Regeneron Announces Start of REGN-COV2 Phase 3 COVID-19 Prevention Trial in Collaboration with National Institute of Allergy and Infectious Diseases (NIAID)

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Anti-viral antibody cocktail REGN-COV2 is also in Phase 2/3 treatment trials following positive Phase 1 safety review

TARRYTOWN, N.Y., July 6, 2020 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced the initiation of late-stage clinical trials evaluating REGN-COV2, Regeneron's investigational double antibody cocktail for the treatment and prevention of COVID-19. A Phase 3 trial will evaluate REGN-COV2's ability to prevent infection among uninfected people who have had close exposure to a COVID-19 patient (such as the patient's housemate), and is being run jointly with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). REGN-COV2 has also moved into the Phase 2/3 portion of two adaptive Phase 1/2/3 trials testing the cocktail's ability to treat hospitalized and non-hospitalized (or "ambulatory") patients with COVID-19.

This clinical progress follows a positive review from the Independent Data Monitoring Committee of REGN-COV2 Phase 1 safety results in an initial cohort of 30 hospitalized and non-hospitalized patients with COVID-19.

The Phase 3 prevention trial is being conducted at approximately 100 sites and is expected to enroll 2,000 patients in the U.S.; the trial will assess SARS-CoV-2 infection status. The two Phase 2/3 treatment trials in hospitalized (estimated enrollment =1,850) and non-hospitalized (estimated enrollment =1,050) patients are planned to be conducted at approximately 150 sites in the U.S., Brazil, Mexico and Chile, and will evaluate virologic and clinical endpoints, with preliminary data expected later this summer. All trials are adaptively-designed, and the ultimate numbers of patients enrolled will depend on trial progress and insights from Phase 2 studies.

"We are running simultaneous adaptive trials in order to move as quickly as possible to provide a potential solution to prevent and treat COVID-19 infections, even in the midst of an ongoing global pandemic," said George D. Yancopoulos, M.D., Ph.D., Co-Founder, President and Chief Scientific Officer of Regeneron. "We are pleased to collaborate with NIAID to study REGN-COV2 in our quest to further prevent the spread of the virus with an anti-viral antibody cocktail that could be available much sooner than a vaccine."

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 isolated 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 for clinical use 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, 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 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; 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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