# aTyr Pharma Receives FDA Fast Track Designation for Efzofitimod (ATYR1923) for Treatment of Pulmonary Sarcoidosis

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**Company is investigating efzofitimod in global pivotal Phase 3 EFZO-FIT™ study in pulmonary sarcoidosis patients**

SAN DIEGO, Aug. 11, 2022 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE) (aTyr or "the Company"), a clinical stage biotherapeutics 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 granted the company Fast Track designation for its lead therapeutic candidate, efzofitimod (ATYR1923), for the treatment of pulmonary sarcoidosis, a major form of interstitial lung disease.

Efzofitimod is a first-in-class immunomodulator that downregulates innate and adaptive immune responses in uncontrolled inflammatory disease states via selective modulation of neuropilin-2 (NRP2). Clinical proof-of-concept was recently established for efzofitimod in a Phase 1b/2a study in patients with pulmonary sarcoidosis, and the company is currently investigating efzofitimod in a global pivotal phase 3 study called EFZO-FIT™. Efzofitimod previously received FDA orphan drug designation for the treatment of sarcoidosis.

"The Fast Track designation for efzofitimod underscores the significant need for a new therapy that provides clinically meaningful outcomes for patients living with pulmonary sarcoidosis," said Sanjay S. Shukla, M.D., M.S., President and CEO of aTyr. "Fast Track designation reinforces the potential of this novel immunomodulator to be a transformative, disease modifying therapy and address a major unmet need for the sarcoidosis community. We are currently investigating efzofitimod in a global pivotal Phase 3 study called EFZO-FIT™ and we look forward to the opportunity to work closely with the FDA to potentially expedite the delivery of a new treatment to patients in need."

"The designation of Fast Track for efzofitimod is important news for the many sarcoidosis patients who remain on prednisone for controlling their disease," said Robert P. Baughman, M.D., Emeritus Profess of Medicine at the University of Cincinnati. "The last drugs approved by the FDA for sarcoidosis were prednisone and other glucocorticoids in the 1950s and most sarcoidosis patients with chronic disease remain on prednisone, with or without other agents which have not been approved by the FDA."

The FDA's Fast Track designation helps facilitate development and expedite the review of drugs to treat serious or life-threatening diseases with unmet need. Fast Track designation provides certain benefits, including more frequent interactions with the FDA throughout the development program, as well as eligibility for accelerated approval, priority review and rolling review.

Sarcoidosis is an immune-mediated disease characterized by the formulation of granulomas, clumps of inflammatory cells, in one or more organs of the body, predominantly in the lungs. Almost 200,000 Americans live with pulmonary sarcoidosis and the prognosis ranges from benign and self-limiting to chronic, debilitating disease, with 1 in 5 cases resulting in scarring, or fibrosis, of the lung, which causes permanent loss of lung function and in many cases 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**

aTyr is developing efzofitimod as a potential therapeutic for patients with fibrotic lung disease. Efzofitimod, a fusion protein comprised of the immunomodulatory 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. aTyr is currently conducting EFZO-FIT™, a global pivotal Phase 3 study of efzofitimod in pulmonary sarcoidosis patients.

**About aTyr**

aTyr is a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform. 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 downregulate immune engagement in fibrotic lung disease. For more information, please visit http://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 and the potential benefits of Fast Track designation. 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC on May 10, 2022 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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