REGENXBIO Enhances Gene Therapy Manufacturing Capabilities by Entering into Strategic Partnership with FUJIFILM Diosynth Biotechnologies

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- REGENXBIO has established internal capability to produce NAV AAV across multiple platforms and at scale of up to 200L

- Agreement with FUJIFILM secures access to dedicated cGMP suite capacity and resources capable of manufacturing NAV AAV at up to 2,000L scale in support of global development and commercialization

ROCKVILLE, Md., Jan. 23, 2018 (GLOBE NEWSWIRE) -- 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 an agreement with FUJIFILM Diosynth Biotechnologies (FUJIFILM) for the manufacture of REGENXBIO's lead product candidates, including RGX-314 and RGX-501, which will support late-stage clinical development and early commercialization. This partnership builds on the foundation of REGENXBIO's internal manufacturing and process development capabilities.

"We are excited to enter into this partnership with FUJIFILM, which secures access to capacity and resources that will enable us to produce our lead product candidates at commercial scale using processes developed at REGENXBIO," said Curran Simpson, Senior Vice President of Technical Operations at REGENXBIO. "By aligning our agreement with FUJIFILM to our internal capabilities, we believe we will be well-positioned to meet the NAV AAV production requirements for our current lead product candidates through early commercialization, and to support new, emerging product candidates that may enter our pipeline."

Under the terms of the agreement with FUJIFILM, REGENXBIO gains guaranteed capacity for the supply of NAV AAV drug substance manufactured under current good manufacturing practice (cGMP) at large scale - up to 2,000L - for three years, with the option to extend the agreement for an additional three years. FUJIFILM facilities are compliant with global regulatory standards in support of the initiation of worldwide clinical trials for any REGENXBIO lead product candidate.

"We look forward to strengthening our relationship with REGENXBIO, a leader in the development of innovative gene therapy products providing hope for patients," said Martin Meeson, President and Chief Operating Officer of FUJIFILM Diosynth Biotechnologies, USA. "With our strong track record of execution, and with facilities and systems that are suitable for late stage and commercial production, we are well positioned to support the manufacturing needs of REGENXBIO as it continues to move multiple product candidates toward commercialization."

The agreement with FUJIFILM does not limit REGENXBIO's flexibility to invest in its own cGMP manufacturing capabilities as clinical data emerge on lead product candidates. REGENXBIO will continue to maintain existing relationships with contract manufacturing organizations for access to additional capacity, if so desired. REGENXBIO continues to extend its manufacturing capabilities and intellectual property at its advanced manufacturing and analytics lab in Rockville, Maryland. REGENXBIO has developed the ability to manufacture NAV AAV across multiple platforms from adherent-based processes to the scale-up of suspension-based systems, and now has the internal capability to produce NAV AAV at a scale of up to 200L.

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 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 product candidates and future operations. 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 of REGENXBIO's clinical trials; the timing and success of preclinical studies and clinical trials 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, 2016 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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