aTyr Pharma Presents Clinical Data for Efzofitimod (ATYR1923) at the American Thoracic Society 2022 International Conference

May 17, 2022

Results from Phase 1b/2a study of efzofitimod in pulmonary sarcoidosis patients demonstrate dose-dependent improvements in key physiologic and quality of life measures in context of a steroid taper.

Efzofitimod treatment reduces pro-inflammatory serum biomarkers in pulmonary sarcoidosis patients.

Global pivotal Phase 3 EFZO-FIT™ study on track to initiate in the third quarter of 2022.

SAN DIEGO, May 17, 2022 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of innovative medicines from its proprietary tRNA synthetase biology platform, today announced that clinical data for efzofitimod (ATYR1923), its lead therapeutic candidate, will be presented in two posters today from 11:15AM – 1:15PM PT at the American Thoracic Society (ATS) 2022 International Conference in San Francisco, CA.

“These posters present the clinical proof-of-concept data from the recently completed Phase 1b/2a study of efzofitimod in patients with pulmonary sarcoidosis. Efzofitimod was safe and well tolerated and demonstrated dose-dependent improvements in key physiologic and quality of life measures in the context of a steroid taper, which according to medical experts, is the first study of any therapy to do so in pulmonary sarcoidosis patients,” said Sanjay S. Shukla, M.D., M.S., President and CEO of aTyr. “Based on these findings, we are advancing efzofitimod to a pivotal Phase 3 study, which we expect to initiate in the third quarter of this year. EFZO-FIT ™, a global, multi-center study to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis, will be the first study in this patient population to evaluate steroid reduction as the primary endpoint and presents an opportunity to deliver a transformative therapy with clinically meaningful outcomes to these patients.”

Details of the poster presentations appear below. The corresponding abstracts are available for review online on the conference website. The posters will be available on the aTyr website once presented.

Title: Safety and Efficacy ATYR1923, a Novel Immunomodulator for Pulmonary Sarcoidosis: Results of a Phase 1b/2a Randomized Placebo-Controlled Trial
Abstract Number: 3932
Poster Number: P559
Poster Session: Inflammatory Modulation in Sarcoidosis, Lung Transplant, and Other Diseases
Date and Time: Tuesday, May 17, 2022 from 11:15AM – 1:15PM PT
Location: Area G, Hall F (North Building, Exhibition Level), Moscone Center

The poster presents findings from a Phase 1b/2a randomized, double-blind, placebo-controlled study of efzofitimod (ATYR1923) in patients with pulmonary sarcoidosis. Monthly dosing of efzofitimod was safe and well tolerated. There was a dose-dependent improvement in efficacy parameters, including corticosteroid (CS) taper, percent-predicted forced vital capacity (FVCPP), and patient reported outcomes. All efzofitimod treatment groups had lower CS use at week 24 compared to placebo, with the largest difference observed in the 5.0 mg/kg treatment group, where three patients were able to taper off CS completely and maintain that taper through the completion of the study. The two higher doses of efzofitimod, 3.0 mg/kg and 5.0 mg/kg, resulted in improvements in FVCPP and percent-predicted diffusing capacity of the lungs for carbon monoxide ($DL_{CO}PP$) through week 24 compared to placebo. Clinically meaningful and statistically significant improvements at week 24 were observed for key symptom measures in the 5.0 mg/kg treatment group. In small studies such as this, which was not powered for statistical significance, dose dependent improvements are strong evidence for efficacy.

Title: ATYR1923 Treatment Reduces Pro-Inflammatory Serum Biomarkers in Pulmonary Sarcoidosis Patients
Abstract Number: 3933
Poster Number: P560
Poster Session: Inflammatory Modulation in Sarcoidosis, Lung Transplant, and Other Diseases
Date and Time: Tuesday, May 17, 2022 from 11:15AM – 1:15PM PT
Location: Area G, Hall F (North Building, Exhibition Level), Moscone Center

The poster presents clinical biomarker findings from a Phase 1b/2a randomized, double-blind, placebo-controlled study of efzofitimod (ATYR1923) in patients with pulmonary sarcoidosis. Efzofitimod demonstrated dose dependent control of inflammatory and sarcoidosis disease biomarkers over 24 weeks in the context of a corticosteroid taper. The affected inflammatory biomarkers, including IFN-γ, IL-6, IP-10, MCP-1 and TNFa, and key markers of sarcoidosis, including IL-2Ra, SAA, ACE enzyme and ACE protein, are key drivers of sarcoidosis and other interstitial lung disease and consistent with results from preclinical animal models and a Phase 2 study of efzofitimod in hospitalized COVID-19 pneumonia patients. These results are the first demonstration of efzofitimod’s anti-inflammatory mechanism in patients with pulmonary sarcoidosis. These analyses were exploratory and not adjusted for multiplicity to control for false positive results and will need to be confirmed in a larger study.

An additional abstract further exploring the molecular and cellular mechanism of action of efzofitimod in sarcoidosis that was also accepted for presentation will instead be submitted for inclusion at another medical conference later this year.

About Efzofitimod

aTyr is developing efzofitimod as a potential therapeutic for patients with fibrotic lung disease. Efzofitimod, 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

innate and adaptive immune response in inflammatory disease states. aTyr's lead indication for efzofitimod is pulmonary sarcoidosis, a major form of interstitial lung disease. Clinical proof-of-concept for efzofitimod was recently established in a Phase 1b/2a multiple-ascending dose, placebo-controlled study of efzofitimod in patients with pulmonary sarcoidosis, which demonstrated safety and a consistent dose response and trends of benefit of efzofitimod compared to placebo on key efficacy endpoints, including steroid reduction, lung function, clinical symptoms and inflammatory biomarkers. aTyr intends to initiate EFZO-FIT ™, a Phase 3 study of efzofitimod in pulmonary sarcoidosis patients, in the third quarter of 2022.

About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of innovative medicines from its proprietary tRNA synthetase biology platform. 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 efzofitimod, a clinical-stage product candidate which binds to the neuropilin-2 receptor and is designed to downregulate immune engagement in fibrotic lung disease. For more information, please visit 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 efzofitimod; timelines and plans with respect to certain development activities (such as the timing of 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC on May 10, 2022 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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Source: aTyr Pharma, Inc.