# aTyr Pharma Announces Positive End-of-Phase 2 Meeting with FDA on Efzofitimod for the Treatment of Pulmonary Sarcoidosis

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**Regulatory path forward supports company's intention to initiate a planned registrational study in the third quarter of 2022.**

SAN DIEGO, March 10, 2022 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE) (aTyr or the "Company"), a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel biological pathways, today announced the positive outcome of a Type B End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding its lead therapeutic candidate, efzofitimod (ATYR1923), for the treatment of pulmonary sarcoidosis. As a result, the Company intends to initiate a planned registrational study of efzofitimod in the third quarter of 2022.

"We are pleased with the very productive feedback we received from the FDA, in particular, the emphasis around the steroid-sparing effects of efzofitimod. As the most advanced clinical development program for pulmonary sarcoidosis, we have an opportunity to establish efficacy endpoints that, if successful in demonstrating clinically meaningful treatment effects, will serve as a basis for future FDA review," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "This is an important milestone for aTyr, and we now have a path forward to initiate a planned registrational study of efzofitimod that will incorporate the feedback we received from the FDA. Preparations for the study are underway, and we are on track to initiate this study in the third quarter of this year."

Following the FDA's review of the data package, including data from the nonclinical program, early clinical trials and the recently completed Phase 1b/2a study, the Company will proceed with the advancement of efzofitimod. The FDA discussed endpoints detailed by the Company in its proposed registrational study and prioritization of outcome measurements that would best support the evaluation of efzofitimod's efficacy. The FDA advised the continued evaluation of multiple doses of efzofitimod in a longer duration study to establish a controlled safety database that supports the determination of the optimal dose for chronic use.

"As an attendee of the meeting, I came away impressed that the FDA appreciated the need for a therapeutic that demonstrates a steroid-sparing effect. This is an important step forward, as the well-recognized complications of steroid use in sarcoidosis present a compelling rationale for the potential use of efzofitimod in sarcoidosis patients," said Robert Baughman, M.D., Professor of Medicine and Pulmonologist at the University of Cincinnati Medical Center.

"On behalf of the sarcoidosis community, we are grateful to aTyr for including us in this meeting and the FDA for their commitment to improving the lives of those with sarcoidosis and for the continued development of efzofitimod as a potential new therapy," said Mary McGowan, CEO of the Foundation for Sarcoidosis Research (FSR). "We are hopeful this study will be a major step forward in providing much-needed, new treatment options for people living with this complex rare disease. FSR looks forward to continuing to work with aTyr and the FDA to support the next phase of this patient-centered research."

**About Efzofitimod**

aTyr is developing efzofitimod as a potential therapeutic for patients with severe inflammatory lung diseases. Efzofitimod, a fusion protein comprised of the immuno-modulatory domain of histidyl-tRNA synthetase fused to the FC region of a human antibody, is a selective modulator of neuropilin-2 that downregulates innate and adaptive immune response in inflammatory disease states. aTyr's lead indication for efzofitimod is pulmonary sarcoidosis, a major form of interstitial lung disease. Clinical proof-of-concept for efzofitimod was recently established in a Phase 1b/2a multiple-ascending dose, placebo-controlled study of efzofitimod in patients with pulmonary sarcoidosis, which demonstrated safety and a consistent dose response and trends of benefit of efzofitimod compared to placebo on key efficacy endpoints, including steroid reduction, lung function, clinical symptoms and inflammatory biomarkers.

**About aTyr**

aTyr is a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel biological pathways. aTyr's research and development efforts are concentrated on a newly discovered area of biology, the extracellular functionality and signaling pathways of tRNA synthetases. aTyr has built a global intellectual property estate directed to a potential pipeline of protein compositions derived from 20 tRNA synthetase genes and their extracellular targets. aTyr's primary focus is efzofitimod, a clinical-stage product candidate which binds to the neuropilin-2 receptor and is designed to down-regulate immune engagement in inflammatory lung diseases. 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 "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "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 statements regarding potential therapeutic benefits and applications of efzofitimod; timelines and plans with respect to certain development activities (such as the timing and design of additional clinical trials and planned interactions with regulatory authorities); 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 or strategies 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 the COVID-19 pandemic, risks associated with the discovery, development and regulation of our product candidates, the risk that we or our partners may cease or delay preclinical or clinical development activities for any of our existing or future product candidates 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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