



aTyr Pharma Announces Achievement of Development Milestone by Partner Kyorin Pharmaceutical, Co., Ltd.

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\$10M milestone payment triggered by advancement of clinical program in Japan.

Multiple centers in the U.S. and Japan are now open for enrollment.

SAN DIEGO, Feb. 06, 2023 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE) (aTyr or the Company), a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced that its partner Kyorin Pharmaceutical Co., Ltd. (Kyorin), a wholly owned subsidiary of Kyorin Holdings, Inc., has dosed the first patient in Japan in EFZO-FIT™, a global pivotal Phase 3 study to evaluate the efficacy and safety of the Company's lead therapeutic candidate, efzofitimid, in patients with pulmonary sarcoidosis, a major form of interstitial lung disease (ILD). This achievement has triggered a \$10 million milestone payment by Kyorin to aTyr pursuant to a collaboration and license agreement between the Company and Kyorin.

Efzofitimid 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 efzofitimid in patients with pulmonary sarcoidosis. Efzofitimid has been granted U.S. Food and Drug Administration (FDA) and E.U. orphan drug and FDA Fast Track designations for sarcoidosis.

"We are very pleased with Kyorin's timely start to EFZO-FIT™ and are happy to have centers open for enrollment in Japan, which is an important part of this large, global study," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Kyorin is responsible for the clinical development of efzofitimid for ILD in Japan and is an essential partner for aTyr as we work to bring this transformative, disease modifying therapy to sarcoidosis patients."

"This study is an important step towards offering a potential new treatment to ILD patients who are with limited medical treatment options in Japan; therefore, the initiation of this study is of much value to Kyorin," said Yutaka Ogihara, President and Chief Executive Officer of Kyorin Holdings, Inc.

Kyorin is aTyr's partner for the development and commercialization of efzofitimid for ILD in Japan. Under the collaboration and license agreement with Kyorin, aTyr has generated \$20 million in upfront and milestone payments to date and is eligible to receive up to an additional \$155 million in the aggregate upon the achievement of certain development, regulatory and sales milestones, as well as tiered royalties on any net sales in Japan. Kyorin has the exclusive rights to develop and commercialize efzofitimid in Japan for all forms of ILD.

The EFZO-FIT™ study is a global Phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of efzofitimid 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 efzofitimid 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 the United States, Europe and Japan. 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 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 Efzofitimid

aTyr is developing efzofitimid as a potential therapeutic for patients with fibrotic lung disease. Efzofitimid, a fusion protein comprised of the immunomodulatory 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 efzofitimid is pulmonary sarcoidosis, a major form of interstitial lung disease. Clinical proof-of-concept for efzofitimid was recently established in a Phase 1b/2a multiple-ascending dose, placebo-controlled study of efzofitimid in patients with pulmonary sarcoidosis, which demonstrated safety and a consistent dose response and trends of benefit of efzofitimid 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 efzofitimid 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 efzofitimid, 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.

About Kyorin

Trusted among patients and professionals in the medical industry, Kyorin Pharmaceutical Co., Ltd. strives to be a company recognized as the one with social significance by improving its presence in the specific therapeutic areas and through its global discovery of novel drugs. Kyorin Pharmaceutical Co., Ltd. uses franchise customer strategy where its marketing efforts are focused on respiratory, otolaryngology and urology. In drug discovery, it is deploying 'selection and concentration' and promoting activities aimed at first-in-class drug discovery, such as actively searching for and introducing external drug discovery themes as well as multi-tiered program development. For more information, please visit <http://www.kyorin-pharm.co.jp>.

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 "intends," "towards," "potential," "plans," 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 efzofitimid, including offering a potential new treatment to ILD patients who are with limited medical treatment options in Japan and plans with respect to certain clinical activities, including the enrollment plans of the EFZO-FIT™ study. 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 September 30, 2022 filed with the SEC on November 10, 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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