aTyr Pharma Presents Additional Findings from Phase 3 EFZO-FIT™ Study in Late-Breaking Oral Abstract at the European Respiratory Society (ERS) Congress 2025

September 30, 2025

Clinical benefit for efzofitimod across multiple disease-related health outcomes reported.

Improvement in Fatigue Assessment Scale Total Score at week 48 observed in the 5.0 mg/kg efzofitimod treatment group vs placebo (p=0.0226).

Improvement in King's Sarcoidosis Questionnaire-General Health score at week 48 observed in the 5.0 mg/kg efzofitimod treatment group vs placebo (p=0.0197).

SAN DIEGO, Sept. 30, 2025 (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 presented additional findings from the Phase 3 EFZO-FIT™ study of efzofitimod in 268 patients with pulmonary sarcoidosis, a major form of interstitial lung disease, in a late-breaking oral abstract presentation by Daniel Culver, D.O., Chair of the Department of Pulmonary Medicine at the Cleveland Clinic and principal investigator of the study, at the European Respiratory Society (ERS) Congress 2025 in Amsterdam, Netherlands.

"Building on the positive data we presented in the topline results for the King's Sarcoidosis Questionnaire (KSQ)-Lung score, the clinical improvements in the Fatigue Assessment Scale (FAS) and KSQ-General Health scores presented at ERS are compelling because these directly address critical symptoms and quality of life measures that profoundly impact pulmonary sarcoidosis patients," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr Pharma. "Crucially, the improvements observed for the KSQ-Lung, FAS and KSQ-General Health scores were achieved rapidly and sustained robustly throughout the study. Despite missing the primary endpoint of the study, efzofitimod has clearly demonstrated the potential to durably improve multiple disease-related health outcomes, including cough, shortness of breath, fatigue and general health. These consistent clinical benefits reinforce our belief in efzofitimod's potential to meaningfully improve quality of life and reduce reliance on chronic steroids for pulmonary sarcoidosis patients."

The ERS presentation included analyses of additional pre-specified outcomes that demonstrated clinical improvements in mean change from baseline in the FAS Total Score (p=0.0226) and KSQ-General Health score (p=0.0197) in patients treated with 5.0 mg/kg efzofitimod vs placebo. Treatment with efzofitimod was also associated with a trend toward a greater proportion of patients achieving steroid-free status for at least six months.

As previously reported in the topline results, the study did not meet its primary endpoint of change from baseline in mean daily oral corticosteroid dose at week 48. However, clinical benefit for 5.0 mg/kg efzofitimod was observed across multiple study efficacy parameters at week 48 compared to placebo, including complete steroid withdrawal and KSQ-Lung score improvement (p=0.0196), improvement in KSQ-Lung score change from baseline (p=0.0479), preservation of forced vital capacity and a well-tolerated safety profile.

Note, the study's statistical analysis plan was designed on a hierarchical assessment basis. Since the primary endpoint was not met, all subsequent statistical testing is reported as nominal findings.

Details of the ERS presentation are as follows:

Title: EFZO-FIT: The Largest Ever Interventional Trial in Pulmonary Sarcoidosis
Authors: Daniel Culver, Francesco Bonella, Lisa Carey, Pavithra Ramesh, Abhijeeth Chandrasekaran, Nelson Kinnersley, Vis Niranjan, Robert Baughman
Presenter: Daniel Culver, D.O., Chair of the Department of Pulmonary Medicine, Cleveland Clinic
Presentation Number: RCT5337
Session: 436 Clinical Trials Session, ALERT 3: Interstitial Lung Disease, Pulmonary Hypertension and Intensive Care Unit

The corresponding abstract is available on the ERS conference website for registered attendees. The ERS presentation will be available on the aTyr website once presented.

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 200,000 Americans live 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 first-in-class 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. In addition to the global Phase 3 EFZO-FIT™ study of efzofitimod in patients with pulmonary sarcoidosis, a major form of ILD, efzofitimod is also being investigated in the Phase 2 EFZO-CONNECT™ study in patients with systemic sclerosis (SSc, or scleroderma)-related 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 first-in-class 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 the potential therapeutic benefits and applications of efzofitimod; the potential for efzofitimod to improve multiple disease related health outcomes and reduce reliance on chronic steroids for treatment; timelines and plans with respect to certain development activities (such as the timing of data from clinical trials); and certain development goals. 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 regarding geopolitical and macroeconomic events, risks associated with the discovery, development and regulation of efzofitimod, 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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Source: aTyr Pharma, Inc.