AbbVie and REGENXBIO Announce Eye Care Collaboration

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- AbbVie and REGENXBIO form a strategic partnership combining eye care and gene therapy expertise

- Companies will develop and commercialize RGX-314, an investigational gene therapy for wet age-related macular degeneration, diabetic retinopathy and other chronic retinal diseases

- REGENXBIO to receive $370 million upfront payment

NORTH CHICAGO, Ill. and ROCKVILLE, Md., Sept. 13, 2021 /PRNewswire/ -- AbbVie (NYSE: ABBV) and REGENXBIO Inc. (Nasdaq: RGNX) today announced a partnership to develop and commercialize RGX-314, a potential one-time gene therapy for the treatment of wet age-related macular degeneration (wet AMD), diabetic retinopathy (DR) and other chronic retinal diseases. RGX-314 is currently being evaluated in patients with wet AMD in a pivotal trial utilizing subretinal delivery, and in patients with wet AMD and DR in two separate Phase II clinical trials utilizing in-office suprachoroidal delivery.

Under the collaboration, REGENXBIO will be responsible for completion of the ongoing trials of RGX-314. AbbVie and REGENXBIO will collaborate and share costs on additional trials of RGX-314, including the planned second pivotal trial evaluating subretinal delivery for the treatment of wet AMD and future trials. AbbVie will lead the clinical development and commercialization of RGX-314 globally. REGENXBIO shall participate in U.S. commercialization efforts as provided under a mutually agreed upon commercialization plan.

"We are committed to finding solutions for patients living with difficult-to-treat retinal diseases and to helping preserve and protect our patients from visual impairment and devastating vision loss," said Tom Hudson, MD, senior vice president, R&D, chief scientific officer, AbbVie. "In collaboration with REGENXBIO, we aim to make a remarkable impact for the millions of patients suffering from vision loss associated with retinal diseases."

"AbbVie is a strong, complementary partner for REGENXBIO. We expect to leverage AbbVie's global developmental and commercial infrastructure within eye care with our expertise in AAV gene therapy clinical development and deep in-house knowledge of manufacturing and production to continue the development of RGX-314," said Kenneth T. Mills, president and chief executive officer of REGENXBIO.

Under the terms of the agreement, AbbVie will pay REGENXBIO a $370 million upfront payment with the potential for REGENXBIO to receive up to $1.38 billion in additional development, regulatory and commercial milestones. REGENXBIO and AbbVie will share equally in profits from net sales of RGX-314 in the U.S. AbbVie will pay REGENXBIO tiered royalties on net sales of RGX-314 outside the U.S. In addition, REGENXBIO will lead the manufacturing of RGX-314 for clinical development and U.S. commercial supply, and AbbVie will lead manufacturing of RGX-314 for commercial supply outside the U.S.

The transaction is expected to close by the end of 2021, subject to the satisfaction of customary closing conditions, including applicable regulatory approvals.

REGENXBIO Conference Call
In connection with this announcement, REGENXBIO will host a webcast and conference call today at 8:00 a.m. ET. To access a live or recorded webcast of the call, please visit the "Investors" section of the REGENXBIO website at www.regenxbio.com. To access the live call by phone, dial (855) 422-8964 (domestic) or (210) 229-8819 (international) and enter the passcode 6379638. The recorded webcast will be available for approximately 30 days following the call.

About RGX-314
RGX-314 is being investigated as a potential one-time treatment for wet AMD, diabetic retinopathy, and other chronic retinal conditions. RGX-314 consists of the NAV AAV8 vector, which encodes an antibody fragment designed to inhibit vascular endothelial growth factor (VEGF). RGX-314 is believed to inhibit the VEGF pathway by which new, leaky blood vessels grow and contribute to the accumulation of fluid in the retina[1].

REGENXBIO is advancing research in two separate routes of administration of RGX-314 to the eye, through a standardized subretinal delivery procedure as well as delivery to the suprachoroidal space. REGENXBIO has licensed certain exclusive rights to the SCS Microinjector® from Clearside Biomedical, Inc. to deliver gene therapy treatments to the suprachoroidal space of the eye.

About Wet AMD
Wet AMD is characterized by loss of vision due to new, leaky blood vessel formation in the retina[2]. Wet AMD is a significant cause of vision loss in the United States, Europe and Japan, with up to 2 million people living with wet AMD in these geographies alone[3]. Current anti-VEGF therapies have significantly changed the landscape for treatment of wet AMD, becoming the standard of care due to their ability to prevent progression of vision loss in the majority of patients[4]. These therapies, however, require life-long repeated intraocular injections, to maintain efficacy[5,6]. Due to the burden of treatment, patients often experience a decline in vision with reduced frequency of treatment over time[7].

About Diabetic Retinopathy
Diabetic retinopathy (DR) is the leading cause of vision loss in adults between 24 and 75 years of age worldwide[8]. DR affects approximately eight million people in the United States alone[9]. The spectrum of DR severity ranges from non-proliferative diabetic retinopathy (NPDR) to proliferative diabetic retinopathy (PDR) and as DR progresses, a large proportion of patients develop vision threatening complications, including diabetic macular

edema (DME) and neovascularization that can lead to blindness[10]. Current treatment options for patients with DR include "watchful waiting", anti-VEGF treatment, retinal laser or surgical treatment[8].

About AbbVie
AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on Twitter, Facebook, Instagram, YouTube and LinkedIn.

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.

AbbVie Forward-Looking Statements
Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, failure to realize the expected benefits from AbbVie's acquisition of Allergan plc ("Allergan"), failure to promptly and effectively integrate Allergan's businesses, competition from other products, challenges to intellectual property, difficulties inherent in the research and development process, adverse litigation or government action, changes to laws and regulations applicable to our industry and the impact of public health outbreaks, epidemics or pandemics, such as COVID-19. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2020 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as updated by its subsequent Quarterly Reports on Form 10-Q. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

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," "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 proposed collaboration with AbbVie and 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 anticipated completion of REGENXBIO's proposed transaction with AbbVie, the outcome of REGENXBIO's proposed collaboration with AbbVie 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, 2020 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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