REGENXBIO to Launch New Manufacturing Facility for NAV Technology-based AAV Gene Therapies

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Internal manufacturing facility expected to support future clinical and commercial production

Facility will use novel platform suspension cell culture process, which can produce scalable, highly purified NAV Technology-based vectors

ROCKVILLE, Md., May 15, 2019 /PRNewswire/ -- REGENXBIO Inc. (Nasdaq: RGNX), a leading clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy based on its proprietary NAV® Technology Platform, today announced its plan to construct a current good manufacturing practice (cGMP) production facility, to be located in Rockville, Maryland. The new cGMP production facility will be integrated into REGENXBIO's previously announced new 132,000 square foot headquarters, for which construction is currently underway, and will allow for production of NAV Technology-based vectors at scales up to 2,000 liters using REGENXBIO's platform suspension cell culture process. The facility will be designed to meet global regulatory requirements and is expected to be operational in 2021. The cGMP production facility will complement the company's current external manufacturing capabilities, enabling a reliable supply of NAV vectors from both internal and external sources. The construction of the facility is not expected to have any effect on REGENXBIO's previously issued financial guidance relating to its cash, cash equivalents and marketable securities as of December 31, 2019.

"REGENXBIO's own cGMP production facility is designed to enable us to reach manufacturing scales suitable for future commercial production," said Curran Simpson, Senior Vice President of Product Development and Chief Technology Officer at REGENXBIO. "The creation of this additional manufacturing capacity using our platform suspension cell culture process will allow us to more efficiently advance our development programs from research stage to the clinic and ultimately to patients, while ensuring manufacturing capacity availability. We expect our manufacturing network to be capable of supporting our internal programs through clinical development and potential commercialization."

"The manufacturing facility design will enable concurrent production of multiple gene-therapy vectors, and the facility will be co-located with our process development and analytical teams. This integrated approach will allow for more efficient development, manufacture and release of vectors for new indications," said Kenneth T. Mills, President and Chief Executive Officer of REGENXBIO. "The new facility will also provide us with scheduling flexibility, allowing for reduced product development timelines at sufficient capacity to meet clinical and projected commercial requirements."

About REGENXBIO Inc.

REGENXBIO is a leading clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. REGENXBIO's NAV Technology Platform, a proprietary adeno-associated virus (AAV) gene delivery platform, consists of exclusive rights to more than 100 novel AAV vectors, including AAV7, AAV8, AAV9 and AAVrh10. REGENXBIO and its third-party NAV Technology Platform Licensees are applying the NAV Technology Platform in the development of a broad pipeline of candidates in multiple therapeutic areas.

Forward-Looking Statements

This press release includes "forward-looking statements," within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements express a belief, expectation or intention and are generally accompanied by words that convey projected future events or outcomes such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or by variations of such words or by similar expressions. The forward-looking statements include statements relating to, among other things, REGENXBIO's future operations and clinical trials. REGENXBIO has based these forward-looking statements on its current expectations and assumptions and analyses made by REGENXBIO in light of its experience and its perception of historical trends, current conditions and expected future developments, as well as other factors REGENXBIO believes are appropriate under the circumstances. However, whether actual results and developments will conform with REGENXBIO's expectations and predictions is subject to a number of risks and uncertainties, including the timing of enrollment, commencement and completion and the success of clinical trials conducted by REGENXBIO, its licensees and its partners, the timing of commencement and completion and the success of preclinical studies conducted by REGENXBIO and its development partners, the timely development and launch of new products, the ability to obtain and maintain regulatory approval of product candidates, the ability to obtain and maintain intellectual property protection for product candidates and technology, trends and challenges in the business and markets in which REGENXBIO operates, the size and growth of potential markets for product candidates and the ability to serve those markets, the rate and degree of acceptance of product candidates, and other factors, many of which are beyond the control of REGENXBIO. Refer to the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of REGENXBIO's Annual Report on Form 10-K for the year ended December 31, 2018 and comparable "risk factors" sections of REGENXBIO's Quarterly Reports on Form 10-Q and other filings, which have been filed with the U.S. Securities and Exchange Commission (SEC) and are available on the SEC's website at www.sec.gov. All of the forward-looking statements made in this press release are expressly qualified by the cautionary statements contained or referred to herein. The actual results or developments anticipated may not be realized or, even if substantially realized, they may not have the expected consequences to or effects on REGENXBIO or its businesses or operations. Such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Readers are cautioned not to rely too heavily on the forward-looking statements contained in this press release. These forward-looking statements speak only as of the date of this press release. REGENXBIO does not undertake any obligation, and specifically declines any obligation, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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