aTyr Pharma Announces Second Positive DSMB Review for Efzofitimod in Phase 3 EFZO-FIT™ Study in Pulmonary Sarcoidosis

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Independent data and safety monitoring board (DSMB) recommends continuation of study without any modifications.

Findings further support favorable safety profile of efzofitimod.

SAN DIEGO, May 14, 2024 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE) (aTyr or the "Company"), a clinical stage biotechnology company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced that an independent data and safety monitoring board (DSMB) recommended that the ongoing Phase 3 EFZO-FIT ™ study of its lead therapeutic candidate, efzofitimod, in patients with pulmonary sarcoidosis could continue without any modifications after a second pre-planned, interim analysis.

"This second DSMB review for EFZO-FIT™ builds upon the favorable safety profile seen with efzofitimod to date. We expect to conduct additional DSMB reviews as we progress throughout the study," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Current standard of care for patients with pulmonary sarcoidosis includes oral corticosteroids, which can incur significant side effects and toxicity. Efzofitimod has the potential to be a safe, non-steroidal treatment option for these patients, which is greatly needed."

EFZO-FIT ™is a global Phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis. This is a 52-week study consisting of three parallel cohorts randomized equally to either 3.0 mg/kg or 5.0 mg/kg of efzofitimod or placebo dosed intravenously once a month for a total of 12 doses. The study intends to enroll up to 264 subjects with pulmonary sarcoidosis at multiple centers in the United States, Europe, Japan and Brazil. The trial design incorporates a forced steroid taper. The primary endpoint of the study is steroid reduction. Secondary endpoints include measures of lung function and sarcoidosis symptoms. More information on the EFZO-FIT ™study is available at www.clinicaltrials.gov (NCT05415137) and www.efzofit.com.

About Efzofitimod

Efzofitimod is a first-in-class biologic immunomodulator in clinical development for the treatment of interstitial lung disease (ILD), a group of immune-mediated disorders that can cause inflammation and fibrosis, or scarring, of the lungs. Efzofitimod is a tRNA synthetase derived therapy that selectively modulates activated myeloid cells through neuropilin-2 to resolve inflammation without immune suppression and potentially prevent the progression of fibrosis. aTyr is currently investigating efzofitimod in the global Phase 3 EFZO-FIT™ study in patients with pulmonary sarcoidosis, a major form of ILD, and in the Phase 2 EFZO-CONNECT™ study in patients with systemic sclerosis (SSc, or scleroderma)-related ILD. These forms of ILD have limited therapeutic options and there is a need for safer and more effective, disease-modifying treatments that improve outcomes.

About aTyr

aTyr is a clinical stage biotechnology company leveraging evolutionary intelligence to translate tRNA synthetase biology into new therapies for fibrosis and inflammation. tRNA synthetases are ancient, essential proteins that have evolved novel domains that regulate diverse pathways extracellularly in humans. aTyr's discovery platform is focused on unlocking hidden therapeutic intervention points by uncovering signaling pathways driven by its proprietary library of domains derived from all 20 tRNA synthetases. aTyr's lead therapeutic candidate is efzofitimod, a first-in-class biologic immunomodulator in clinical development for the treatment of interstitial lung disease, a group of immune-mediated disorders that can cause inflammation and progressive fibrosis, or scarring, of the lungs. 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 "anticipate," "believes," "designed," "can," "expects," "intends," "may," "plans," "potential," "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, among others, statements regarding the clinical development for efzofitimod, including the potential of efzofitimod to be an improved treatment for pulmonary sarcoidosis over the standard of care, the timing and results of future DSMB reviews, and our expectations with respect to the conduct, timing, enrollment, and results of EFZO-FIT™. 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, strategies or prospects 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 geopolitical and macroeconomic events, risks associated with the discovery, development and regulation of efzofitimod, the risk that we or our partners may cease or delay preclinical or clinical development activities for efzofitimod 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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