



Regeneron Announces Manufacturing and Supply Agreement for BARDA and U.S. Department of Defense for REGN-COV2 Anti-Viral Antibody Cocktail

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TARRYTOWN, N.Y., July 7, 2020 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that, as part of Operation Warp Speed, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, and the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense have awarded Regeneron a \$450 million contract to manufacture and supply REGN-COV2. REGN-COV2 is Regeneron's investigational double antibody cocktail that is currently in two Phase 2/3 clinical trials for the treatment of COVID-19 and in a [Phase 3 trial](#) for the prevention of COVID-19 infection.

Regeneron began scaling up manufacturing of REGN-COV2 at business risk in spring of 2020. This agreement supports continued manufacturing so that the product could be made available immediately in the United States if clinical trials are successful and the U.S. Food and Drug Administration (FDA) grants Emergency Use Authorization (EUA) or product approval. The agreement covers a fixed number of bulk lots that are intended to be completed in the fall of 2020, as well as fill/finish and storage activities. The ongoing REGN-COV2 clinical program is evaluating multiple dosages and will help establish the exact number of potential treatment doses (estimated range of 70,000 to 300,000) or prevention doses (estimated range of 420,000 to 1,300,000) available from these lots in total. Initial doses may be ready as early as end of summer. If EUA or product approval is granted, the government has committed to making doses from these lots available to the American people at no cost and would be responsible for their distribution.

"Regeneron's thirty years of investment in our innovative *VelociSuite*[®] antibody discovery and development technologies and our large-scale manufacturing facilities, coupled with the expertise and passion of our people, has enabled us to move the REGN-COV2 program forward at remarkable speed," said Leonard S. Schleifer, M.D., Ph.D., Co-Founder, President and Chief Executive Officer of Regeneron. "We made the decision early on to begin large-scale manufacturing at our own risk in order to ensure that product would be available immediately if our clinical trials prove successful and an Emergency Use Authorization is granted. This manufacturing and supply agreement with BARDA and the Department of Defense could help REGN-COV2 reach many people quickly, hopefully helping to change the course of this deadly and still-raging pandemic."

Regeneron continues to work to maximize manufacturing capacity of REGN-COV2 within Regeneron and with potential partners.

About REGN-COV2

Regeneron scientists evaluated thousands of fully-human antibodies produced by the company's proprietary *VelocImmune*[®] mice, which have been genetically-modified to have a human immune system, as well as antibodies identified from humans who have recovered from COVID-19. They selected the two most potent, non-competing and virus-neutralizing antibodies to create REGN-COV2 and have scaled up this dual-antibody cocktail with the company's in-house *VelociMab*[®] and manufacturing capabilities. REGN-COV2's two antibodies bind non-competitively to the critical receptor binding domain of the virus's spike protein, which diminishes the ability of mutant viruses to escape treatment and protects against spike variants that have arisen in the human population, as detailed in [recent Science publications](#). More recent research also demonstrates coverage against [the now prevalent D614G variant](#).

Regeneron used the same 'rapid response' capabilities and cocktail approach to develop REGN-EB3, a novel triple antibody treatment for Ebola that is now under regulatory review by the FDA. REGN-COV2's development and manufacturing has been funded in part with federal funds from the BARDA under OT number: HHSO100201700020C.

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, other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs (including those discussed in this press release), 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 product candidates and research and clinical programs now underway or planned, including without limitation REGN-COV2 (Regeneron's investigational dual antibody cocktail for the prevention and treatment of COVID-19) and REGN-EB3 (Regeneron's novel triple antibody treatment for Ebola); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates (such as REGN-COV2 and REGN-EB3) and new indications for Regeneron's Products; unforeseen safety issues resulting from the administration of Regeneron's Products and product candidates (such as REGN-COV2 and REGN-EB3) 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 meet any drug product manufacturing milestones set forth in the manufacturing and supply agreement with the Biomedical Advanced Research and Development Authority and the Joint Project Executive Office for Chemical, Biological, Radiological and Nuclear Defense with the U.S. Department of Defense (collectively, the "U.S. Government") discussed in this press release (the "Manufacturing and Supply Agreement"), the amount of payments (if any) Regeneron may receive pursuant to the Manufacturing and Supply Agreement, and whether the Manufacturing and 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-COV2 and REGN-EB3; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; 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 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 Regeneron's Products and product candidates; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; 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, labelling, 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 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.

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 (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

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