



aTyr Pharma Announces Positive Interim Safety Results from Ongoing Phase 1b/2a Clinical Trial of ATYR1923

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ATYR1923 safe and well tolerated in initial 15 randomized patients with pulmonary sarcoidosis

No drug-related serious adverse events observed

SAN DIEGO, Dec. 12, 2019 (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 the results of a pre-planned, blinded interim analysis of safety and tolerability, the primary endpoint of its ongoing Phase 1b/2a clinical trial of its lead therapeutic candidate, ATYR1923, in patients with pulmonary sarcoidosis. Study drug (ATYR1923 or placebo) was observed to be generally safe and well tolerated with no drug-related serious adverse events (SAEs), consistent with the earlier Phase 1 study results in healthy volunteers. Adverse events (AEs) were mostly mild or moderate in severity and assessed by the study investigators as unrelated to study drug.

"We are very encouraged by these initial safety findings which provide an early indication for ATYR1923 meeting our expectations for the primary endpoint of safety and tolerability," said Sanjay Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Having accomplished this first important interim step in our study, we can now also begin to focus on demonstrating activity of ATYR1923. Pulmonary sarcoidosis and other interstitial lung diseases present a significant opportunity for novel therapeutic approaches that can ideally slow or halt disease progression and the resulting decline in lung function. These favorable interim safety results allow us to advance our trial to provide evidence of the potential of ATYR1923 as a treatment option to improve the lives of patients with pulmonary sarcoidosis."

Phase 1a/2b clinical trial design:

This Phase 1b/2a study is a multiple-ascending dose, placebo-controlled, first-in-patient study of ATYR1923 that has been designed to evaluate safety, tolerability and immunogenicity of multiple doses of ATYR1923, as well as to evaluate established clinical endpoints and potential biomarkers to assess preliminary efficacy. The study is being conducted in partnership with the Foundation for Sarcoidosis Research (FSR).

Additional highlights from the interim safety analysis:

Interim safety data results announced today are from 15 pulmonary sarcoidosis patients who have received a minimum of one dose of blinded study drug (ATYR1923 or placebo). The average age of patients evaluated was approximately 51 years. The patient population consisted of 53% males and 47% females, of which 73% were Caucasian and 27% were African American. No induction of anti-drug antibodies was observed with repeat dosing of study drug. There were no notable trends for clinical laboratory values or vital signs.

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 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. aTyr is focused on the therapeutic translation of the Resokine pathway, comprised of extracellular proteins derived from the histidyl tRNA synthetase gene family. ATYR1923 is a clinical-stage product candidate which binds to the neuropilin-2 receptor and is designed to down-regulate immune engagement in interstitial lung diseases and other immune-mediated 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, including 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 continued conduct of clinical trials and the announcement of top-line results) and accomplish certain development goals, and the timing of such events; and the potential markets for our product candidates. 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 risk that interim clinical results may not be predictive of later or final results, 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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