aTyr Pharma Announces Dosing of First Patient in Phase 2 EFZO-CONNECT™ Study of Efzofitimod in Patients with SSc-ILD

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Multiple centers in the U.S. are open for enrollment

SAN DIEGO, Oct. 31, 2023 (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 it has dosed the first patient in its Phase 2 EFZO-CONNECT™ study. The proof-of-concept study will evaluate the efficacy, safety and tolerability of the Company's lead therapeutic candidate, efzofitimod, compared to placebo in patients with systemic sclerosis (SSc, or scleroderma)-related interstitial lung disease (ILD).

Efzofitimod is a first-in-class biologic immunomodulator that selectively modulates activated myeloid cells through neuropilin-2 (NRP2) to resolve inflammation without immune suppression and potentially prevent the progression of fibrosis. Efzofitimod has been granted U.S. Food and Drug Administration (FDA) and European Union orphan drug and U.S. FDA Fast Track designations for SSc.

"We are very pleased to begin patient dosing in EFZO-CONNECT™, which is our second clinical study for efzofitimod in ILD," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Efzofitimod has been shown preclinically to reduce lung and skin fibrosis in models of SSc, and NRP2, efzofitimod's binding partner, is expressed in the skin of SSc patients. We believe there is compelling rationale that efzofitimod has the potential to target the underlying disease pathology central to this form of ILD and positively impact lung function and improve outcomes in these patients."

"Patients with SSc-ILD have limited treatment options and poor prognosis, with ILD being their leading cause of death," said Kristin Highland, M.D., Director, Rheumatic Lung Disease Program at the Cleveland Clinic. "This study, which evaluates a therapy that targets the inflammatory and fibrotic characteristics of this disease, is an important step forward towards developing a treatment that can potentially improve the prognosis and quality of life for patients in need."

The Phase 2 study is a randomized, double-blind, placebo-controlled, proof-of-concept study to evaluate the efficacy, safety and tolerability of efzofitimod in patients with SSc-ILD. This is a 28-week study with three parallel cohorts randomized 2:2:1 to either 270 mg or 450 mg of efzofitimod or placebo dosed intravenously monthly for a total of 6 doses. The study intends to enroll 25 patients at multiple centers in the United States. The primary objective of the study is to evaluate the efficacy of multiple doses of intravenous efzofitimod on pulmonary, cutaneous and systemic manifestations in patients with SSc-ILD. Secondary objectives include safety and tolerability.

More information on the EFZO-CONNECT ™study is available at www.clinicaltrials.gov (NCT05892614).

About SSc-ILD

Systemic sclerosis is a chronic, progressive, autoimmune disease characterized by inflammation and fibrosis of connective tissues throughout the body, including the skin and other internal organs. SSc that occurs in the lungs is called SSc-ILD. It is estimated that approximately 100,000 people in the U.S. are affected by SSc and up to 80% may develop ILD. SSc-ILD causes inflammation in the lungs and, if left untreated, can result in scarring, or fibrosis, that causes permanent loss of lung function. ILD is the primary cause of death in patients with SSc. Current treatment options for SSc-ILD are limited, mainly focus on slowing lung function decline and are associated with significant toxicity.

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 "believes," "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 enrollment of patients in the EFZO-CONNECT™ study and the potential of efzofitimod to target the

underlying disease pathology, positively impact lung function and improve outcomes in patients with SSc-ILD. 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 Report on Form 10-Q and in our subsequent 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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