



## **aTyr Pharma Announces Positive Topline Results from Phase 2 Clinical Trial of ATYR1923 in COVID-19 Patients with Severe Respiratory Complications**

January 4, 2021

*Study met primary safety endpoint in moderate to severe hospitalized COVID-19 patients.*

*A single dose of 3.0 mg/kg of ATYR1923 resulted in a median time to recovery of 5.5 days.*

*83% of patients receiving 3.0 mg/kg dose of ATYR1923 achieved recovery in less than a week.*

*Management to host conference call and webcast today, January 4, at 5:00pm ET/2:00pm PT.*

SAN DIEGO, Jan. 04, 2021 (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 positive topline results from its Phase 2 double-blind, placebo-controlled clinical trial of its lead therapeutic candidate, ATYR1923, in hospitalized COVID-19 patients with severe respiratory complications who do not require mechanical ventilation. The trial met its primary endpoint of safety, demonstrating that a single, intravenous (IV) dose of ATYR1923 was generally safe and well-tolerated in both the 1.0 and 3.0 mg/kg treatment groups, with no drug-related serious adverse events.

"We are pleased with the results of this study which continue to demonstrate ATYR1923's favorable safety profile in inflammatory lung conditions," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "We are very encouraged by the signal of clinical activity seen in the 3.0 mg/kg cohort of ATYR1923. The relatively faster time to recovery seen by adding a single dose of ATYR1923 to standard of care treatment and the greater proportion of patients recovering within a week compared to placebo give us further confidence in this signal."

The study demonstrated a preliminary signal of activity through clinical improvement in the high dose cohort with the assessment of time to recovery, defined as either achieving a WHO ordinal scale score of  $\leq 3$  or hospital discharge with no requirement of supplemental oxygen. Patients who received the 3.0 mg/kg dose of ATYR1923 experienced a median time to recovery of 5.5 days compared to 6 days in the placebo group. In addition, 83% of patients receiving the high dose of ATYR1923 achieved recovery by day 6, compared to 56% in the placebo arm. Patients in the 1.0 mg/kg treatment arm experienced a median time to recovery of 7 days. All patients in the study received standard of care treatment at the time of enrollment, which included remdesivir and/or dexamethasone.

Adverse events were mostly mild or moderate in severity and generally assessed as unrelated to the study drug. This is in line with previous safety assessments of ATYR1923, including an interim safety analysis from an ongoing Phase 1b/2a trial in patients with pulmonary sarcoidosis, a chronic form of interstitial lung disease. There were two deaths observed in the study, both in the 1.0 mg/kg treatment arm, which were deemed not related to ATYR1923 by an independent data safety monitoring board.

The Phase 2 clinical trial was a randomized, double blind, placebo-controlled study of ATYR1923 in 32 hospitalized COVID-19 patients with severe respiratory complications, who did not require mechanical ventilation, at hospitals in the U.S. and Puerto Rico. Patients enrolled in the trial were randomized 1:1:1 to a single IV dose of either 1.0 or 3.0 mg/kg of ATYR1923 or placebo. Patients were followed for 60 days post treatment. The study was not powered for statistical significance and was designed to evaluate safety and identify preliminary signs of activity of ATYR1923 as compared to placebo.

"Against the backdrop of the rapidly evolving standard of care for COVID-19 patients, we have reaffirmed the positive safety profile of ATYR1923 observed in our ongoing trial in patients with pulmonary sarcoidosis, a chronic form of inflammatory lung disease. We have also elucidated a signal of drug activity from a single 3.0 mg/kg dose of ATYR1923 in this small trial. I would like to thank the clinical sites, investigators and patients that contributed to these important findings," said Dr. Shukla.

aTyr Pharma will host a conference call and webcast to discuss the results today, January 4, at 5:00pm ET/2:00pm PT. Interested parties may access the call by dialing toll-free 844-358-9116 from the US, or 209-905-5951 internationally and using conference ID 8045947. Links to a live audio webcast and replay may be accessed on the aTyr website events page at: <http://investors.atyrpharma.com/events-and-webcasts>. An audio replay will be available for at least 90 days following the event.

### **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 recently completed enrollment in a proof-of-concept Phase 1b/2a trial evaluating ATYR1923 in patients with pulmonary sarcoidosis. 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 pharmacokinetic profile of multiple doses of ATYR1923. In response to the COVID-19 pandemic, aTyr completed a Phase 2 clinical trial with ATYR1923 in COVID-19 patients with severe respiratory complications. This Phase 2 study was a randomized, double blind, placebo-controlled study that was 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.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 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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