aTyr Pharma Announces First Quarter 2023 Results and Provides Corporate Update

May 9, 2023

Phase 3 EFZO-FIT™ study of efzofitimod in patients with pulmonary sarcoidosis currently enrolling in the U.S., Europe and Japan.

Phase 2 proof-of-concept study of efzofitimod in patients with SSc-ILD expected to initiate in the third quarter of 2023.

Company to host multiple presentations for efzofitimod at the upcoming American Thoracic Society (ATS) 2023 International Conference.

February follow-on common stock offering generated $48.1 million in net proceeds.

Ended the first quarter 2023 with $117.6 million in cash, cash equivalents and investments.

SAN DIEGO, May 09, 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 first quarter 2023 results and provided a corporate update.

"We are pleased with the start to the year and the progress we have made with our efzofitimod clinical development program for interstitial lung disease (ILD)," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Our global pivotal Phase 3 EFZO-FIT™ study in patients with pulmonary sarcoidosis, the most prevalent form of ILD, continues to enroll in the U.S., Europe and Japan, and we are on track with our plans to initiate a Phase 2 study in patients with systemic sclerosis (SSc, or scleroderma)-associated ILD (SSc-ILD), a major form of connective tissue disease-related ILD, in the third quarter of this year."

"We finished the first quarter of 2023 with $117.6 million in cash, cash equivalents and investments. With our current cash position and the opportunity for additional milestone payments from our partner Kyorin Pharmaceutical Co., Ltd., we believe we are well capitalized to complete and read out our two efzofitimod clinical trials."

First Quarter 2023 and Subsequent Period Highlights

- **Continued enrollment in the global pivotal Phase 3 EFZO-FIT ™ study to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis.** This is a randomized, double-blind, placebo-controlled, 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 monthly for a total of 12 doses. The study intends to enroll up to 264 subjects with pulmonary sarcoidosis. Enrollment is in progress at centers in the U.S., Europe and Japan.
- **Progressed plans to initiate a Phase 2 proof-of-concept study to evaluate the efficacy, safety and tolerability of efzofitimod in patients with SSc-ILD**. This study will be a randomized, double-blind, placebo-controlled, 28-week study consisting of 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 is expected to enroll 25 patients at multiple centers in the U.S. The primary objective of the study will be to evaluate the efficacy of multiple doses of intravenous efzofitimod on pulmonary, cutaneous and systemic manifestations in patients with SSc-ILD. The study is expected to initiate in the third quarter of 2023.
- **Announced the publication of the first review article for efzofitimod in the peer-reviewed journal *Sarcoidosis, Vasculitis and Diffuse Lung Diseases***. In the article, titled, "Efzofitimod: a novel anti-inflammatory agent for sarcoidosis," the authors, led by Robert P. Baughman, M.D., Professor of Medicine at the University of Cincinnati Medical Center, describe the mechanism for efzofitimod as it relates to the granulomatous inflammation central to the pathophysiology of sarcoidosis and review the preclinical and clinical data generated for efzofitimod that support its anti-inflammatory properties and the potential for it to be a novel therapeutic approach to immune-mediated fibrotic lung diseases such as pulmonary sarcoidosis.
- **Announced multiple presentations for efzofitimod at the upcoming American Thoracic Society (ATS) 2023 International Conference.** The conference is scheduled to take place May 19 – 24, 2023, in Washington, D.C.
    - **Respiratory Innovation Summit –** Showcase Five: Fibrosis Innovators on Saturday, May 20, 2023, at 3:45 p.m.
    - **Mini Symposium 9209 –** Efzofitimod, a Novel Immunomodulator for Pulmonary Sarcoidosis, Modulates Patient Inflammatory Responses Through Myeloid Cells on Monday, May 22, 2023, at 3:15 p.m.
    - **Thematic Poster P645 –** Exposure-Efficacy Analysis Supports Proof of Concept for Efzofitimod in Pulmonary Sarcoidosis on Tuesday, May 23, 2023, from 11:30 a.m. to 1:15 p.m.
    - **Industry Theater Presentation –** Efzofitimod: An Emerging Treatment for Sarcoidosis? on Tuesday, May 23, 2023, at 1:30 p.m.

