Passage Bio Teams with Catalent to Start CGMP Manufacturing for Lead Gene Therapy Products

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- Completion of dedicated CGMP suite enhances manufacturing readiness and secures supply chain control to support lead CNS gene therapy product candidates as they advance through clinical trials to commercialization -

PHILADELPHIA and SOMERSET, N.J., Dec. 07, 2020 (GLOBE NEWSWIRE) -- Passage Bio, Inc. (Nasdaq: PASG), a genetic medicines company focused on developing transformative therapies for rare, monogenic central nervous system (CNS) disorders, and Catalent, the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products, today announced that manufacturing operations have commenced to support adeno-associated virus (AAV) production for Passage Bio's lead gene therapy product candidates for the treatment of rare monogenic CNS disorders. This announcement follows the recent completion of construction and Current Good Manufacturing Practice (CGMP) qualification of a dedicated manufacturing suite for Passage Bio at Catalent Cell & Gene Therapy's facility in Harmans, Maryland.

"The completion of our dedicated CGMP suite at Catalent is a significant milestone for Passage Bio, enabling us to initiate manufacturing in support of our gene therapy product candidates," said Bruce Goldsmith, Ph.D., president and chief executive officer of Passage Bio. "Solidifying our manufacturing readiness is a core element in our strategic commitment to deliver innovative gene therapies that are safe and effective for patients with rare CNS disorders. Having a dedicated manufacturing suite focused solely on our products allows us to control our critical production supply chain, providing the flexibility and scalable capacity to more rapidly advance our product candidates from clinical trials to commercialization."

The completion of the dedicated CGMP manufacturing suite results from Passage Bio's ongoing collaboration agreement with Catalent first announced in July 2019. Catalent's commercial-scale facility is located in Maryland, near Baltimore/Washington International Thurgood Marshall Airport, within close proximity to Passage Bio's corporate headquarters in Philadelphia. To support the production of AAV, Passage Bio is using the Pall Corporation's iCELLis ® single-use fixed-bed bioreactor technology. This fully integrated bioreactor system provides a scalable alternative for the cultivation of adherent cells and is capable of meeting demand for both clinical and commercial-scale volumes.

Catalent also will play an important role in delivering Passage Bio's therapy candidates to clinical trial sites for administration to patients. Catalent is providing packaging, labeling and distribution services through its FastChain® demand led supply offering, which is particularly well suited to studies of advanced therapy medicinal products where speed, efficiency and flexibility are vitally important.

Manja Boerman, Ph.D., president, Catalent Cell & Gene Therapy, added, "With the opening of its CGMP manufacturing suite, Passage Bio has taken a critical step in its commitment to manufacturing excellence. We are pleased to partner our gene therapy manufacturing scale-up expertise and world-class facilities with their scientific leadership to create a pathway for the development and delivery of safe, high-quality gene therapies for patients with rare diseases who are waiting for new treatment options."

In addition to its dedicated manufacturing suite and clinical supply through its collaboration with Catalent Cell & Gene Therapy, Passage Bio supports its preclinical programs through its partnership with the University of Pennsylvania's (Penn's) Gene Therapy Program, which provides access to preclinical and toxicology research-grade vector supplies.

"Investing in dedicated CGMP manufacturing infrastructure at Catalent, augmented by our access to vector supplies, technology, and expertise at Penn, provides us the flexibility and capacity to advance multiple programs in parallel and to rapidly deliver supplies to support clinical trials worldwide," said Alex Fotopoulos, MSc., MBA, chief technical officer of Passage Bio. "Our ability to create an agile, global supply chain as we advance our lead product candidates positions us for clinical and commercial success, enhancing our competitiveness in the gene therapy arena."

iCELLis® is a trademark of the Pall Corporation.

Notes for Editors

About Catalent Cell & Gene Therapy

With deep experience in viral vector scale-up and production, Catalent Cell & Gene Therapy is a full-service partner for adeno-associated virus (AAV) and lentiviral vectors, and CAR-T immunotherapies. When it acquired MaSTherCell, Catalent added expertise in autologous and allogeneic cell therapy development and manufacturing to position it as a premier technology, development and manufacturing partner for innovators across the entire field of advanced biotherapeutics. Catalent has a global cell and gene therapy network of dedicated, large-scale clinical and commercial manufacturing facilities, and fill-finish and packaging capabilities located in both the U.S. and Europe. An experienced partner, Catalent Cell & Gene Therapy has worked with industry leaders across 70+ clinical and commercial programs.

About Catalent

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable global clinical and commercial product supply. Catalent employs approximately 14,000 people, including around 2,400 scientists and technicians, at more than 45 facilities, and in fiscal year 2020 generated $3 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com

More products. Better treatments. Reliably supplied.™

About Passage Bio

At Passage Bio (Nasdaq: PASG), we are on a mission to provide life-transforming gene therapies for patients with rare, monogenic CNS diseases that replace their suffering with boundless possibility, all while building lasting relationships with the communities we serve. Based in Philadelphia, PA, our company has established a strategic collaboration and licensing agreement with the renowned University of Pennsylvania's Gene Therapy Program to conduct our discovery and IND-enabling preclinical work. This provides our team with unparalleled access to a broad portfolio of gene therapy candidates and future gene therapy innovations that we then pair with our deep clinical, regulatory, manufacturing and commercial expertise to rapidly advance our robust pipeline of optimized gene therapies into clinical testing. As we work with speed and tenacity, we are always mindful of patients who may be able to benefit from our therapies. More information is available at www.passagebio.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995, including, but not limited to: our expectations about timing and execution of anticipated milestones, including our planned IND submissions, initiation of clinical trials and the availability of clinical data from such trials; our expectations about our collaborators' and partners' ability to execute key initiatives; our expectations about manufacturing plans and strategies; our expectations about cash runway; and the ability of our lead product candidates to treat the underlying causes of their respective target monogenic CNS disorders. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "potential," "possible," "will," "would," and other words and terms of similar meaning. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our ability to develop and obtain regulatory approval for our product candidates; the timing and results of preclinical studies and clinical trials; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events; the risk that positive results in a preclinical study or clinical trial may not be replicated in subsequent trials or success in early stage clinical trials may not be predictive of results in later stage clinical trials; failure to protect and enforce our intellectual property, and other proprietary rights; our dependence on collaborators and other third parties for the development and manufacture of product candidates and other aspects of our business, which are outside of our full control; risks associated with current and potential delays, work stoppages, or supply chain disruptions caused by the coronavirus pandemic; and the other risks and uncertainties that are described in the Risk Factors section in documents the company files from time to time with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. Passage Bio undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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