



aTyr Pharma Announces Phase 2 Study of ATYR1923 in COVID-19 Patients with Severe Respiratory Complications Following FDA Acceptance of IND Application

April 21, 2020

SAN DIEGO, April 21, 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 the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application to evaluate its lead therapeutic candidate, ATYR1923, in a Phase 2 study in COVID-19 patients with severe respiratory complications.

"Many COVID-19 patients with severe disease experience serious, sometimes fatal, respiratory complications caused by an excessive inflammatory response in the lung, primarily driven by T-cells," said Dr. Sanjay Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "The inflammatory lung injury related to COVID-19 may be similar to that of interstitial lung diseases, or ILDs, for which ATYR1923 is currently being investigated."

ATYR1923 has been shown pre-clinically to downregulate T-cell responses, thereby dampening the inflammatory cytokine and chemokine signaling that has been implicated in these severe COVID-19 cases. ATYR1923 has also been shown to improve lung function, as well as to reduce inflammation and fibrosis, in multiple animal models of immune-mediated acute lung injury.

"We believe there is strong scientific rationale for the development of ATYR1923 to treat COVID-19 patients," said Dr. Shukla. "By targeting aberrant immune responses, we believe that ATYR1923's mechanism of action has substantial overlap with this disease pathology and presents a compelling opportunity to potentially treat this subset of COVID-19 patients for which there are no approved therapies. We look forward to urgently implementing and advancing this important study as we seek to play a significant role in the global battle against COVID-19."

The Phase 2 clinical trial will be a randomized, double blind, placebo-controlled study with ATYR1923 in 30 confirmed COVID-19 positive patients at up to 10 centers in the United States. 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. The study will look to demonstrate safety and preliminary efficacy of ATYR1923 in COVID-19 patients with severe respiratory complications.

Interim safety data results from a Phase 1b/2a study of ATYR1923 in patients with pulmonary sarcoidosis were announced in December 2019. Study drug (ATYR1923 or placebo) was observed to be generally safe and well tolerated with no drug-related serious adverse events, consistent with Phase 1 study results in healthy volunteers.

About ATYR1923

aTyr is developing ATYR1923 as a potential therapeutic for patients with interstitial 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. 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.

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 interstitial 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 Litigation Reform Act. 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 our product candidates; our ability to successfully advance our product candidates, undertake 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 accomplish certain development goals, and the timing of such events; and the scope and strength of our intellectual property portfolio. 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, 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.