

Regeneron and Roche Collaborate to Significantly Increase Global Supply of REGN-COV2 Investigational Antibody Cocktail for COVID-19

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REGN-COV2 is Regeneron's two-antibody 'cocktail' currently in late-stage clinical trials for the treatment and prevention of COVID-19 infection

The companies will collaborate on developing and manufacturing REGN-COV2; Regeneron will distribute REGN-COV2 in the U.S. and Roche will be responsible for distribution outside the U.S.

Under this agreement, overall capacity of REGN-COV2 is expected to increase by at least three and a half times, substantially increasing the number of doses available to patients in the U.S. and around the world

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Roche announced today that they are joining forces in the fight against COVID-19 to develop, manufacture and distribute REGN-COV2, Regeneron's investigational anti-viral antibody cocktail, to people around the globe. REGN-COV2 could provide a much-needed treatment option for people already experiencing symptoms of COVID-19, and also has the potential to prevent infection in people exposed to the virus, thus slowing the spread of the global pandemic. This collaboration is expected to increase supply of REGN-COV2 to at least three and a half times the current capacity, with the potential for even further expansion.

REGN-COV2 is currently being studied 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 in household contacts of infected individuals. If it proves safe and effective in clinical trials and regulatory approvals are granted, Regeneron will distribute and record sales for REGN-COV2 in the U.S. and Roche will be responsible for distribution outside the U.S.

"We are excited about the potential for one medicine to serve both as a treatment for those infected as well as protection for people exposed to the virus. REGN-COV2 could be a critical line of defense against the COVID-19 pandemic," said Bill Anderson, Chief Executive Officer of Roche Pharmaceuticals. "We're committing our manufacturing expertise and capacity, and our global distribution network, to bring Regeneron's potential antibody combination to as many people around the world as we possibly can."

"Regeneron has progressed the REGN-COV2 research and development program at record speed and worked tirelessly to maximize our in-house manufacturing capacity," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "This major collaboration with Roche provides important scale and global expertise to bring REGN-COV2 to many more patients in the United States and around the globe."

Under the terms of the agreement, each company has committed to dedicate a certain manufacturing capacity to REGN-COV2 each year, and the collaborators have already begun the technology transfer process. Each company will bear its own distribution expenses in their designated territories. The collaborators will jointly fund and execute the ongoing Phase 3 prevention and Phase 1 healthy volunteer safety studies, as well as any additional global studies to evaluate further the potential for REGN-COV2 in treating or preventing COVID-19. Roche will be primarily responsible for securing regulatory approvals outside the U.S., following the initial European Medicines Agency (EMA) approval, and conducting any additional studies specifically required for approval by regulators outside the U.S.

About REGN-COV2

REGN-COV2 was designed specifically by Regeneron scientists to block infectivity of SARS-CoV-2, the virus that causes COVID-19. They 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. The two potent, virus-neutralizing antibodies that form REGN-COV2 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 <u>recent</u> <u>Science publications</u>.

REGN-COV2's development, manufacturing and clinical trials have been funded in part by 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 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 and 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 two-antibody cocktail for the treatment and prevention of COVID-19); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates (such as 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-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 the technology transfer process discussed in this press release will be completed in the expected time frame or at all and whether the collaboration with Roche discussed in this press release will result in an increase in the current manufacturing and distribution capacity for REGN-COV2; 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; 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, 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), as well as Regeneron's collaboration with Roche discussed in this press release, to be cancelled or terminated without any 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® (aflibercept) 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 June 30, 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 (<u>http://newsroom.regeneron.com</u>) and its Twitter feed (<u>http://twitter.com/regeneron</u>).

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