



NEWS RELEASE

bridgebio pharma's gene therapy subsidiaries enter strategic partnership with catalent for dedicated gene therapy development and manufacturing capacity

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- The deal is designed to accelerate BridgeBio's gene therapy programs
- The dedicated suite will support clinical and commercial supply needs for BridgeBio's gene therapy programs for congenital adrenal hyperplasia (BBP-631) and Canavan disease (BBP-812)

PALO ALTO, Calif., Jan. 10, 2020 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (NASDAQ: BBIO) today announced a collaboration agreement with Catalent to establish dedicated gene therapy development and manufacturing capacity at Catalent's Paragon Gene Therapy clinical and commercial manufacturing center in Harmans, Maryland. The agreement is intended to support the clinical and commercial manufacturing needs for BridgeBio's gene therapy product candidates for congenital adrenal hyperplasia, BBP-631, and Canavan disease, BBP-812.

Catalent's commercial facility is fully compliant with cGMP requirements and allows for up to 5000 liters of production. The over 400,000 square feet footprint is complete with all necessary support functions for storage and fill finish for final product supply.

"Having flexibility and greater certainty in manufacturing capacity is critical to success in gene therapy," said Eric David, M.D., J.D., CEO of BridgeBio's gene therapy subsidiaries. "Catalent's Paragon Gene Therapy arm has been our trusted partner for almost two years, and this expansion of our relationship is intended to allow for smoother clinical and commercial development, as well as an acceleration of our pipeline programs, helping us move faster to address critical unmet health needs for patients and their families."

“Catalent’s expertise in the cGMP manufacturing of viral vectors complements our internal investment in the CMC process and analytical development to support our gene therapy portfolio,” said Fred Porter, Ph.D., senior vice president of CMC and technical development of BridgeBio’s gene therapy subsidiaries. “Securing dedicated capacity for the delivery of clinical and commercial supply is critical to our long-term strategy.”

Pete Buzy, president of Paragon Gene Therapy, commented, “It is Catalent’s continued goal to grow with our customers and to be able to offer them secure, state-of-the-art gene therapy facilities for their critical clinical and commercial needs. For gene therapies, the manufacturing scale-up process is complex and unique. Therefore, for our partners, having access to advanced adeno-associated virus production expertise and experience is vital to progress these pioneering treatments towards commercialization and the patients who need them.”

About BridgeBio Pharma

BridgeBio is a team of experienced drug discoverers, developers and innovators working to create life-altering medicines that target well-characterized genetic diseases at their source. BridgeBio was founded in 2015 to identify and advance transformative medicines to treat patients who suffer from Mendelian diseases, which are diseases that arise from defects in a single gene, and cancers with clear genetic drivers. BridgeBio’s pipeline of over 15 development programs includes product candidates ranging from early discovery to late-stage development. For more information, visit [bridgebio.com](https://www.bridgebio.com).

About Paragon Gene Therapy

Paragon Gene Therapy, a unit of Catalent Biologics, is an industry leader focusing on transformative technologies, including adeno-associated virus (AAV) gene therapies, next-generation vaccines, and oncology immunotherapies. Paragon Gene Therapy has facilities in Harmans and Baltimore, Maryland, which are 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.

About Catalent

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, 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 nearly 13,000 people, including over 2,400 scientists and technicians, at more than 35 facilities, and in fiscal year 2019 generated over \$2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com.

BridgeBio Pharma Forward-Looking Statements

This press release contains forward-looking statements. Statements we make in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which 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 the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including statements relating to expectations, plans and prospects regarding the clinical development plans, clinical trial designs, the clinical and therapeutic potential, and the strategy of BridgeBio's gene therapy product candidates, the clinical and commercial manufacturing supply needs of BridgeBio's gene therapy product candidates, the ability of Catalent to provide adequate clinical and commercial supplies of active pharmaceutical ingredient to BridgeBio's gene therapy product candidates that adhere to current good manufacturing practices (cGMP) regulations, the success of the collaboration agreement with Catalent, and the timing of these events, 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 those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, Catalent's ability to provide adequate clinical and commercial supply of active pharmaceutical ingredient for BridgeBio's gene therapy product candidates that comply with cGMP regulations, BridgeBio's ability to maintain the collaboration agreement with Catalent, the benefits that will be derived from the collaboration agreement with Catalent, BridgeBio's ability to support its gene therapy portfolio and advance its gene therapy product candidates through clinical development, and the novel nature of gene therapy technology and the related heightened challenges for obtaining and maintaining regulatory approval, as well as those risks set forth in the Risk Factors section of BridgeBio Pharma, Inc.'s most recent Quarterly Report on Form 10-Q and our other SEC filings. Moreover, BridgeBio operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of BridgeBio's management as of the date of this release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable 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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