO, May 11, 2026 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: ATYR) ("aTyr" or the "Company"), a clinical stage biotechnology company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced the path forward for its lead therapeutic candidate, efzofitimod, in pulmonary sarcoidosis, a major form of interstitial lung disease (ILD), following the receipt of the official meeting minutes from a Type C meeting with the U.S. Food and Drug Administration (FDA).

The purpose of the meeting was to review the results of the Phase 3 EFZO-FIT™ study and determine the next steps for the program in pulmonary sarcoidosis. Based on feedback from the FDA, the Company plans to continue the development of efzofitimod in pulmonary sarcoidosis in a new Phase 3 study in patients with chronic, symptomatic pulmonary sarcoidosis with restrictive lung disease utilizing forced vital capacity (FVC) as the primary endpoint of the study and the King's Sarcoidosis Questionnaire (KSQ)-Lung score as the key secondary endpoint. The Company chose these endpoints based on the FDA's indication that FVC and KSQ-Lung are direct measures of how patients suffering from pulmonary sarcoidosis function and feel, and the Company concluded FVC to be a more appropriate primary endpoint at this time pending further content validation work for the KSQ-Lung as recommended by the FDA. The Company plans to submit an investigational new drug (IND) application for this study in June 2026.

"We are pleased with the feedback we received from the FDA on the path forward for efzofitimod in pulmonary sarcoidosis and the productive discussion we had regarding the most clinically relevant endpoints for this disease, including that FVC is a direct measure of function. To align with this feedback, we will prioritize FVC as the primary endpoint in our next study," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr Pharma. "Evidence from EFZO-FIT™ shows that patients with restrictive lung disease (defined as FVC percent predicted ≤ 80%) experienced a clinically meaningful benefit for FVC when treated with efzofitimod compared to the observed decline in placebo. Furthermore, these more severe patients from EFZO-FIT™ also experienced positive trends of improvement across multiple patient-reported outcomes, including the KSQ-Lung score. We believe that focusing on these two key endpoints that are viewed as direct measures of function and feel by the FDA and doing so in a defined patient population where we have a demonstrated benefit for efzofitimod is the appropriate strategy for the next step in evaluating efzofitimod as a potential new treatment for patients with pulmonary sarcoidosis."

"As part of our discussion with the FDA regarding the benefit risk profile for efzofitimod, we plan to increase the frequency of dosing of 5.0 mg/kg efzofitimod or placebo from once every four weeks in past trials to once every three weeks in this next trial. Considering the consistent safety profile we have seen for efzofitimod in trials to date, we believe this strategy to increase drug exposure, coupled with additional risk mitigation strategies and safety surveillance, may enhance the effects of efzofitimod without incurring additional safety concerns. Now that we have a clear path forward, we are preparing to submit an IND for this study next month."

The Phase 3 trial is expected to be a global, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of efzofitimod in patients with moderate to severe pulmonary sarcoidosis. The 54-week study will consist of two parallel cohorts randomized equally to either 5.0 mg/kg efzofitimod or placebo dosed intravenously once every 3 weeks for a total of 17 doses. The study is intended to enroll up to approximately 372 patients with symptomatic pulmonary sarcoidosis with restrictive lung disease who are receiving a stable dose of ≤ 5.0 mg daily oral corticosteroid (OCS) and/or a background immunosuppressant. All background treatment will remain stable throughout the duration of the study. The primary endpoint of the study will be change from baseline in FVC at week 48 and the key secondary endpoint will be change from baseline in the KSQ-Lung score at week 48.

Conference Call and Webcast

aTyr will host a conference call and webcast to discuss the regulatory and clinical update for efzofitimod in pulmonary sarcoidosis today May 11 at 4:30pm ET / 1:30pm PT. Interested parties may access the call by registering here in order to obtain a dial in, personalized passcode and webcast information. Links to a live audio webcast and replay may be accessed on the aTyr website events page at: http://investors.atyrpharma.com/events-and-webcasts. An audio replay will be available for at least 90 days following the event.

