



Regeneron Announces Agreement with BARDA Supporting Development of Next-Generation Antibody Therapy for COVID-19 Prevention

August 22, 2023 at 2:15 PM EDT

Program is part of U.S. Government's 'Project NextGen' and provides partial funding for clinical development of a novel monoclonal antibody therapy

TARRYTOWN, N.Y., Aug. 22, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that the Biomedical Advanced Research and Development Authority (BARDA) has entered into an agreement with Regeneron to support clinical development, clinical manufacturing and the regulatory licensure process of a next-generation COVID-19 monoclonal antibody therapy for the prevention of SARS-CoV-2 infection. The agreement is part of '[Project NextGen](#),' an initiative by the U.S. Department of Health and Human Services (HHS) to advance a pipeline of new, innovative vaccines and therapeutics for COVID-19.

BARDA, part of the Administration for Strategic Preparedness and Response at HHS, and Regeneron have previously worked together to deliver novel medicines for [Ebola](#) and [COVID-19](#) at unprecedented speed and under urgent circumstances. The new program announced today falls under Regeneron and BARDA's ongoing Other Transactions Agreement initiated in [2017](#) to develop a portfolio of antibodies targeting up to 10 pathogens that pose significant risk to public health. For the new COVID-19 program, HHS will fund up to 70 percent of Regeneron's costs for certain clinical development activities for a next-generation monoclonal antibody therapy with broad neutralizing activity against SARS-CoV-2, the virus that causes COVID-19. The new contract has an estimated value of up to approximately \$326 million of government funding.

"We're pleased to expand our longstanding BARDA relationship, which is predicated on Regeneron's decades of investment in deep scientific research and enabling technologies," said Leonard S. Schleifer, M.D., Ph.D., Board Co-Chair, President and Chief Executive Officer of Regeneron. "Although COVID-19 has moved to an endemic stage, many people – including those with immunocompromising conditions – continue to face exposure that impacts their everyday life and could cause serious health consequences. We believe Regeneron can once again apply our drug discovery and development expertise to help prevent disease in vulnerable populations. American biopharmaceutical companies developed remarkable COVID-19 therapeutics and vaccines in record time, successfully changing the course of the pandemic, and we're gratified that the U.S. Government continues to support early research from this uniquely innovative industry."

Under the project structure, Regeneron independently invents and proposes an antibody candidate, which BARDA and Regeneron will then evaluate and agree upon for further development, manufacturing and regulatory activities. Regeneron's most advanced next-generation antibody candidate under this agreement is expected to enter clinical trials later this year.

Starting in early 2020, Regeneron scientists rapidly responded to the COVID-19 pandemic by discovering and manufacturing a highly potent, anti-spike antibody cocktail that successfully neutralized many SARS-CoV-2 variants, including Delta. Developed at record speed and first granted Emergency Use Authorization in [November 2020](#), the antibody cocktail was used as a COVID-19 treatment and preventative for millions of people around the globe, with nearly 3 million [doses](#) delivered to the U.S. Government between 2020 and 2022.

The next-generation antibody project is being funded in part with federal funds from BARDA under OT number: HHSO100201700020C.

About Regeneron

Regeneron is a leading biotechnology company that invents, develops, and commercializes life-transforming medicines for people with serious diseases. Founded and led for 35 years by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all of which were homegrown in Regeneron's laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about Regeneron, please visit www.regeneron.com or follow Regeneron on [LinkedIn](#).

Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Regeneron's next-generation COVID-19 monoclonal antibody therapy for the prevention of SARS-CoV-2 infection discussed in this press release (the "next-generation COVID-19 antibody candidate"); the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees (such as those referenced in this press release related to the next-generation COVID-19 antibody candidate) may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable) to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA[®] (afibercept) Injection and REGEN-COV[®] (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2022 and its Form 10-Q for the quarterly period ended June 30, 2023. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<https://investor.regeneron.com>) and its LinkedIn page (<https://www.linkedin.com/company/regeneron-pharmaceuticals>).

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Source: Regeneron Pharmaceuticals, Inc.