aTyr Pharma Announces Positive Biomarker Data from Phase 2 Clinical Trial of ATYR1923 Demonstrating Anti-Inflammatory Effects in COVID-19 Patients with Severe Respiratory Complications

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Data provides first-in-patient mechanistic proof-of-concept for ATYR1923.

ATYR1923 reduced key inflammatory cytokines that are implicated in sarcoidosis and other ILDs, consistent with findings from animal models.

SAN DIEGO, March 15, 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 biomarker 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 receiving standard of care, including remdesivir and/or dexamethasone, who did not require mechanical ventilation. Patients treated with ATYR1923 demonstrated a trend of overall improvement in key biomarkers analyzed compared to placebo. In particular, patients treated with ATYR1923 had greater reduction in levels of several inflammatory cytokines and chemokines, including interferon gamma (IFNγ), interleukin-6 (IL-6) and monocyte chemoattractant protein 1(MCP-1). Furthermore, patients treated with ATYR1923 also had a statistically significant reduction in levels of serum amyloid A (SAA), a marker of inflammation and fibrosis that has implications in sarcoidosis.

"We are very pleased with these findings, which provide the first mechanistic proof-of-concept for ATYR1923 in patients and demonstrate that ATYR1923 is impacting inflammation in patients consistent with what we have seen preclinically," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Notably, the cytokines that we saw reduced to the greatest extent as a result of ATYR1923 treatment in these COVID-19 patients are the same cytokines we have seen ATYR1923 downregulate in our animal models. We also saw an impact on SAA, a biomarker that is associated with disease progression in sarcoidosis, a highly inflammatory form of interstitial lung disease (ILD) and the lead indication in which ATYR1923 is being evaluated. These findings further support our understanding of ATYR1923's anti-inflammatory mechanism of action."

The biomarker results build upon the positive topline data the company released demonstrating that ATYR1923 met its primary safety endpoint and improved median time to recovery to 5.5 days in patients receiving a single dose of 3.0 mg/kg ATYR1923 vs 6 days in the placebo group. Demographic and baseline disease characteristics data included in the topline results showed that the ATYR1923 treatment groups had more patients over the age of 65, with severe hypoxia or with multiple comorbidities compared to placebo, factors associated with a greater risk of COVID-19 complications and worse outcomes. Biomarker data confirms that at baseline, patients enrolled in the ATYR1923 treatment arms compared to placebo had higher levels of inflammatory cytokines and known COVID-19 biomarkers including ferritin, D-dimer and C-reactive protein (CRP), indicating a more inflamed patient population in the ATYR1923 treatment arms.

"While this was a small study, overall trends showing a reduction of these biomarkers combined with the higher baseline levels in the ATYR1923 treatment groups suggest that we have drug activity and ATYR1923 appears to provide an added anti-inflammatory benefit even when given concomitantly with steroids. These findings further demonstrate the potential of ATYR1923 as a therapeutic for severe inflammatory lung disease, including pulmonary sarcoidosis and other ILD," said Dr. Shukla.

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.

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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