FDA Accepts for Priority Review Biologics License Application for REGN-EB3 to Treat Ebola

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- *REGN-EB3 developed via same rapid response platform currently being leveraged to develop novel COVID-19 antibody therapy*

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review a new Biologics License Application (BLA) for REGN-EB3, an investigational triple antibody cocktail treatment for Ebola virus infection. The target action date for the FDA decision is October 25, 2020.

The REGN-EB3 BLA is supported by data from the randomized, controlled PALM clinical trial conducted in the Democratic Republic of Congo. In August 2019, the trial was stopped early when preliminary results showed that REGN-EB3 crossed the pre-specified superiority threshold for preventing death compared to the control arm, ZMapp. REGN-EB3 demonstrated superior efficacy compared to ZMapp across multiple measures, including reduced mortality and fewer days until the Ebola virus was no longer detected in the bloodstream.

"Developed using Regeneron's proprietary *VelociSuite*® rapid response technologies, REGN-EB3 was shown to save lives in the PALM trial, which evaluated multiple therapies against the current standard of care," said George D. Yancopoulos, M.D., Ph.D., Co-Founder, President and Chief Scientific Officer of Regeneron. "Regeneron is now applying this same approach to develop an antibody medicine that can potentially prevent and treat COVID-19, with initial clinical trials expected to begin in June."

Regeneron's *VelociSuite* technologies enable the efficient creation and selection of potent fully-human antibodies against a specific biological target, which is particularly critical for addressing new and/or quickly-spreading pathogens that cause diseases such as Ebola and COVID-19. These technologies facilitate the rapid cloning and generation of optimized fully-human antibodies from both *VelocImmune*® mice (which are genetically-engineered to have genetically-humanized immune systems) and convalescing human volunteers, and allow for the rapid escalation of fully-human antibodies into manufacturing-quality cell line production and large-scale bioreactor manufacturing. Once strong therapeutic antibody candidates are identified, the company's in-house preclinical, clinical and commercial-scale manufacturing capabilities allow for fast scale-up and flexibility to adapt to current need.

REGN-EB3 has received Orphan Drug and Breakthrough Therapy designation from the FDA. It is being developed under an ongoing collaboration and with funding provided by the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services (USG Contract Nos. HHSO100201700016C and HHSO100201500013C).

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, 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 Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation Regeneron's investigational triple antibody cocktail treatment for Ebola virus infection ("REGN-EB3") and Regeneron's novel antibody cocktail for the prevention and treatment of the SARS-CoV-2 virus (the "COVID-19 Multi-antibody Therapy"); 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 lead to therapeutic applications; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates (such as REGN-EB3 and the COVID-19 Multi-antibody Therapy) and new indications for Regeneron's Products; unforeseen safety issues resulting from the administration of Regeneron's Products and product candidates 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; 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 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 the agreements with the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services referenced in this press release, 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. 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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