aTyr Pharma Announces Dosing of First Patient in Phase 2 Trial of ATYR1923 in COVID-19 Patients with Severe Respiratory Complications

June 15, 2020

Trial opens for enrollment of hospitalized patients at multiple centers throughout the U.S.

SAN DIEGO, June 15, 2020 (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 that it has dosed the first patient in a Phase 2 study evaluating its lead therapeutic candidate, ATYR1923, in COVID-19 patients with severe respiratory complications. The study is expected to enroll 30 patients at up to 10 centers in the U.S. and the company expects to have the majority of centers enrolling within the coming weeks.

ATYR1923 is a potential first-in-class immunomodulator that has been shown preclinically to downregulate T-cell responses and improve inflammation and lung function. ATYR1923 is currently being evaluated in a Phase 1b/2a multi-center trial for patients with pulmonary sarcoidosis, a serious inflammatory lung disease. There is strong scientific rationale for the hypothesis that ATYR1923 may help regulate the excessive inflammatory response in the lungs, primarily driven by T-cells, seen in many COVID-19 patients.

“As patients continue to be hospitalized due to COVID-19 throughout the U.S., there is a need for effective therapies to treat severe inflammation associated with this disease. ATYR1923 is a novel therapeutic candidate specifically designed to address aberrant immune response and inflammation in the lung,” said Dr. Sanjay Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. “This is an important step forward to assess the potential utility of ATYR1923 in this subset of COVID-19 patients who experience serious respiratory complications that can lead to longer hospitalization stays and in some cases the need for mechanical ventilation and intensive care treatment.”

The Phase 2 clinical trial is a randomized, double blind, placebo-controlled study of ATYR1923 in hospitalized COVID-19 positive patients with severe respiratory complications who do not require mechanical ventilation. Patients enrolled in the trial will be assigned to one of three cohorts of 10 patients each. Patients will receive a single intravenous (IV) dose of either 1.0 or 3.0 mg/kg ATYR1923 or placebo. Patients will be 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 such as fever and hypoxia as well as inflammatory biomarkers.

“We are encouraged by the significant interest that we have received from respiratory specialists throughout the country wanting to participate in this trial. We have currently initiated five sites and expect the majority of sites to be active within the coming weeks. We look forward to completing this important study and report data from this trial later this year,” said Dr. Shukla.

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 recently initiated 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 immunological 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 the potential therapeutic benefits and applications of ATYR1923; timelines and plans with respect to 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 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 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 of unexpected expenses or other demands on our cash resources, 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:
Joyce Allaire
Managing Director, LifeSci Advisors, LLC
jallaire@lifesciadvisors.com

Source: aTyr Pharma, Inc.