

aTyr Pharma Announces Completion of Enrollment in Phase 2 Clinical Trial of ATYR1923 in COVID-19 Patients with Severe Respiratory Complications

October 26, 2020

Topline results are expected in the fourth quarter of 2020.

Trial evaluating the preliminary safety and efficacy of ATYR1923 vs placebo has exceeded enrollment.

SAN DIEGO, Oct. 26, 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 enrollment in its Phase 2 clinical trial of its lead therapeutic candidate, ATYR1923, in COVID-19 patients with severe respiratory complications. The study enrolled a total of 32 patients at hospitals in the U.S. and Puerto Rico, exceeding the target enrollment of 30 patients. The company expects to report topline data from this trial by the end of this year.

"We are pleased to have completed the full enrollment of this study, which is an important step forward in our effort to aid in the fight against the global COVID-19 pandemic," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Throughout the course of this year, we have continued to advance our knowledge of the disease pathology of COVID-19, which in many patients includes a form of interstitial pneumonia that causes severe respiratory complications which can lead to long-term lung damage. We believe ATYR1923 leverages newly discovered biological pathways to down-regulate excessive inflammatory responses which may restore immune balance in the lung, offering the potential of a differentiated approach to treat this subset of patients with severe lung inflammation for which there are limited available treatment options. We look forward to sharing topline results of this study later this year."

The Phase 2 clinical trial is a randomized, double blind, placebo-controlled study of ATYR1923 in hospitalized COVID-19 patients with severe respiratory complications who do not require mechanical ventilation. Patients enrolled in the trial were randomized 1:1:1 to a single intravenous dose of either 1.0 or 3.0 mg/kg of ATYR1923 or placebo. Patients are followed for 60 days post treatment. The trial is designed to evaluate the preliminary safety and efficacy of ATYR1923 as compared to placebo through the assessment of key clinical outcome measures.

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 is conducting 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.atvrpharma.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 completing clinical trials or negative data from preclinical studies or 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.

Contact:

Ashlee Dunston Investor Relations, aTyr Pharma adunston@atyrpharma.com

Source: aTyr Pharma, Inc.