



aTyr Pharma Announces Publication of Positive Data from Phase 1b/2a Clinical Study of Efzofitimid for the Treatment of Pulmonary Sarcoidosis in the Journal CHEST

November 9, 2022

First therapy in sarcoidosis to reduce steroid burden while demonstrating improvements in key physiologic and quality of life measures.

Global pivotal Phase 3 EFZO-FIT™ study currently enrolling.

SAN DIEGO, Nov. 09, 2022 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced the publication in the journal *CHEST* of positive results from a Phase 1b/2a randomized, double-blind, placebo-controlled clinical trial of its lead therapeutic candidate, efzofitimid, in patients with pulmonary sarcoidosis, a major form of interstitial lung disease. The publication, entitled, "Efzofitimid for the treatment of pulmonary sarcoidosis," is available on the journal's website and at: <https://doi.org/10.1016/j.chest.2022.10.037>.

"The dose-dependent improvements of several clinically relevant endpoints seen with efzofitimid compared to placebo, along with the desirable safety and tolerability profile, are very important findings," said Daniel A. Culver, D.O., Chair of the Department of Pulmonary Medicine at The Cleveland Clinic and lead author of the publication. "The ongoing EFZO-FIT™ study presents the opportunity to evaluate the steroid sparing effects of efzofitimid in a broader clinical trial. We are hopeful that this study will lead to a safe and effective treatment that reduces steroid burden and has a major impact on quality of life for patients with pulmonary sarcoidosis, which is greatly needed."

The study demonstrated that efzofitimid was safe and well-tolerated at all doses and exhibited a consistent dose response on key efficacy endpoints and improvements compared to placebo, including measures of steroid reduction, lung function, sarcoidosis symptom measures and inflammatory biomarkers.

"The publication of this manuscript marks the first peer-reviewed publication of clinical data for efzofitimid in a major medical journal. These data indicate that efzofitimid is providing substantial benefit to patients — improving lung function and symptoms of cough, shortness of breath and fatigue — all while reducing their toxic steroid burden," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "EFZO-FIT™ is expected to be the largest interventional study for patients with sarcoidosis to date, and we believe efzofitimid is well positioned to be the first disease modifying therapy to market for patients with this debilitating disease."

Efzofitimid 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). Efzofitimid is currently being investigated in a global pivotal Phase 3 study in patients with pulmonary sarcoidosis known as EFZO-FIT™, which is supported by safety and efficacy data from the Phase 1b/2a study. Efzofitimid has been granted FDA orphan drug and Fast Track designations for sarcoidosis.

Phase 1b/2a Clinical Trial in Patients with Pulmonary Sarcoidosis

The Phase 1b/2a study was a randomized, double-blind, placebo-controlled, multiple-ascending dose clinical trial in 37 patients with pulmonary sarcoidosis. The trial consisted of three cohorts testing doses of 1.0 mg/kg, 3.0 mg/kg and 5.0 mg/kg of efzofitimid or placebo, dosed intravenously every month for six months. The primary objective of the study was to evaluate the safety, tolerability, immunogenicity and pharmacokinetic profile of multiple doses of efzofitimid compared to placebo. Secondary objectives included the potential steroid-sparing effects of efzofitimid, in addition to other exploratory assessments of efficacy, such as lung function.

About Pulmonary Sarcoidosis

Sarcoidosis is an immune-mediated disease characterized by the formation 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 fibrosis, or scarring, of the lungs, 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 Efzofitimid

aTyr is developing efzofitimid as a potential therapeutic for patients with fibrotic lung disease. Efzofitimid, 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 efzofitimid is pulmonary sarcoidosis, a major form of interstitial lung disease. Clinical proof-of-concept for efzofitimid was recently established in a Phase 1b/2a multiple-ascending dose, placebo-controlled study of efzofitimid in patients with pulmonary sarcoidosis, which demonstrated safety and a consistent dose response and trends of benefit of efzofitimid compared to placebo on key efficacy endpoints, including steroid reduction, lung function, clinical symptoms and inflammatory biomarkers. aTyr is currently conducting EFZO-FIT™ a Phase 3 study of efzofitimid 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 efzofitimid, 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 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 of efzofitimod and plans with respect to certain clinical activities. 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 June 30, 2022 filed with the SEC on August 15, 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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Source: aTyr Pharma, Inc.