aTyr Pharma Announces Fourth Quarter and Full Year 2023 Results and Provides Corporate Update

March 14, 2024

Phase 3 EFZO-FIT™ study of efzofitimod in pulmonary sarcoidosis anticipated to complete enrollment in the second quarter of 2024.

Company launches Individual Patient Expanded Access Program (EAP), allowing access to efzofitimod for patients who complete EFZO-FIT™.

Phase 2 EFZO-CONNECT™ study of efzofitimod in SSc-ILD currently enrolling.

Ended 2023 with $101.7 million in cash, cash equivalents and investments.

Company to host conference call and webcast today, March 14th, at 5:00 p.m. EDT / 2:00 p.m. PDT.

SAN DIEGO, March 14, 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 fourth quarter and full year 2023 results and provided a corporate update.

"Throughout 2023 we made meaningful progress with our clinical development program for our lead therapeutic candidate, efzofitimod, in interstitial lung disease (ILD)," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Our primary focus for 2024 is completing enrollment in our global pivotal Phase 3 EFZO-FIT™ study in patients with pulmonary sarcoidosis, a major form of ILD, which is anticipated in the second quarter."

"We ended 2023 with more than $100 million in cash, restricted cash, cash equivalents and investments. Based on our current cash position and operational plans, we believe our financial resources are sufficient to fund the Company's operations through the filing of a Biologics License Application (BLA) for efzofitimod in pulmonary sarcoidosis."

Fourth 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 patients with pulmonary sarcoidosis. The study is currently enrolling at more than 90 centers in 9 countries. A positive data and safety monitoring board review assessed that the study could continue unmodified. Based on current enrollment projections, the Company anticipates completing enrollment in the study in the second quarter of 2024.
- **Announced an Individual Patient Expanded Access Program (EAP) for efzofitimod for patients with pulmonary sarcoidosis.** The EAP has been initiated based on blinded EFZO-FIT™ study investigator and patient participant feedback. The program is designed 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.
- **Continued enrollment in the Phase 2 EFZO-CONNECT™ study to evaluate the efficacy, safety and tolerability of efzofitimod in patients with SSc-ILD.** This proof-of-concept study is 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 intends to enroll up to 25 patients with SSc-ILD and is open for enrollment at multiple centers in the U.S.
- **Poster for efzofitimod accepted for presentation at the upcoming American Thoracic Society (ATS) 2024 International Conference.** The conference is scheduled to take place May 17 – 22, 2024, in San Diego, CA.
    - Poster 8837 – Efzofitimod is an Immunomodulator of Myeloid Cell Function and Novel Therapeutic Candidate for Interstitial Lung Diseases on Sunday, May 19, 2024, at 2:15 p.m. PDT.
- **Presented two posters highlighting the importance of neuropilin-2 (NRP2) in immune regulation at the Keystone Symposia on Myeloid Cell Diversity.** The findings further demonstrate that efzofitimod modulates myeloid cells via the NRP2 receptor to promote a unique anti-inflammatory mechanism and validates the role of NRP2 in the immune system by the activity of an NRP2 blocking antibody in preclinical models.
- **Announced Wayne A. I. Frederick, M.D., President Emeritus of Howard University, as an advisor to the Company**. Dr. Frederick is a distinguished physician executive with extensive knowledge on disparities in healthcare and will advise the Company on its efzofitimod program in ILD.
- **Poster for ATYR0750 accepted for presentation at the upcoming Gordon Research Conference Fibroblast Growth**

Factors in Development and Disease. The conference is scheduled to take place March 24 – 29, 2024, in Galveston, TX.

- Poster – Alanyl-tRNA Synthetase Fragment Binds to FGFR4 and Induces Morphological Changes and Downstream Signaling in Liver Cells with Functional Similarities to FGF2.

