aTyr Pharma Announces Third Quarter 2022 Results and Provides Corporate Update

November 10, 2022

First patient dosed in Phase 3 EFZO-FIT™ study in patients with pulmonary sarcoidosis; multiple centers in the U.S. are open for enrollment.

Company to prioritize resources towards largest value driver efzofitimod program.

Ended the third quarter 2022 with $79.6 million in cash, restricted cash, cash equivalents and investments.

Company to host conference call and webcast today, November 10th, at 5:00 p.m. EST / 2:00 p.m. PST.

SAN DIEGO, Nov. 10, 2022 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of first-in-class medicines from its proprietary tRNA synthetase platform, today announced third quarter 2022 results and provided a corporate update.

"The third quarter saw the initiation of EFZO-FIT™, a global pivotal Phase 3 study of our lead therapeutic candidate, efzofitimod, in patients with pulmonary sarcoidosis, the most prevalent form of interstitial lung disease (ILD)," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "Given current market conditions, we intend to focus our resources on the EFZO-FIT™ study, which is our largest value driver, to ensure a timely and successful completion of this study."

"As part of this prioritization, we have made the strategic decision not to use internal resources to initiate a Phase 1 study of ATYR2810 this year. The data we have generated for ATYR2810 firmly support its therapeutic potential in rare aggressive tumors, thus we intend to pursue alternative non-dilutive funding avenues, including academic collaborations, to advance this program."

Third Quarter 2022 and Subsequent Period Highlights

- Dosed the first patient in EFZO-FIT™, a global pivotal 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 is currently enrolling and intends to enroll up to 264 subjects with pulmonary sarcoidosis at multiple centers in the U.S., Europe and Japan.
- Announced the publication of results of the Phase 1b/2a study of efzofitimod in patients with pulmonary sarcoidosis in the peer-reviewed medical journal *CHEST*. The study demonstrated that efzofitimod was safe and well-tolerated at all doses and exhibited a consistent dose response on key efficacy endpoints and improvements compared to placebo, including measures of steroid reduction, lung function, sarcoidosis symptom measures and inflammatory biomarkers.
- Received U.S. Food and Drug Administration (FDA) Fast Track designation for efzofitimod for the treatment of systemic sclerosis (SSc, or scleroderma)-associated ILD. Fast Track designation helps facilitate development and expedite the review of drugs to treat serious or life-threatening diseases with unmet medical need. Fast Track designation provides certain benefits, including enhanced interactions with the FDA throughout the development program, as well as eligibility for accelerated approval, priority review and rolling review.
- Presented a poster at the European Respiratory Society International Congress 2022 on findings for an antibody for immunohistochemical detection of neuropilin-2 (NRP2) protein, efzofitimod's binding partner, in patient tissue samples. The antibody may provide a useful tool for patient selection or stratification for sarcoidosis, other ILD, oncology or other indications where NRP2 is implicated.
- Completed IND-enabling activities and received a notice of allowance for a patent for ATYR2810, a fully humanized monoclonal antibody targeting NRP2, in preclinical development for cancer.
- Announced a research collaboration with Dualsystems Biotech AG, a company specializing in custom proteomics, aimed at accelerating drug discovery and generating new therapeutics based on aTyr's extensive intellectual property portfolio. Under the collaboration, which is exclusive with respect to tRNA related molecules, Dualsystems will utilize their proprietary receptor screening technology and research expertise to attempt to identify and validate 10 new target receptors for tRNA synthetases by 2025. aTyr previously worked with Dualsystems to identify fibroblast growth factor 4 (FGFR4) as the target receptor for a fragment of alanyl-tRNA synthetase (AARS).

Third Quarter 2022 Financial Highlights and Cash Position

- **Cash & Investment Position:** Cash, restricted cash, cash equivalents and investments as of September 30, 2022, were $79.6 million.

- **R&D Expenses:** Research and development expenses were $9.9 million for the third quarter of 2022, which consisted of product development and manufacturing costs for the efzofitimod and ATYR2810 programs, as well as startup costs for the Phase 3 EFZO-FIT™ study.
- **G&A Expenses:** General and administrative expenses were $3.6 million for the third quarter of 2022.
- **Shares Outstanding:** Common shares outstanding were 29,009,382 as of September 30, 2022.

Conference Call and Webcast Details
aTyr will host a conference call and webcast today at 5:00 p.m. EST / 2:00 p.m. PST 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
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 and adaptive immune response 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 event.

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," "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 the expected 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. 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, the fact that NRP2 and tRNA synthetase biology is not fully understood, uncertainty regarding the COVID-19 pandemic, and geopolitical conflicts, including 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 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(unaudited)			
Operating expenses:				
Research and development	$ 9,867	$ 5,138	$ 27,898	$ 17,309
General and administrative	3,625	2,590	10,556	8,066
Total operating expenses	13,492	7,728	38,454	25,375
Loss from operations	(13,492)	(7,728)	(38,454)	(25,375)
Total other income (expense), net	247	59	634	159
Consolidated net loss	(13,245)	(7,669)	(37,820)	(25,216)

Net loss attributable to noncontrolling interest in Pangu BioPharma Limited	1	2	3	7
Net loss attributable to aTyr Pharma, Inc.	$ (13,244)	$ (7,667)	$ (37,817)	$ (25,209)
Net loss per share, basic and diluted	$ (0.46)	$ (0.42)	$ (1.34)	$ (1.56)
Shares used in computing net loss per share, basic and diluted	28,663,047	18,159,231	28,184,698	16,145,351

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

	September 30, 2022	December 31, 2021
	(unaudited)	
Cash, cash equivalents, restricted cash and available-for-sale investments	$ 79,613	$ 107,911
Other receivables	873	435
Property and equipment, net	1,275	543
Operating lease, right-of-use assets	6,971	1,267
Financing lease, right-of-use assets	768	—
Prepaid expenses and other assets	6,555	5,381
Total assets	$ 96,055	$ 115,537
Accounts payable, accrued expenses and other liabilities	$ 10,398	$ 5,033
Current portion of operating lease liability	657	980
Current portion of financing lease liability	158	—
Long-term operating lease liability, net of current portion	7,218	398
Long-term financing lease liability, net of current portion	618	—
Total stockholders' equity	77,006	109,126
Total liabilities and stockholders' equity	$ 96,055	$ 115,537

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Source: aTyr Pharma, Inc.