aTyr Pharma Completes Enrollment in Global Pivotal Phase 3 EFZO-FIT™ Study of Efzofitimod in Pulmonary Sarcoidosis

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Study enrolled 268 patients, exceeding target enrollment.

Largest interventional study ever to be conducted in pulmonary sarcoidosis.

Topline data are expected in the third quarter of 2025.

SAN DIEGO, July 22, 2024 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: ATYR), 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 it has completed enrollment in its global pivotal Phase 3 EFZO-FIT™ study of its lead therapeutic candidate, efzofitimod, in patients with pulmonary sarcoidosis, a major form of interstitial lung disease with limited treatment options. The study enrolled 268 patients at 85 centers in 9 countries, exceeding target enrollment. Topline data from the study are expected in the third quarter of 2025.

“Completing enrollment in this landmark study is an important milestone that brings us one step closer to delivering a potentially groundbreaking treatment to address the significant unmet need for pulmonary sarcoidosis patients,” said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. “We are grateful to all of the patients and their caregivers, our principal investigators and their teams, our many advocacy partners and our partner Kyorin Pharmaceutical Co., Ltd., who helped make this accomplishment possible. The historic number of patients enrolled in this study signifies the strong patient demand for a new treatment option such as efzofitimod.”

“This is a monumental achievement for the sarcoidosis community. It is by far the largest interventional study ever to be conducted in sarcoidosis. We expect the results of this trial to yield valuable insights that will inform sarcoidosis research and treatment in the years to come,” said Daniel A. Culver, D.O., Chair of the Division of Pulmonary Medicine at The Cleveland Clinic and Lead Primary Investigator of the study. “We are optimistic based on the positive Phase 1b/2a results that efzofitimod could be a potentially transformative therapy for sarcoidosis patients, which is greatly needed. We look forward to the readout from this study in 2025.”

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. Efzofitimod has received orphan drug designation in the U.S., E.U. and Japan for sarcoidosis and Fast Track designation in the U.S. for pulmonary sarcoidosis.

About the EFZO-FIT ™Study

The EFZO-FIT ™study 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 enrolled 268 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 benefits and therapeutic application of efzofitimod, timelines and plans with respect to certain development activities (such as the timing of data from clinical trials), the potential

benefits of the EFZO-FIT ™ study results to other research and treatment 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, 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, risks associated with clinical trials and their resulting data generally, 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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