About Pulmonary Sarcoidosis

Pulmonary sarcoidosis is an inflammatory disease characterized by the formulation of granulomas, clumps of inflammatory cells, in one or more organs of the body. Approximately 160,000 Americans are diagnosed with pulmonary sarcoidosis and the prognosis ranges from benign and self-limiting to chronic, debilitating disease, permanent loss of lung function and death. Current treatment options include corticosteroids and other immunosuppressive therapies, which have limited efficacy and are associated with serious side-effects that many patients cannot tolerate long-term.

About Efzofitimod

Efzofitimod is a novel biologic immunomodulator in clinical development for the treatment of interstitial lung disease (ILD), a group of immune-mediated disorders that can cause inflammation and fibrosis, or scarring, of the lungs. Efzofitimod is a tRNA synthetase derived therapy that selectively modulates activated myeloid cells through neuropilin-2 to resolve inflammation without immune suppression and potentially prevent the

progression of fibrosis. Efzofitimod is currently being investigated in the Phase 2 EFZO-CONNECT™ study in patients with systemic sclerosis (SSc, or scleroderma)-related ILD, and aTyr intends to submit an investigational new drug (IND) application in June 2026 for a global Phase 3 study of efzofitimod in patients with pulmonary sarcoidosis, a major form of ILD. These forms of ILD have limited therapeutic options and there is a need for safer and more effective, disease-modifying treatments that improve outcomes.

About aTyr

aTyr is a clinical stage biotechnology company leveraging evolutionary intelligence to translate tRNA synthetase biology into new therapies for fibrosis and inflammation. tRNA synthetases are ancient, essential proteins that have evolved novel domains that regulate diverse pathways extracellularly in humans. aTyr's discovery platform is focused on unlocking hidden therapeutic intervention points by uncovering signaling pathways driven by its proprietary library of domains derived from all 20 tRNA synthetases. aTyr's lead therapeutic candidate is efzofitimod, a novel biologic immunomodulator in clinical development for the treatment of interstitial lung disease, a group of immune-mediated disorders that can cause inflammation and progressive fibrosis, or scarring, of the lungs. For more information, please visit www.atyrpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are usually identified by the use of words such as "anticipate," "believes," "can," "could," "designed," "expects," "intends," "may," "plans," "potential," "upcoming," "will," and variations of such words or similar expressions. We intend these forward-looking statements to be covered by such safe harbor provisions for forward-looking statements and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements include, among others, statements regarding our continued development of efzofitimod in pulmonary sarcoidosis, the potential therapeutic benefits and applications of efzofitimod, our timelines and plans with respect to certain development activities and goals, including the submission (and planned timing of submission) of an IND for a Phase 3 study of efzofitimod in pulmonary sarcoidosis in June 2026, the proposed design of our planned Phase 3 study of efzofitimod in pulmonary sarcoidosis, including the dosing regimen, enrollment expectations, targeted endpoints, strategy to focus on a more limited patient population and strategy to mitigate additional safety concerns, and our interpretation of the results of the EFZO-FIT™ study and the meaning of those interpretations for our planned Phase 3 study. These forward-looking statements also reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects, as reflected in or suggested by these forward-looking statements, are reasonable, we can give no assurance that the plans, intentions, expectations, strategies or prospects will be attained or achieved. All forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain. Furthermore, actual results may differ materially from those described in these forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, uncertainty related to interactions with the FDA in general, uncertainty regarding geopolitical and macroeconomic events, risks associated with the discovery, development and regulation of efzofitimod, the risks associated with targeting a more limited patient population in our planned Phase 3 study of efzofitimod in pulmonary sarcoidosis, the risk that we or our partners may cease or delay preclinical or clinical development activities for efzofitimod for a variety of reasons (including difficulties or delays in patient enrollment in planned clinical trials), the possibility that existing collaborations could be terminated early, and the risk that we may not be able to raise the additional funding required for our business and product development plans, as well as those risks set forth in our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and in our other SEC filings. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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