aTyr Pharma Announces First Quarter 2021 Results and Provides Corporate Update

May 13, 2021

Data from Phase 1b/2a clinical trial of ATYR1923 in pulmonary sarcoidosis expected in the third quarter.

Preclinical data for IND candidate ATYR2810 showed anti-tumor effects in models of TNBC and NSCLC.

Bispecific antibody project with subsidiary Pangu BioPharma achieved milestones for first of two-year project.

Ended the quarter with $50.6 million in cash, cash equivalents and investments.

Company to host conference call and webcast today, May 13, at 5:00 p.m. EDT / 2:00 p.m. PDT.

SAN DIEGO, May 13, 2021 (GLOBE NEWSWIRE) -- aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel biological pathways, today announced first quarter 2021 results and provided a corporate update.

“During the first quarter, we remained focused on advancing our lead therapeutic candidate, ATYR1923. We are tracking towards the readout from our Phase 1b/2a proof-of-concept study in pulmonary sarcoidosis, our initial interstitial lung disease (ILD) indication, which is expected in the third quarter of this year,” said Sanjay S. Shukla, M.D., M.S., President and Chief Executive Officer of aTyr. “We have key mechanistic insights regarding ATYR1923’s anti-inflammatory effects in patients from our Phase 2 study in COVID-19 related respiratory complications. This clinical data is consistent with what we have seen preclinically for key anti-inflammatory cytokines that are implicated in sarcoidosis and other ILD.”

“Furthermore, we generated additional preclinical data for ATYR2810, our lead anti-Neuropilin-2 (NRP2) antibody and IND candidate, including research presented at the American Academy of Cancer Research (AACR) Annual Meeting demonstrating tumor inhibitory effects in triple-negative breast cancer (TNBC) and non-small cell lung cancer (NSCLC), as both a single agent and in combination with chemotherapy and the targeted agent bevacizumab. Our manufacturing agreement with Lonza for the production of this antibody reflects our commitment to this program. We are off to a strong start in 2021 and look forward to building upon this progress throughout the year.”

First Quarter 2021 and Subsequent Period Highlights

- Progressed its Phase 1b/2a multiple-ascending dose, placebo-controlled study of ATYR1923 in 37 patients with pulmonary sarcoidosis. Data is expected in the third quarter of this year.

- Reported positive results from its Phase 2 study of ATYR1923 in COVID-19 patients with severe respiratory complications, which provided proof-of-mechanism for ATYR1923. The study met its primary safety endpoint and demonstrated signals of clinical activity. Biomarker data showed that ATYR1923 reduced levels of several inflammatory cytokines and chemokines, including those that are implicated in sarcoidosis and other ILD, which is consistent with findings from animal models.

- Appointed leading sarcoidosis advocate Andrea Wilson as a patient advisor to the company. Ms. Wilson, Co-Founder and former member of the Board of Directors for the Foundation for Sarcoidosis Research (FSR), will advise the company on patient strategies related to its clinical program for ATYR1923 in pulmonary sarcoidosis.

- Participated in a Virtual Town Hall on Steroids and Sarcoidosis in collaboration with the FSR to discuss the burden of steroid treatment for patients with sarcoidosis and the need for new treatments.

- Presented two posters at the AACR Annual Meeting related to preclinical research for ATYR2810 in conjunction with the company’s scientific advisor Dr. Arthur Mercurio and his lab at the Department of Molecular, Cell and Cancer Biology at the University of Massachusetts Medical School. In models of TNBC, ATYR2810 administered in combination with widely used anti-cancer therapeutics, including chemotherapy or the targeted VEGF antibody bevacizumab, increased the anti-tumor effects of each agent. ATYR2810 also down-regulated epithelial-mesenchymal transition genes, which may be a mechanism that mediates its anti-tumor effects. In animal models of NSCLC, ATYR2810 inhibited tumor growth when administered both as a single agent and in combination with chemotherapy.

- Entered into an agreement with Lonza, a leading contract development and manufacturing organization, for the manufacture of ATYR2810 to support the progression of ATYR2810 to clinical stage development.

- Pangu BioPharma, the company’s Hong Kong subsidiary, together with the Hong Kong University of Science and Technology, achieved the milestones of the first year of a two-year project funded in part by the Hong Kong Government’s Innovation and Technology Commission to develop a high-throughput platform for the development of bispecific antibodies

targeting NRP2.

- Promoted Leslie Nangle, Ph.D., to Vice President, Research. Dr. Nangle will serve as a member of the company's executive leadership team, managing research and scientific operations.

