aTyr Pharma Announces Dosing of First Patient in Pivotal Phase 3 EFZO-FIT™ Study of Efzofitimod in Patients with Pulmonary Sarcoidosis

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Multiple centers in the U.S. are open for enrollment for double-blind, randomized, placebo-controlled study.

Primary endpoint will evaluate steroid-sparing effect of efzofitimod compared to placebo.

EFZO-FIT™ builds on positive results from Phase 1b/2a study which demonstrated dose dependent improvements across steroid reduction, lung function and symptom control endpoints.

SAN DIEGO, Sept. 27, 2022 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced that it has dosed the first patient in the global pivotal EFZO-FIT™ study. The Phase 3 study will evaluate the efficacy and safety of the company's lead therapeutic candidate, efzofitimod, compared to placebo in patients with pulmonary sarcoidosis, a major form of interstitial lung disease (ILD).

Efzofitimod is a first-in-class immunomodulator that downregulates innate and adaptive immune responses in uncontrolled inflammatory diseases states via selective modulation of neuropilin-2 (NRP2). The design of the EFZO-FIT™ study is supported by safety and efficacy data from a Phase 1b/2a study of efzofitimod in patients with pulmonary sarcoidosis. Efzofitimod has been granted FDA Orphan Drug and Fast Track designations for sarcoidosis.

"We are delighted to begin patient dosing in EFZO-FIT™. With multiple centers in theU.S. open for enrollment, this very important study for patients with pulmonary sarcoidosis is underway," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "This is an important step forward to delivering a transformative, disease modifying therapy that we believe can reduce the burden of steroids and provide clinically meaningful outcomes for patients with this complex disease."

"We are excited to collaborate with aTyr as they advance this study of a promising new treatment that could potentially improve the lives of sarcoidosis patients worldwide," said Mary McGowan, Chief Executive Officer of the Foundation for Sarcoidosis Research.

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 intends to enroll 264 subjects with pulmonary sarcoidosis at multiple centers in North America, Europe and Japan. The trial design will incorporate 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 Pulmonary Sarcoidosis

Sarcoidosis is an immune-mediated disease characterized by the formulation of granulomas, clumps of inflammatory cells, in one or more organs of the body, predominantly in the lungs. Almost 200,000 Americans live with pulmonary sarcoidosis and the prognosis ranges from benign and self-limiting to chronic, debilitating disease, with 1 in 5 cases resulting in fibrosis, or scarring, of the lungs, which causes permanent loss of lung function and in many cases death. Current treatment options include corticosteroids and other immunosuppressive therapies, which have limited efficacy and are associated with serious side effects that many patients cannot tolerate long-term.

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 is currently conducting EFZO-FIT ™, a Phase 3 study of efzofitimod in pulmonary sarcoidosis patients.

About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase 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 of efzofitimod and plans with respect to certain clinical activities. 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 June 30, 2022 filed with the SEC on August 15, 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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