Regeneron Confirms that REGN-COV2 Antibody Cocktail Provided to President Trump Under Compassionate Use Request

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today confirmed that, as announced by the White House Press Secretary, Regeneron provided a single 8 gram dose of REGN-COV2, a cocktail of two monoclonal antibodies, for use by President Trump. REGN-COV2 is an investigational COVID-19 therapy, which was provided in response to an Individual Patient Investigational New Drug (IND) application (commonly known as ‘compassionate use’ request) from the President’s physicians.

Regeneron has a compassionate use program with certain established criteria and review committee. As a matter of policy, the company does not disclose whether any individual has or has not submitted a request for compassionate use without their consent or prior disclosure.

The company’s current priority is to maintain a sufficient supply of REGN-COV2 in order to conduct rigorous clinical trials that fully evaluate its safety and efficacy. In addition to the clinical trial supply and product being manufactured under an agreement with the U.S. government, there is limited product available for compassionate use requests that have been approved under rare, exceptional circumstances on a case-by-case basis. Requests for compassionate use must be initiated by a treating physician.

REGN-COV2 is being evaluated for both the treatment and prevention of COVID-19. Clinical trials are actively enrolling hospitalized and non-hospitalized patients, as well as people at risk of infection who have had close household exposure to a COVID-19 patient. Earlier this week, Regeneron announced early data showing a reduction in viral levels and improved symptoms with REGN-COV2 treatment in non-hospitalized COVID-19 patients.

Individuals interested in participating in one of Regeneron’s COVID-19 clinical trials may complete a brief online screener at ClinLife.com/COVID to see if they qualify. More than 2,000 people have been enrolled across the overall REGN-COV2 development program to date, and no unexpected safety findings have been reported by the Independent Data Monitoring Committee.

About REGN-COV2
REGN-COV2 is a combination of two monoclonal antibodies (REGN10933 and REGN10987) and was designed specifically to block infectivity of SARS-CoV-2, the virus that causes COVID-19.

To develop REGN-COV2, Regeneron scientists evaluated thousands of fully-human antibodies produced by the company’s 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
Science. Preclinical studies have shown that REGN-COV2 reduced the amount of virus and associated damage in the lungs of non-human primates.

REGN-COV2’s development and manufacturing has been funded in part with federal funds from 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. Regeneron has recently partnered with Roche to increase the global supply of REGN-COV2. If REGN- COV2 proves safe and effective in clinical trials and regulatory approvals are granted, Regeneron will manufacture and distribute it in the U.S. and Roche will develop, manufacture and distribute it outside the U.S.

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 statement 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 and its collaborators’ ability to continue to conduct research and clinical programs (including those discussed in this statement); the nature, timing, and possible success and therapeutic applications of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron’s Products") and Regeneron’s product candidates and research and clinical programs now underway or planned, including without limitation the development program relating to REGN-COV2 (Regeneron’s investigational two-antibody cocktail for the treatment and prevention of COVID-19) discussed in this statement; 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; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators (including without limitation the early data from the trial evaluating REGN-COV2 in non-hospitalized COVID-19 patients referenced in this statement) may be replicated and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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; ongoing regulatory obligations and oversight impacting Regeneron’s Products, research and clinical programs (such as REGN-COV2), 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; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron’s Products and product candidates; 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; 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; risks associated with intellectual property of other parties and pending or future litigation relating thereto, 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; and 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 relating to REGN-COV2, to be cancelled or terminated. 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-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 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 (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

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