aTyr Pharma Announces Alignment with FDA on Phase 3 Study of Efzofitimod in Pulmonary Sarcoidosis

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Global Phase 3 study will evaluate efzofitimod in patients with pulmonary sarcoidosis with restrictive lung disease utilizing FVC as primary endpoint.

Company expects to initiate study-related activities in the fourth quarter of 2026.

SAN DIEGO, Sept. 24, 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 that it has reached alignment with the U.S. Food and Drug Administration (FDA) on the protocol for a Phase 3 study of its lead therapeutic candidate, efzofitimod, in patients with chronic, symptomatic pulmonary sarcoidosis with restrictive lung disease. The Company expects to focus on regulatory submissions in the U.S. and Europe as it initiates study-related activities in the fourth quarter of 2026.

"We received feedback earlier this week from the FDA and we are very pleased to have reached alignment on the protocol for our planned Phase 3 study of efzofitimod in pulmonary sarcoidosis, a major form of interstitial lung disease," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr Pharma. "This important milestone reflects the progress of our efforts to advance efzofitimod for patients with pulmonary sarcoidosis. With limited treatment options available, particularly for patients requiring chronic therapy, we believe efzofitimod has the potential to become an important new treatment option."

The planned Phase 3 trial will 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 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 forced vital capacity (FVC) at week 48 and the key secondary endpoint will be change from baseline in the King's Sarcoidosis Questionnaire (KSQ)-Lung score at week 48.

The study design is supported by data from a subgroup analysis of the Phase 3 EFZO-FIT™ study that showed that patients with pulmonary sarcoidosis with restrictive lung disease (defined as FVC percent predicted ≤ 80% with a normal FEV1/FVC ratio) who were treated with 5.0 mg/kg efzofitimod experienced a clinically meaningful benefit in FVC and improvements in multiple patient-reported outcomes, including the KSQ-Lung score, compared to placebo. These findings were presented at the World Association of Sarcoidosis and Other Granulomatous Disorders 2026 Congress.

Future development of efzofitimod in the planned Phase 3 study in pulmonary sarcoidosis will require the Company to obtain additional capital through equity or debt offerings, grant funding, collaborations, strategic partnerships and/or licensing arrangements.

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 plans to initiate study-related activities for a global Phase 3 study of efzofitimod in patients with pulmonary sarcoidosis, a major form of ILD, in the fourth quarter of 2026. 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, including the additional capital that we expect to be necessary for future development; timelines and plans with respect to certain regulatory and development milestones, activities and goals, including our plans to initiate study-related activities in the fourth quarter of 2026 for the planned Phase 3 study; the proposed design of our planned Phase 3 study of efzofitimod in pulmonary sarcoidosis, including the dosing regimen, enrollment

expectations, targeted endpoints, and strategy to focus on a more limited patient population; and our interpretation of the results of the Phase 3 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, risks that the results from the planned Phase 3 study may not ultimately support FDA approval of efzofitimod in pulmonary sarcoidosis, 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 future 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 future 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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