U.S. District Court Issues Decision on REGENXBIO and University of Pennsylvania NAV® Technology Patent Infringement Lawsuit

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ROCKVILLE, Md., Jan. 8, 2024 /PRNewswire/ -- REGENXBIO Inc. (Nasdaq: RGNX) today announced the U.S. District Court for the District of Delaware granted Sarepta Therapeutics, Inc. (Sarepta) summary judgment on invalidity in a patent infringement suit arising from Sarepta's manufacture and use of cultured host cell technology covered by a University of Pennsylvania (Penn) patent that Sarepta uses to make clinical and commercial supplies of SRP-9001 (also known as ELEVIDYS in the U.S.), for itself and Roche, for the treatment of Duchenne muscular dystrophy. REGENXBIO intends to file an immediate appeal.

REGENXBIO exclusively licensed the patent, U.S. Patent No. 10,526,617 ('617), from Penn, which is a joint plaintiff in the lawsuit. The lawsuit was filed September 30, 2020, and a trial was scheduled for the end of January 2024. The ruling on this expired patent does not impact REGENXBIO's current licenses or therapeutic pipeline.

"We are disappointed by the decision and believe the court got it wrong. We will appeal," said Patrick J. Christmas, J.D., Chief Legal Officer of REGENXBIO. "REGENXBIO will continue to take appropriate steps to vigorously defend our patent rights."

"The strong patent protections in the U.S. have enabled the robust development of new medicines and spurred growth in the biotechnology industry," said Kenneth T. Mills, President and Chief Executive Officer of REGENXBIO. "We are proud of the impact our NAV® Technology Platform has had on the gene therapy field and the thousands of patients that have been treated with AAV gene therapies built on our patented technology. We are not attempting to halt development or production of gene therapies; we are seeking fair and reasonable compensation for deliberate infringement."

A separate patent infringement action on a different Penn patent brought by REGENXBIO and Penn against Sarepta in June 2023 is also pending. This second infringement action concerns Sarepta's commercial launch of products covered by U.S. Patent No. 11,680,274 ('274), which covers Sarepta's AAVrh74-based gene therapy vector products, including ELEVIDYS, and that are partnered with Roche outside the U.S. The term of the '274 patent extends to October 2027 and damages are being sought to compensate REGENXBIO and its licensor, Penn.

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 and AAV9. REGENXBIO and its third-party NAV Technology Platform Licensees are applying the NAV Technology Platform in the development of a broad pipeline of candidates, including late-stage and commercial programs, 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 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 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, 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, 2022, 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.

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