aTyr Pharma Announces Completion of Enrollment in Phase 1b/2a Clinical Trial of ATYR1923 in Patients with Pulmonary Sarcoidosis

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SAN DIEGO, Dec. 21, 2020 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel biological pathways, today announced that it has completed the target enrollment in its Phase 1b/2a clinical trial of its lead therapeutic candidate, ATYR1923, in patients with pulmonary sarcoidosis, a form of interstitial lung disease (ILD). The study enrolled 36 patients.

The company expects to report data from this trial in the third quarter of 2021. Results of this study will inform future development for ATYR1923 in ILD, which may include a registrational trial in pulmonary sarcoidosis and expansion into trials for other forms of ILD.

“We are pleased to meet the target enrollment of this important study, especially during the COVID-19 pandemic. Reaching this significant milestone for our ATYR1923 clinical program and the interest we’ve seen from patients to join the trial highlights the need for new therapies for this chronic, debilitating disease,” said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. “We look forward to sharing the results in the third quarter of next year, which will provide meaningful insights into ATYR1923’s therapeutic potential in patients with pulmonary sarcoidosis and other major immune-driven forms of ILD.”

The Phase 1b/2a study is a multiple-ascending dose, double-blind, placebo-controlled study that is designed to evaluate the safety, tolerability, immunogenicity and pharmacokinetic profile of multiple doses of ATYR1923 compared to placebo, as well as to evaluate preliminary efficacy measures including steroid sparing effect, measures of lung function and potential disease biomarkers.

“Treatment options remain limited for pulmonary sarcoidosis, which affects around 200,000 people in the U.S. By restoring immune balance, ATYR1923 offers a potential new mechanism to resolve pathologic lung inflammation, prevent subsequent fibrosis, and improve lung function and patient outcomes in people living with pulmonary sarcoidosis with less toxicity than currently available treatments,” said Dr. Shukla.

In addition to pulmonary sarcoidosis, ATYR1923 is being evaluated in a Phase 2 trial in hospitalized COVID-19 patients with severe respiratory complications, which include an acute form of interstitial pneumonia. The company recently completed enrollment in this study and expects to report topline data in the coming weeks.

About ATYR1923

aTyr is developing ATYR1923 as a potential therapeutic for patients with inflammatory lung diseases. ATYR1923, 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 the innate and adaptive immune response in inflammatory disease states. aTyr is currently enrolling a proof-of-concept Phase 1b/2a trial evaluating ATYR1923 in patients with pulmonary sarcoidosis, a form of interstitial lung disease. This Phase 1b/2a study is a multi-ascending dose, placebo-controlled, first-in-patient study of ATYR1923 that has been designed to evaluate the safety, tolerability, steroid sparing effect, immunogenicity and pharmacokinetics profile of multiple doses of ATYR1923. In response to the COVID-19 pandemic, aTyr initiated and completed enrollment in a Phase 2 clinical trial with ATYR1923 in COVID-19 patients with severe respiratory complications. This Phase 2 study is a randomized, double blind, placebo-controlled study that has been designed to evaluate the safety and preliminary efficacy of a single dose of ATYR1923.

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 ATYR1923, 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 http://www.atyrrpharma.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 the potential therapeutic benefits and applications of ATYR1923; timelines and plans with respect to certain development activities (such as the timing of data from clinical trials) 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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