Year Ended 2023 Financial Highlights and Cash Position

- **Cash & Investment Position:** Cash, cash equivalents, restricted cash and investments as of December 31, 2023, were $101.7 million. Based on the Company's current operational plans and existing cash, the Company maintains its prior guidance and believes its cash runway will be sufficient to fund the Company's operations through the filing of a BLA for efzofitimod in pulmonary sarcoidosis.
- **R&D Expenses:** Research and development expenses were $42.3 million for the year ended 2023, which consisted primarily of clinical trial costs for the Phase 3 EFZO-FIT™ and Phase 2 EFZO-CONNECT™ studies, 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 $13.0 million for the year ended 2023.

Conference Call and Webcast Details

aTyr will host a conference call and webcast today at 5:00 p.m. EDT / 2:00 p.m. PDT to discuss its financial results and provide a corporate update. Interested parties may access the call by registering here in order to obtain a dial in, personalized passcode and webcast information. Links to a live audio webcast and replay may be accessed on the aTyr website Events page at: http://investors.atyrpharma.com/events-and-webcasts. An audio replay will be available for at least 90 days following the event.

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 "anticipates," "believes," "designed," "expects," "intends," "may," "plans," "potential," "project," "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 runway to fund the Company's operations through the filing of a BLA for efzofitimod for pulmonary sarcoidosis; the expected size of, and number and nationality of patients to be enrolled in, the EFZO-FIT™ and EFZO-CONNECT™ studies; the design and benefits of our EAP for efzofitimod for patients with pulmonary sarcoidosis; the potential therapeutic benefits and applications of efzofitimod; and timelines and plans with respect to certain development activities and development goals, including our expectation that our Phase 3 EFZO-FIT™ study of efzofitimod in patients with pulmonary sarcoidosis will complete enrollment in the second quarter of 2024. 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, our assumptions and expectations underlying our belief that we will have sufficient cash runway to fund the Company's operations through the filing of a BLA for efzofitimod for pulmonary sarcoidosis may not be accurate, the fact that NRP2 and tRNA synthetase biology is not fully understood, uncertainty regarding the ultimate long-term impact of evolving macroeconomic and geopolitical conditions, 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, 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.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenues:				
License and collaboration agreement revenues	$ —	$ 10,386	$ 353	$ 10,386
Total revenues	—	10,386	353	10,386
Operating expenses:				
Research and development	12,755	14,910	42,293	42,808
General and administrative	3,204	3,426	12,979	13,982
Total operating expenses	15,959	18,336	55,272	56,790
Loss from operations	(15,959)	(7,950)	(54,919)	(46,404)
Total other income (expense), net	1,198	427	4,522	1,061
Consolidated net loss	(14,761)	(7,523)	(50,397)	(45,343)
Net loss attributable to noncontrolling interest in Pangu BioPharma Limited	1	2	8	5
Net loss attributable to aTyr Pharma, Inc.	$ (14,760)	$ (7,521)	$ (50,389)	$ (45,338)
Net loss per share, basic and diluted	$ (0.25)	$ (0.26)	$ (0.94)	$ (1.60)
Shares used in computing net loss per share, basic and diluted	59,261,219	29,116,524	53,606,488	28,419,569

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents, restricted cash and available-for-sale investments	$ 101,650	$ 69,311
Other receivables	2,436	11,775
Property and equipment, net	5,531	3,059
Operating lease, right-of-use assets	6,727	7,250
Financing lease, right-of-use assets	1,788	1,248
Prepaid expenses and other assets	2,521	3,143
Total assets	$ 120,653	$ 95,786
Accounts payable and accrued expenses	$ 15,088	$ 12,968
Current portion of operating lease liability	831	630
Current portion of financing lease liability	497	264
Long-term operating lease liability, net of current portion	12,339	9,633
Long-term financing lease liability, net of current portion	1,428	1,007
Total stockholders' equity	90,470	71,284
Total liabilities and stockholders' equity	$ 120,653	$ 95,786

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

Source: aTyr Pharma, Inc.