Regeneron Begins First Clinical Trials of Anti-Viral Antibody Cocktail REGN-COV2 for the Treatment and Prevention of COVID-19

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Clinical program consists of four separate study populations: two for treatment and two for prevention

First studies evaluate safety and efficacy in hospitalized and non-hospitalized patients with COVID-19

Two-antibody 'cocktail' is designed to help protect against viral escape

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced initiation of the first clinical trial of REGN-COV2, its investigational dual antibody cocktail for the prevention and treatment of COVID-19. The REGN-COV2 clinical program will consist of four separate study populations: hospitalized COVID-19 patients, non-hospitalized symptomatic COVID-19 patients, uninfected people in groups that are at high-risk of exposure (such as healthcare workers or first responders) and uninfected people with close exposure to a COVID-19 patient (such as the patient's housemate). The placebo-controlled trials will be conducted at multiple sites.

"We have created a unique anti-viral antibody cocktail with the potential both to prevent and treat infection, and also to preempt viral 'escape,' a critical precaution 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. "REGN-COV2 could have a major impact on public health by slowing spread of the virus and providing a needed treatment for those already sick – and could be available much sooner than a vaccine. The antibody cocktail approach may also have long-term utility for elderly and immuno-compromised patients, who often do not respond well to vaccines. Ultimately, the world needs multiple solutions for COVID-19, and the innovative biopharma industry is collectively working hard to help as many people as possible with a variety of complementary approaches."

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 and have scaled them up for clinical use with the company's in-house *VelociMab*® and manufacturing capabilities. The two antibodies bind non-competitively to the critical receptor binding domain (RBD) of the virus's spike protein, which diminishes the ability of mutant viruses to escape treatment, as demonstrated in upcoming *Science* publications of preclinical research.

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 U.S. Food and Drug Administration (FDA). REGN-COV2's preclinical development and preclinical/clinical 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.

The first two adaptive Phase 1/2/3 studies are evaluating REGN-COV2 (REGN10933+REGN10987) as a treatment for hospitalized and non-hospitalized patients with COVID-19. The Phase 1 portion will focus on virologic and safety endpoints, and the Phase 2 portion will focus on virologic and clinical endpoints. Data from the Phase 1 and Phase 2 studies will be used to refine the endpoints and determine size for the Phase 3 studies.

"We are particularly excited to begin studies of REGN-COV2, which is a novel antibody cocktail targeted specifically against SARS-CoV-2," said trial investigator Dr. Suraj Saggar, Chief of Infectious Disease at Holy Name Medical Center in Teaneck, New Jersey. "Over the last long months, we have learned that repurposing existing medicines unfortunately does not offer a broadly effective solution for COVID-19. For this reason, we need to investigate custom-designed approaches like REGN-COV2. The first studies will evaluate if REGN-COV2 can improve disease outcomes in both hospitalized and non-hospitalized patients with COVID-19."

About Regeneron's Anti-Viral Antibodies
When faced with a harmful pathogen, such as a virus or bacteria, the human immune system typically produces antibodies to fight the invader. Specifically, the immune system produces 'anti-viral' antibodies that recognize, bind, and kill or neutralize the virus. Vaccination involves injecting a dead or weakened virus, or a critical small piece of a virus, to induce this protective immune response, resulting in the same antibodies the immune system would typically make in a person who actually had the infectious disease.

Regeneron's core technologies allow for rapid and efficient generation of these protective anti-viral antibodies outside of the body,

derived from either genetically-humanized mice or convalescent humans. The resulting antibodies correspond to the most potent of anti-viral antibodies that could be elicited by a vaccine or through exposure to a pathogen. These antibodies can be delivered to people via injection, providing "passive immunity" and protection from the disease immediately, though they must be re-administered to remain effective over time. These antibodies can also treat an existing infection, unlike vaccines which can only be used preventatively.

The concept that drug cocktails can prevent viral escape has previously been demonstrated for traditional antiviral drugs used to treat HIV and other viruses. In the upcoming *Science* publications, Regeneron scientists report the fundamental realization that this can also be true for antibody-based therapies. Regeneron's preclinical studies demonstrate that, in the setting of a single therapeutic antibody that blocks the ability of a virus to infect healthy cells, spontaneously arising mutant forms of the virus are able to 'escape' or evade the antibody's blocking action. These mutants are then 'selected' (i.e., are able to survive and proliferate despite the single antibody treatment) and may ultimately become the dominant strain of the virus. Regeneron therefore pursues a multi-antibody cocktail approach designed to decrease the potential for the virus to escape.

Regeneron has developed additional technologies that allow for the large-scale manufacturing and purification of these anti-viral antibodies, potentially allowing many people to be granted immunity before vaccines become widely available.

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.

Regeneron 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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