



BARDA Procures Regeneron's REGN-EB3 Investigational Ebola Treatment for National Preparedness

July 29, 2020

TARRYTOWN, N.Y., July 29, 2020 /PRNewswire/ --

REGN-EB3 is a novel anti-viral antibody cocktail developed using the same rapid response technologies as REGN-COV2, Regeneron's investigational COVID-19 antibody cocktail

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) announced today that the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services (HHS), has entered into an agreement to procure REGN-EB3 as part of the HHS' goal of building national preparedness for public health emergencies.

REGN-EB3 is Regeneron's investigational triple antibody cocktail treatment for Ebola virus infection and is currently under Priority Review by the U.S. Food and Drug Administration (FDA), with a target action date of October 25, 2020. Contingent on FDA approval, Regeneron expects to deliver an established number of treatment doses over the course of six years and receive compensation of approximately \$10 million in 2021 and an average of \$67 million per year for each of the next five years (2022-2026).

"Developed using Regeneron's proprietary *VelociSuite*[®] rapid response technologies, REGN-EB3 was shown to save lives in the PALM trial, which evaluated multiple therapies against the previous standard of care for Ebola," said Leonard S. Schleifer, M.D., Ph.D., Co-Founder, President and Chief Executive Officer of Regeneron. "Regeneron's thirty years of investment in our technology and people enabled the development of REGN-EB3, which reinforces the importance of having at-the-ready tools to fight emerging pathogens. As we push through the current COVID-19 pandemic, it's important for governments and industry to ensure preparedness for the next global health crisis by continuing to invest in innovative science and broad manufacturing capacity."

"The current COVID-19 pandemic provides an important lesson in preparation for potential biological threats to our nation's health security," said BARDA acting director Gary Disbrow, Ph.D. "REGN-EB3 is the result of years of collaboration, which demonstrates the fundamental value of public-private partnership in protecting Americans from global epidemics. Whether the next one is another coronavirus, an Ebola virus or a completely novel disease, we must do everything we can to be prepared."

In 2019, the randomized controlled PALM clinical trial conducted in the Democratic Republic of the Congo was stopped early when preliminary results showed that REGN-EB3 crossed the pre-specified superiority threshold for preventing death compared to the control arm, ZMapp[®]. REGN-EB3 [demonstrated superior efficacy](#) compared to ZMapp across multiple measures, including reduced mortality and fewer days until the Ebola virus was no longer detected in the bloodstream. During the trial, there were three serious adverse events for REGN-EB3, compared to seven for ZMapp. REGN-EB3 is being developed with collaboration and funding provided by BARDA under ongoing USG Contract Nos. HHSO100201700016C and HHSO100201500013C.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, 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 the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation REGN-EB3 (Regeneron's investigational triple antibody cocktail treatment for Ebola virus infection) and REGN-COV2 (Regeneron's investigational COVID-19 antibody cocktail); uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's Products and product candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates (such as REGN-EB3 and REGN-COV2) and new indications for Regeneron's Products; safety issues resulting from the administration of Regeneron's Products and product candidates (such as REGN-EB3 and REGN-COV2) in

patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; whether Regeneron will be able to deliver the established number of treatment doses set forth in its agreement with the Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services (HHS), (collectively, the "U.S. Government") discussed in this press release (the "Supply Agreement"), the amount of payments (if any) Regeneron may receive pursuant to the Supply Agreement, and whether the Supply Agreement is terminated by the U.S. Government or otherwise prior to completion; 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 product candidates, including without limitation REGN-EB3 and REGN-COV2; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; 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 product candidates; 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 product candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and 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 or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; 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, Dupixent® (dupilumab), and Praluent® (alirocumab)), 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, 2019 and its Form 10-Q for the quarterly period ended March 31, 2020. 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 any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Contacts:

Media Relations

Alexandra Bowie

Tel: +1 (914) 847-3407

alexandra.bowie@regeneron.com

Investor Relations

Mark Hudson

Tel: +1 (914) 847-3482

mark.hudson@regeneron.com

 View original content: <http://www.prnewswire.com/news-releases/barda-procures-regenerons-regn-eb3-investigational-ebola-treatment-for-national-preparedness-301101733.html>

SOURCE Regeneron Pharmaceuticals, Inc.