aTyr Pharma Announces Initiation of Phase 1b/2a Study of ATYR1923 in Patients with Pulmonary Sarcoidosis and Collaboration with the Foundation for Sarcoidosis Research (FSR)

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FSR Clinical Studies Network to assist with clinical site initiation to expedite patient enrollment

SAN DIEGO, Dec. 04, 2018 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel immunological pathways, today announced the initiation of a Phase 1b/2a study evaluating its lead candidate, ATYR1923, in patients with pulmonary sarcoidosis following acceptance of the Company's investigational new drug application by the US Food and Drug Administration.

aTyr also announced that it is collaborating with the Foundation for Sarcoidosis Research (FSR), the nation's leading nonprofit organization dedicated to finding a cure for sarcoidosis and improving care for sarcoidosis patients. Under the terms of the collaboration, FSR will assist with clinical trial site initiation and patient enrollment. aTyr anticipates that up to twelve sites in the United States will participate in the study. FSR's Clinical Studies Network (FSR-CSN), which is led by a steering committee consisting of principal investigators from leading clinical centers, has voted to support this proof-of-concept study.

"We accomplished our previously-stated goal of initiating this proof-of-concept Phase 1b/2a study of ATYR1923 this quarter, and we look forward to data that we believe will demonstrate the first signals of clinical activity in pulmonary sarcoidosis patients," said Sanjay Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "As we seek to advance ATYR1923 efficiently through clinical development, we are grateful to FSR for their support and assistance with this important trial, and we anticipate a long and mutually beneficial partnership."

"We are pleased to collaborate with the team at aTyr Pharma as they work to advance clinical development of a promising new treatment for pulmonary sarcoidosis, a potentially debilitating inflammatory lung disease with no known cure," said Ginger Spitzer, Executive Director of FSR. "Any step supporting the study of a new therapeutic candidate is a step towards a potential groundbreaking discovery that could improve the lives of sarcoidosis patients worldwide."

This Phase 1b/2a study is a multiple-ascending dose, placebo-controlled, first-in-patient study of ATYR1923 that has been designed to evaluate safety, tolerability and immunogenicity of multiple doses of ATYR1923, as well as to evaluate established clinical endpoints and potential biomarkers to assess preliminary efficacy.

About ATYR1923

aTyr scientists successfully engineered ATYR1923, a fusion protein comprised of the immuno-modulatory domain of histidyl tRNA synthetase (HARS) fused to the FC region of a human antibody. aTyr is developing ATYR1923 as a potential therapeutic for patients with interstitial lung diseases. aTyr announced data from a first-in-human Phase 1 clinical trial of ATYR1923 in June 2018. This randomized, double-blind, placebo-controlled study investigated the safety, tolerability, immunogenicity, and pharmacokinetics (PK) of intravenous ATYR1923 in 36 healthy volunteers. The results indicate that the drug was generally well-tolerated at all dose levels tested with no significant adverse events, and the observed PK profile supports the potential for a once-monthly dosing regimen.

About Pulmonary Sarcoidosis

Sarcoidosis is an inflammatory disease characterized by the formation of granulomas, clumps of inflammatory cells, in one or more organs in the body. Sarcoidosis affects people of all ages, but typically presents before the age of 50 years, with the incidence peaking at 20 to 39 years. The disorder usually begins in the lungs, skin or lymph nodes, but can affect almost any organ. Sarcoidosis in the lungs is called pulmonary sarcoidosis and 90% or more of patients with sarcoidosis have lung involvement. Pulmonary sarcoidosis is a major form of interstitial lung disease (ILD) a group of immune-mediated disorders which cause progressive fibrosis of lung tissue. Estimates of prevalence vary; however, aTyr believes that approximately 200,000 Americans live with pulmonary sarcoidosis. The prognosis for patients with pulmonary sarcoidosis ranges from benign and self-limiting to chronic, debilitating disease with mortality.

About FSR

The Foundation for Sarcoidosis Research is the nation's leading nonprofit organization dedicated to finding a cure for this disease and to improving care for sarcoidosis patients. Driven by dedicated patients, scientists, caregivers and donors, FSR's initiatives aim to make an impact on the lives of sarcoidosis patients around the world. The FSR provides support to fund CSN operations and carries out both core and elective studies to forward its mission of addressing unanswered questions in the sarcoidosis space. The FSR Clinical Studies Network (FSR-CSN) is led by a Steering Committee composed of the Principal Investigators from each participating institution. FSR-CSN is composed of 12 sites, two international and 10 U.S.-based. For more information about FSR, visit www.stopsarcoidosis.org.

About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel immunological pathways. aTyr's research and development efforts are concentrated on a newly discovered area of biology, the extracellular functionality 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. aTyr is focused on the therapeutic translation of the Resokine pathway, comprised of extracellular proteins derived from the histidyl tRNA synthetase gene family. ATYR1923 is a clinical-stage product candidate which binds to the neuropilin-2 receptor and is designed to down-regulate immune engagement in interstitial lung diseases and other immune-mediated diseases. 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 Litigation Reform Act. 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, including statements regarding the potential therapeutic benefits and applications of our product candidates; our ability to successfully advance our product candidates, undertake certain development activities (such as the initiation of clinical trials, clinical trial enrollment, the conduct of clinical trials and the announcement of top-line results) and accomplish certain development goals, and the timing of such events; and the scope and strength of our intellectual property portfolio. 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. 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, risks associated with the discovery, development and regulation of our product candidates, the risk that we 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), 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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