aTyr Pharma and FUJIFILM Diosynth Biotechnologies Announce Manufacturing Agreement for aTyr's Lead Therapeutic Candidate ATYR1923

November 30, 2021

SAN DIEGO, Nov. 30, 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, and FUJIFILM Diosynth Biotechnologies, a leading contract development and manufacturing organization (CDMO) for biologics, viral vaccines and viral vectors, today announced a manufacturing agreement for ATYR1923, aTyr Pharma's lead therapeutic candidate that is currently in clinical development for pulmonary sarcoidosis, a major form of interstitial lung disease (ILD).

Under the terms of the agreement, FUJIFILM Diosynth Biotechnologies will support process development and scale up of ATYR1923, including the manufacture of bulk drug substance for additional clinical trials in ILD. These activities are anticipated to lay the foundation for additional process characterization and validation activities to support a new Biologics License Application for ATYR1923, and expand the manufacturing capability of ATYR1923 to support commercial demand.

"We are very pleased to work with FUJIFILM Diosynth Biotechnologies as we advance ATYR1923 to late-stage clinical development," Sanjay S. Shukla, M.D., M.S., president and chief executive officer of aTyr Pharma. "The ability to work with a leading, commercially capable CDMO such as FUJIFILM Diosynth Biotechnologies, particularly as it expands its capacity and capabilities across its global network, is an opportunity to ensure the continuity of the supply of ATYR1923 to fulfill future needs for our clinical program in ILD."

"We look forward to supporting aTyr Pharma as they advance their novel tRNA synthetase derived therapy," said Christine Vannais, chief operating officer of FUJIFILM Diosynth Biotechnologies, North Carolina. "Our team welcomes the chance to partner with aTyr Pharma to support late-phase manufacturing of ATYR1923 with the goal of getting ready to deliver this potentially life-impacting therapy to patients."

About ATY1923

aTyr is developing ATYR1923 as a potential therapeutic for patients with severe inflammatory lung diseases. 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 innate and adaptive immune response in inflammatory disease states. aTyr's lead indication for ATYR1923 is pulmonary sarcoidosis, a major form of interstitial lung disease. Clinical proof-of-concept for ATYR1923 was recently established in a Phase 1b/2a multiple-ascending dose, placebo-controlled study of ATYR1923 in patients with pulmonary sarcoidosis, which demonstrated safety and a consistent dose response and trends of benefit of ATYR1923 compared to placebo on key efficacy endpoints, including steroid reduction, lung function, clinical symptoms and inflammatory biomarkers.

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 www.atyrpharma.com.

About FUJIFILM Diosynth Biotechnologies

FUJIFILM Diosynth Biotechnologies an industry-leading Biologics Contract Development and Manufacturing Organization (CDMO) with locations in Teesside, UK, RTP, North Carolina, College Station, Texas, and Hillerød, Denmark. FUJIFILM Diosynth Biotechnologies has over three decades of experience in the development and manufacturing of recombinant proteins, vaccines, monoclonal antibodies, among other large molecules, viral products and medical countermeasures expressed in a wide array of microbial, mammalian, and host/virus systems. The company offers a comprehensive list of services from cell line development using its proprietary pAVEway™ microbial and Apollo™ cell line systems to process development, analytical development, clinical and FDA-approved commercial manufacturing. FUJIFILM Diosynth Biotechnologies is a partnership between FUJIFILM Corporation and Mitsubishi Corporation. For more information, go to: www.fujifilmdiosynth.com.

About FUJIFILM

FUJIFILM Corporation is an operating company of FUJIFILM Holdings Corporation. FUJIFILM Holdings Corporation, Tokyo, Japan, brings cutting edge solutions to a broad range of global industries by leveraging its depth of knowledge and fundamental technologies developed in its relentless pursuit of innovation. Its proprietary core technologies contribute to the various fields including healthcare, highly functional materials, document solutions and imaging products. These products and services are based on its extensive portfolio of chemical, mechanical, optical, electronic and imaging technologies. For the year ended March 31, 2021, the company had global revenues of $21 billion, at an exchange rate of 106 yen to the dollar. Fujifilm is committed to responsible environmental stewardship and good corporate citizenship. For more information, please visit: www.fujifilmholdings.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 potential therapeutic benefits and applications of ATYR1923; timelines and plans with respect to certain development activities (such as the timing of additional clinical trials and planned interactions with regulatory authorities); 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, uncertainty regarding the COVID-19 pandemic, risks associated with the discovery, development and regulation of our product candidates, the risk that we or our partners may cease or delay preclinical or clinical development activities for any of our existing or future product candidates for a variety of reasons (including difficulties or delays in patient enrollment in planned clinical trials), the possibility that existing collaborations could be terminated early, 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.

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