Passage Bio Announces New Dedicated Gene Therapy Manufacturing Suite

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Dedicated cGMP suite to be built under strategic partnership agreement with Paragon Gene Therapy to support future clinical and commercial production for Passage Bio's AAV-delivered gene therapies

/EIN News/ -- PHILADELPHIA, July 10, 2019 (GLOBE NEWSWIRE) -- Passage Bio, a genetic medicines company developing AAV-delivered gene therapies for the treatment of rare monogenic central nervous system diseases, today announced that it has entered into a collaboration agreement with Paragon Gene Therapy, a unit of Catalent Biologics, for the development of a dedicated manufacturing suite at their facility near Baltimore, Maryland.

The new cGMP suite will be built in accordance with global regulatory guidelines and will be capable of supporting Passage Bio from clinical through commercial supply. The suite is expected to be operational in the second half of 2020 and will be located in Harmans, Maryland, which is five miles from the Baltimore Washington Airport and within close proximity to Passage Bio's corporate headquarters in Philadelphia, Pennsylvania.

Passage Bio will be using the iCELLis® single-use fixed-bed bioreactor technology, a fully-integrated bioreactor system, which provides a scalable alternative for the cultivation of adherent cells, allows for a more robust and reproducible process and is capable of meeting demand for both clinical and commercial-scale volumes.

"We understand that manufacturing is a critical part of a successful gene therapy program and securing our own dedicated manufacturing suite, through this new strategic partnership with Paragon Gene Therapy, is a key facet of our business plan for Passage Bio. We look forward to the build-out of this facility soon," said Stephen Squinto, co-founder and interim chief executive officer at Passage Bio. "This milestone is evidence of how our team is applying its deep orphan drug development, manufacturing and commercialization know-how to ensure we are able to most efficiently advance our therapies through clinical development and subsequently to ensure they are readily available to patients upon approval."

Pete Buzy, president of Paragon Gene Therapy, added, "We are pleased to be able to support Passage Bio throughout their clinical and commercial milestones. We highly value partnering with our clients to achieve successful patient treatments. Combining Passage Bio's scientific knowledge with our world-class facilities and extensive AAV scale-up expertise perfectly aligns with our strategic goals in this time of gene therapy growth."

This manufacturing partnership follows a successful Series A financing by Passage Bio earlier in 2019 for their development portfolio of five therapeutic candidates.

About Passage Bio
Passage Bio is a privately-held fully integrated genetic medicines company with a mission to develop a portfolio of life-transforming AAV-delivered therapeutics for the treatment of rare monogenic central nervous system diseases. The company is based in Philadelphia, PA and has a research, collaboration and license agreement with the University of Pennsylvania and its Gene Therapy Program (GTP) as well as the Orphan Disease Center (ODC). The GTP conducts the IND-enabling preclinical work and Passage Bio conducts all clinical development, regulatory strategy and commercialization activities. The company has a development portfolio of five product candidates, with the option to license seven more, with lead programs in GM1 gangliosidosis, frontotemporal dementia (FTD) and Krabbe disease, all three of which will be in the clinic in 2020. In early 2019, the company completed a $115.5 million Series A financing with investments from OrbiMed, Frazier Healthcare Partners, Versant Ventures, Lily Asia Ventures, New Leaf Venture Partners, and Vivo Capital.

About Paragon Gene Therapy
Paragon Gene Therapy, a unit of Catalent Biologics, is an industry leader focusing on transformative technologies, including gene therapies (AAV), next-generation vaccines, and oncology immunotherapies. Paragon Gene Therapy has two facilities in Baltimore, Maryland dedicated to process development through commercial manufacturing of most scalable AAV platforms across multiple serotypes. Since 2016, Paragon Gene Therapy has completed over 100 clinical GMP AAV batches across 40 programs.

For further information, please contact:

Investors:
Sarah McCabe
Stern Investor Relations, Inc.
212-362-1200
sarah.mccabe@sternir.com

Media:
Sarah Plumridge
HDMZ
312-506-5219
passagebio@hdmz.com