REGENXBIO Opens State-of-the-Art Gene Therapy Manufacturing Facility

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- *In-house facility to produce NAV Technology-based AAV gene therapies at 2,000 liters scale*
- *$65 million invested in new facility, enabling end-to-end control of gene therapy manufacturing in Montgomery County, Maryland*

ROCKVILLE, Md., June 9, 2022 /PRNewswire/ -- REGENXBIO Inc. (Nasdaq: RGNX) today is celebrating the opening of its new *Manufacturing Innovation Center* gene therapy manufacturing facility.

"Launching operations at our Manufacturing Innovation Center is an important milestone in the evolution of REGENXBIO," said Kenneth T. Mills, President and Chief Executive Officer of REGENXBIO. "We believe our in-house manufacturing capabilities will enable us to rapidly transition production processes across the product lifecycle, and efficiently advance new AAV Therapeutics from research and early development to clinical programs to commercial readiness, and into the hands of patients who may benefit from these potential one-time administration therapies."

Located in REGENXBIO's 132,000 square foot headquarters in Rockville, Maryland, the state-of-the-art good manufacturing practice (GMP) facility will enable the company to boost manufacturing of NAV Technology-based adeno-associated virus (AAV) vectors at scales up to 2,000 liters. The facility will implement REGENXBIO's NAVXpress™ platform suspension cell culture process, which has demonstrated the ability to increase product purity and yield.

The GMP facility is designed to meet global clinical and commercial regulatory standards, and includes two independent bulk drug substance production suites, a final drug product suite and integrated quality control labs. REGENXBIO is one of only a few gene therapy companies worldwide with a GMP facility capable of production at scales up to 2,000 liters.

"In-house manufacturing is a key differentiator for REGENXBIO as a leader in gene therapy," said Curran Simpson, Chief Operations and Technology Officer at REGENXBIO. "Quality manufacturing is crucial to all stages of AAV gene therapy development, and we're extremely proud of this cutting-edge facility and the experienced team we have to lead these efforts. Bringing our manufacturing in-house allows us to control the process from beginning to end and provides flexibility to support a wide range of clinical and commercial needs."

Through December 31, 2021, REGENXBIO had invested more than $100 million into the buildout of its Rockville headquarters, including more than $65 million dedicated to the Manufacturing Innovation Center. In preparation to establish end-to-end capabilities in gene therapy from research and early development to commercial ready manufacturing, the company has hired 200 people over the past two years.

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. REGENXBIO is committed to a "5x'25" strategy to progress five AAV Therapeutics from our internal pipeline and licensed programs into pivotal-stage trials or commercial products by 2025.

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," "assume," "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 manufacturing capabilities. 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, the impact of the COVID-19 pandemic or similar public health crises on REGENXBIO's business, 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, 2021, 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. Except as required by law, 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., Inc. All other trademarks referenced herein are registered trademarks of REGENXBIO.

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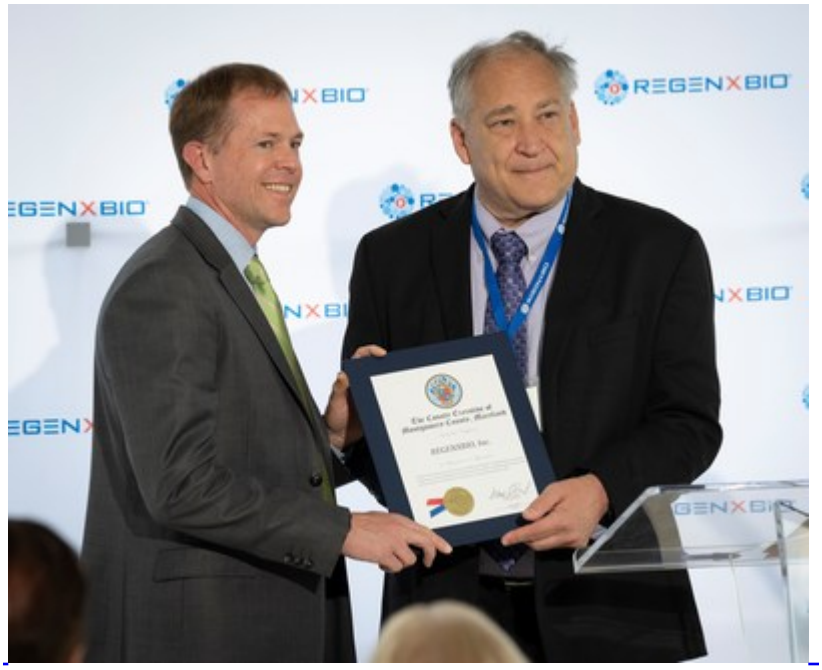

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