aTyr Pharma Announces Expanded Access Program (EAP) for EFZO-FIT™ Clinical Trial Participants

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Individual Patient EAP allows access to efzofitimod for patients who complete the Phase 3 EFZO-FIT ™study in pulmonary sarcoidosis.

Company initiating program based on blinded EFZO-FIT ™study investigator and patient participant feedback.

SAN DIEGO, Feb. 21, 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 plans to initiate an Individual Patient Expanded Access Program (EAP) for its lead therapeutic candidate, efzofitimod, for patients with pulmonary sarcoidosis. The Individual Patient EAP is intended to allow access for patients who complete the Phase 3 EFZO-FIT™ study and wish to receive treatment with efzofitimod outside of the clinical trial.

"We are pleased to make efzofitimod available to patients beyond the duration of the EFZO-FIT™ clinical trial through this Individual Patient EAP," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Based on interest from Principal Investigators (PIs) and patients who have or are in the process of completing the EFZO-FIT™ study, we have decided to implement this program in part to continue to support those patients who have dedicated their time and entrusted us with their health by participating in this important study. This program reflects our ongoing commitment to the sarcoidosis community as we work to develop a safe and effective treatment for a condition that has a high unmet medical need."

EAPs are designed to provide access to potential therapies before they are approved by the U.S. Food and Drug Administration (FDA). Sometimes called "compassionate use," Expanded Access is a pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic or medical device) for treatment outside of clinical trials when no satisfactory alternative therapy options are available.

By implementing the EAP, the Company does not anticipate any risk to its efzofitimod drug supply, which it believes to be adequate for its two ongoing clinical trials, or expect a significant impact to its financial resources. The administration of efzofitimod as part of the Individual Patient EAP will occur independent of the EFZO-FIT™ study protocol, and the Company, PIs and patients will remain blinded to the treatment that occurred as part of the EFZO-FIT™ study. As this EAP will occur independent of the EFZO-FIT™ study, this program is not an open-label extension (OLE) and no long-term data will be collected by the Company.

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 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 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 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 implementation, timing, availability and protocols of an Individual Patient EAP for patients with pulmonary sarcoidosis, the benefits patients may derive from the Individual Patient EAP, and anticipated effects of the Individual Patient EAP on the Company's efzofitimod drug supply, its ongoing clinical trials and its financial resources. 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, possible unavailability of, or unexpected results in, the Individual Patient EAP, unanticipated effects on the Company's efzofitimod drug supply, 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.

Contact:
Ashlee Dunston
Director, Investor Relations and Public Affairs
adunston@atyrpharma.com

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