aTyr Pharma Announces Scheduling of FDA Type C Meeting to Discuss Efzofitimod Program in Pulmonary Sarcoidosis

February 3, 2026

Meeting with the FDA to review the results from the Phase 3 EFZO-FIT™ study and determine the path forward for efzofitimod in pulmonary sarcoidosis is scheduled for mid-April 2026.

SAN DIEGO, Feb. 03, 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 the U.S. Food and Drug Administration (FDA) has accepted the Company’s meeting request to discuss its lead therapeutic candidate, efzofitimod, for the treatment of pulmonary sarcoidosis. The Type C meeting is scheduled for mid-April 2026.

“We look forward to meeting with the FDA in mid-April to review the results of our Phase 3 EFZO-FIT™ study and determine the path forward for 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. “We expect to provide an update regarding the outcome of the meeting following the receipt of the official meeting minutes.”

EFZO-FIT™ was a Phase 3 study of efzofitimod in 268 patients with symptomatic pulmonary sarcoidosis. While the study did not meet its primary endpoint of change from baseline in mean daily oral corticosteroid dose at week 48, clinical benefit for 5.0 mg/kg efzofitimod was observed across multiple study efficacy parameters at week 48 compared to placebo, including improvement in change from baseline for the King’s Sarcoidosis Questionnaire (KSQ)-Lung score (p=0.0479), Fatigue Assessment Scale score (p=0.0226), KSQ-General Health score (p=0.0197), and complete steroid withdrawal with KSQ-Lung score improvement (p=0.0196). Additionally, treatment with efzofitimod maintained lung function as a measure of forced vital capacity and was well-tolerated with a safety profile consistent with prior trials conducted to date.

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. 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 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 the potential therapeutic benefits and applications of efzofitimod; and timelines and plans with respect to certain development activities and goals, including the occurrence and timing of our meeting with the FDA to review the results of the Phase 3 EFZO-FIT™ study and determine the path forward for efzofitimod in pulmonary sarcoidosis, as well as our expectations with respect to the outcome of that meeting, the timing of our update for that meeting and next steps for the development of efzofitimod in pulmonary sarcoidosis. 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 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.

Contact:
Ashlee Dunston
Sr. Director, Investor Relations and Public Affairs
adunston@atyrpharma.com

Source: aTyr Pharma, Inc.