First Quarter 2021 Financial Results

Total revenues were $0 and $8.1 million for the three months ended March 31, 2021 and 2020, respectively. Revenues for the three months ended March 31, 2020 consisted primarily of license and collaboration agreement revenues under company's license agreement with Kyorin. Research and development expenses were $4.5 million and $3.6 million for the three months ended March 31, 2021 and 2020, respectively. The increase was due primarily to manufacturing costs related to ATYR1923, increased research and development expenses related to ATYR2810 and increased expenses related to the research program between Pangu BioPharma, Hong Kong University and the Government of the Hong Kong Special Administration Region. General and administrative expenses were consistent between periods at $2.7 million and $2.6 million for the three months ended March 31, 2021 and 2020, respectively.

During the first quarter of 2021, the company raised gross proceeds of $9.9 million through its at-the-market offering program with H.C. Wainwright & Co., LLC and $15.3 million through its common stock purchase agreement with Aspire Capital Fund, LLC. As of March 31, 2021, aTyr had $50.6 million in cash, cash equivalents and investments.

The company expects its expenses to continue to increase in 2021 as research and development of ATYR1923 and ATYR2810 progress.

Conference Call and Webcast Details

aTyr will host a conference call and webcast today at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time 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 US, or 209-905-5951 internationally and using conference ID 6867948. 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 ATYR1923

aTyr is developing ATYR1923 as a potential therapeutic for patients with inflammatory lung disease. ATYR1923, a fusion protein comprised of the immuno-modulatory domain of histidyl tRNA synthetase fused to the FC region of a human antibody, is a selective modulator of Neuropilin-2 that downregulates the innate and adaptive immune response in inflammatory disease states. aTyr recently completed enrollment in a proof-of-concept Phase 1b/2a trial evaluating ATYR1923 in patients with pulmonary sarcoidosis. This Phase 1b/2a study is a multi-ascending dose, placebo-controlled, first-in-patient study of ATYR1923 that has been designed to evaluate the safety, tolerability, steroid sparing effect, immunogenicity and pharmacokinetics profile of multiple doses of ATYR1923. In response to the COVID-19 pandemic, aTyr completed a Phase 2 clinical trial with ATYR1923 in COVID-19 patients with severe respiratory complications. This Phase 2 study was a randomized, double blind, placebo-controlled study that was designed to evaluate the safety and preliminary efficacy of a single dose of ATYR1923.

About aTyr

aTyr is a biotherapeutics company engaged in the discovery and development of innovative medicines based on novel biological pathways. 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 ATYR1923, a clinical-stage product candidate which binds to the Neuropilin-2 receptor and is designed to down-regulate immune engagement in inflammatory lung diseases. 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," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "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 ATYR1923, ATYR2810 and our discovery programs; timelines and plans with respect to certain development activities (including the further development of ATYR9123, ATYR2810 and our discovery programs) and value to be derived therefrom; expected activities under our collaboration agreements 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 enrollment 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.

Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	
Revenues:		
License and collaboration agreement revenues	$ —	$ 8,065
Total revenues	—	8,065
Operating expenses:		
Research and development	4,516	3,616
General and administrative	2,686	2,590
Total operating expenses	7,202	6,206
Income (loss) from operations	(7,202)	1,859
Total other income (expense), net	47	(107)
Consolidated net income (loss)	$ (7,155)	$ 1,752
Net loss attributable to noncontrolling interest in Pangu BioPharma Limited	4	1
Net income (loss) attributable to aTyr Pharma, Inc.	$ (7,151)	$ 1,753
Basic, net income (loss) per share	$ (0.51)	$ 0.25
Shares used in computing basic net income (loss) per share	14,103,783	6,881,791
Diluted net income (loss) per share	$ (0.51)	$ 0.25
Shares used in computing diluted net income (loss) per share	14,103,783	6,884,797

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

	March 31, 2021	December 31, 2020
	(unaudited)	
Cash, cash equivalents and available-for-sale investments	$ 50,637	$ 31,689
Other receivables	89	2,039
Property and equipment, net	874	899
Right-of-use assets	1,886	2,083
Prepaid expenses and other assets	1,642	2,016
Total assets	$ 55,128	$ 38,726
Accounts payable, accrued expenses and other liabilities	$ 3,561	$ 5,003
Current portion of operating lease liability	890	861
Long-term operating lease liability, net of current portion	1,145	1,378
Total stockholders' equity	49,532	31,484
Total liabilities and stockholders' equity	$ 55,128	$ 38,726

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

Source: aTyr Pharma, Inc.