aTyr Pharma Announces First Quarter 2022 Results and Provides Corporate Update

May 9, 2022

Company to present clinical data for efzofitimod (ATYR1923) in pulmonary sarcoidosis at upcoming American Thoracic Society International Conference in May.

Planned registrational study of efzofitimod in pulmonary sarcoidosis on track to initiate in the third quarter of 2022.

FDA granted orphan drug designation for efzofitimod for the treatment of systemic sclerosis; company to explore potential expansion of clinical program in other ILD.

Ended the first quarter 2022 with $98.7 million in cash, cash equivalents and investments.

Company to host conference call and webcast today, May 9th, at 5:00 p.m. EDT / 2:00 p.m. PDT.

SAN DIEGO, May 09, 2022 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of innovative medicines based on its proprietary tRNA synthetase biology platform, today announced first quarter 2022 results and provided a corporate update.

"We are pleased with the start of 2022 and the continued progress throughout the first quarter for our efzofitimod clinical program in pulmonary sarcoidosis, our initial interstitial lung disease (ILD) indication," said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. "With the receipt of U.S. Food and Drug Administration (FDA) orphan drug designation and a positive End-of-Phase 2 meeting with the FDA, we are on track to initiate a planned registrational study of efzofitimod in pulmonary sarcoidosis in the third quarter of this year."

"The second quarter is shaping up to be an important period, as we prepare to present the clinical data for the Phase 1b/2a study of efzofitimod in pulmonary sarcoidosis at the upcoming American Thoracic Society (ATS) International Conference and anticipate the potential publication of a related manuscript. We are focused on preparation for the planned registrational study so that the balance of the year may center upon initiating the study in the U.S. and Europe and supporting our partner Kyorin Pharmaceutical with the anticipated launch of the study in Japan."

First Quarter 2022 and Subsequent Period Highlights

- Announced posters accepted for presentation for efzofitimod in pulmonary sarcoidosis at the upcoming ATS 2022 International Conference. The posters will present clinical data from the recently completed Phase 1b/2a study of efzofitimod in patients with pulmonary sarcoidosis, which demonstrated safety, tolerability and consistent dose response for efzofitimod on key efficacy endpoints and improvements compared to placebo, including measures of steroid reduction, lung function, sarcoidosis symptom measures and inflammatory biomarkers.
- Announced a company reception at the upcoming ATS 2022 International Conference in San Francisco, CA, on Monday, May 16, 2022. The event, which will convene sarcoidosis medical experts, principal investigators, advocacy organizations, analysts and investors, will review results from the Phase 1b/2a study of efzofitimod in pulmonary sarcoidosis and discuss an outlook for the planned registrational study that the company expects to initiate in the third quarter of 2022.
- Received FDA orphan drug designation for efzofitimod for the treatment of systemic sclerosis (SSc, or scleroderma), a chronic, progressive autoimmune disease in which many patients may develop associated ILD, known as SSc-ILD. Orphan drug designation is granted to support the development of medicines for patients with unmet needs for rare disorders affecting fewer than 200,000 people in the U.S. and provides certain benefits, including the potential for seven years of market exclusivity following regulatory approval. The company expects to explore the potential expansion of its efzofitimod clinical program into other forms of ILD with high unmet medical need.
- Presented preclinical research in a poster at the American Association for Cancer Research Annual Meeting characterizing the effects of ATYR2810, the company's lead anti-Neuropilin-2 (NRP2)/VEGF antibody and IND candidate, in highly aggressive tumor subtypes, including triple-negative breast cancer. The findings suggest that ATYR2810 reduces metastasis and enhances chemosensitivity by downregulating key genes linked to these processes. The company expects to initiate a phase 1 study of ATYR2810 in cancer patients in the second half of 2022.

First Quarter 2022 Financial Highlights and Cash Position

- **Cash & Investment Position:** Cash, cash equivalents and investments as of March 31, 2022, were $98.7 million.
- **R&D Expenses:** Research and development expenses were $8.9 million for the first quarter of 2022, which consisted primarily of product development and manufacturing costs for the efzofitimod and ATYR2810 programs.
- **G&A Expenses:** General and administrative expenses were $3.5 million for the first quarter of 2022.

- **Shares Outstanding:** Common shares outstanding were 28,056,249 as of March 31, 2022.

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 dialing toll-free 844-358-9116 from the U.S., or 209-905-5951 internationally and using conference ID 9273437. 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 intends to initiate a planned registrational study of efzofitimod in pulmonary sarcoidosis in the third quarter of 2022.

About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of innovative medicines based on its proprietary tRNA synthetase biology 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 http://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," "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 the potential therapeutic benefits and applications of efzofitimod, ATYR2810 and our discovery programs; timelines and plans with respect to certain development activities (including the further development of efzofitimod and ATYR2810 and the timing and design of future clinical trials) and certain 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, 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 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.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021
	(unaudited)	
Operating expenses:		
Research and development	$ 8,896	$ 4,516
General and administrative	3,482	2,686
Total operating expenses	12,378	7,202
Loss from operations	(12,378)	(7,202)
Total other income (expense), net	224	47
Consolidated net loss	(12,154)	(7,155)
Net loss attributable to noncontrolling interest in Pangu BioPharma Limited	1	4
Net loss attributable to aTyr Pharma, Inc.	$ (12,153)	$ (7,151)
Net loss per share, basic and diluted	$ (0.44)	$ (0.51)

Shares used in computing net loss per share, basic and diluted	27,818,379	14,103,783

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

	March 31, 2022	December 31, 2021
	(unaudited)	
Cash, cash equivalents and available-for-sale investments, short-term	$ 98,666	$ 107,911
Other receivables	426	435
Property and equipment, net	433	543
Right-of-use assets	1,050	1,267
Prepaid expenses and other assets	4,201	5,381
Total assets	$ 104,776	$ 115,537
Accounts payable, accrued expenses and other liabilities	$ 5,257	$ 5,033
Current portion of operating lease liability	1,012	980
Long-term operating lease liability, net of current portion	133	398
Total stockholders' equity	98,374	109,126
Total liabilities and stockholders' equity	$ 104,776	$ 115,537

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

Source: aTyr Pharma, Inc.