First Quarter 2023 Financial Highlights and Cash Position

- **Cash & Investment Position:** Cash, restricted cash, cash equivalents and investments as of March 31, 2023, were

$117.6 million. During the first quarter of 2023, the Company raised net proceeds of $48.1 million through the public offering of common stock. Based on the Company's current operational plans and existing cash, the Company maintains its prior guidance and believes its cash runway will extend into 2026.

- **R&D Expenses:** Research and development expenses were $9.4 million for the first quarter 2023, which consisted primarily of clinical trial costs for the Phase 3 EFZO-FIT™ study, manufacturing costs for the efzofitimod program and research and development costs for the efzofitimod and discovery programs.
- **G&A Expenses:** General and administrative expenses were $3.4 million for the first quarter 2023.

About Efzofitimod

aTyr is developing efzofitimod as a potential therapeutic for patients with fibrotic lung disease. Efzofitimod, 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 immune responses 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 "believes," "expects," "intends," "may," "plans," "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 our belief that we will have sufficient cash to fund both of our efzofitimod clinical trials and the company's operations into 2026; the expected size of, and number of patients to be enrolled in, the EFZO-FIT™ study; the potential therapeutic benefits and applications of efzofitimod and our discovery programs; and timelines and plans with respect to certain development activities and development goals, including our expectation that our Phase 2 proof-of-concept study of efzofitimod in patients with SSc-ILD will begin in the third quarter of 2023. 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, our assumptions and expectations underlying our belief that we will have sufficient cash runway into 2026 may not be accurate, the fact that NRP2 and tRNA synthetase biology is not fully understood, uncertainty regarding macroeconomic and geopolitical conflicts, the risk of delays in our clinical trials, risks associated with the discovery, development and regulation of our product candidates, including the risk that results from clinical trials or other studies may not support further development, the risk that we may cease or delay preclinical or clinical development activities for any of our existing or future product candidates for a variety of reasons, the fact that our collaboration agreements are subject to early termination, 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 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.

ATYR PHARMA INC.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
	(unaudited)	
Operating expenses:		
Research and development	$ 9,379	$ 8,896
General and administrative	3,408	3,482
Total operating expenses	12,787	12,378
Loss from operations	(12,787)	(12,378)
Total other income (expense), net	835	224
Consolidated net loss	(11,952)	(12,154)
Net loss attributable to noncontrolling interest in Pangu BioPharma Limited	1	1

Net loss attributable to aTyr Pharma, Inc.	$ (11,951)	$ (12,153)
Net loss per share, basic and diluted	$ (0.29)	$ (0.44)
Shares used in computing net loss per share, basic and diluted	41,897,706	27,818,379

ATYR PHARMA INC.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents, restricted cash and available-for-sale investments	$ 117,575	$ 69,311
Other receivables	1,625	11,775
Property and equipment, net	5,167	3,059
Operating lease, right-of-use assets	6,942	7,250
Financing lease, right-of-use assets	1,948	1,248
Prepaid expenses and other assets	3,581	3,143
Total assets	$ 136,838	$ 95,786
Accounts payable, accrued expenses and other liabilities	$ 12,853	$ 12,968
Current portion of operating lease liability	381	630
Current portion of financing lease liability	420	264
Long-term operating lease liability, net of current portion	11,916	9,633
Long-term financing lease liability, net of current portion	1,570	1,007
Total stockholders' equity	109,698	71,284
Total liabilities and stockholders' equity	$ 136,838	$ 95,786

Contact:
Ashlee Dunston
Director, Investor Relations and Corporate Communications
adunston@atyrpharma.com

Source: aTyr Pharma, Inc.