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Regeneron Announces New Collaborations with HHS to Develop Antibodies Against Ebola, Influenza and Multiple Other Emerging Pathogens

TARRYTOWN, N.Y., Oct. 2, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced two new collaborations with 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 (HHS), to develop new treatments combating infectious diseases. The first collaboration is focused on discovery, research, development and manufacturing of a portfolio of antibodies targeting up to 10 pathogens that pose significant risk to public health, starting with Influenza virus. The second collaboration ([announced by HHS on September 29](#)) builds on a prior agreement to develop and manufacture Regeneron's potential therapy for Ebola virus. This investigational treatment has completed a Phase 1 clinical study and received Orphan Drug Designation from the U.S. Food and Drug Administration.

Both drug development efforts utilize Regeneron's proprietary *VelociSuite*[®] technologies that facilitate rapid identification, preclinical validation and development of suitable antibody candidates.

"We look forward to expanding upon our prior work with BARDA, as we continue our joint efforts to address serious public health threats," said George Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "Our decades of investment in foundational technology platforms have resulted in a cutting-edge approach to drug discovery and development, and we're proud to apply this technology against serious infectious threats such as Influenza virus and Ebola virus."

The emerging pathogens treatment portfolio will be pursued using an Other Transaction Agreement (OTA), which provides a funding and collaboration vehicle for HHS to promote innovation in technology for advanced research and development. Under the OTA, which has a term of 10 years, HHS will fund 80 percent of Regeneron's costs for research, development and manufacturing activities for antibodies that are selected to move forward. Up to 10 target pathogens may be jointly selected by BARDA and Regeneron. The first selected program will target Influenza virus and receive initial funding of more than \$18 million for early-stage antibody discovery, development and manufacturing.

"Influenza and other emerging infectious diseases present serious threats to our nation's health security," said Rick Bright, Ph.D., BARDA Director. "This partnership will support much-needed treatment options for those who are severely ill with influenza and the rapid drug development that is critical to save lives when a new disease emerges."

"Regeneron's unique rapid response platform enables us to move from preclinical research to clinical development in a matter of months instead of years," said Neil Stahl, Ph.D., Executive Vice President of Research and Development at Regeneron. "We can apply our technologies swiftly against known and currently unknown infectious agents, giving us the dexterity to potentially help as many people as possible should a public health emergency arise."

Under the separate Ebola agreement, HHS will provide approximately \$40 million in initial committed funding for continued development of REGN3470-3471-3479, a single therapy that contains three monoclonal antibodies. Subsequent phases of funding may support clinical investigation, a potential Biologics Licensing Application (BLA) and initial procurement of the therapy for the Strategic National Stockpile. BARDA and Regeneron [announced in September 2015](#) an agreement to support development of this antibody therapy through its first Phase 1 trial.

Regeneron and BARDA also have [an existing agreement](#) to develop a treatment for Middle East Respiratory Syndrome (MERS). Regeneron has identified and validated Spike-protein blocking antibodies, and an NIH-sponsored Phase 1 clinical trial in adult patients is expected to be initiated by the end of the year.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led by physician-scientists for nearly 30 years, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and more than a dozen product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, and infectious and rare diseases. Regeneron is accelerating and improving the traditional drug development process through its unique *VelociSuite*[®] technologies, including *VelociGene*[®] and *VelocImmune*[®], and ambitious initiatives such as The Regeneron Genetics Center, 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 news 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 nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation Regeneron's potential antibody therapies for the treatment of Ebola, Influenza, Middle East Respiratory Syndrome, and other emerging pathogens; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in later studies and lead to therapeutic applications; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including without limitation Regeneron's potential antibody therapies for the treatment of Ebola, Influenza, Middle East Respiratory Syndrome, and other emerging pathogens; serious complications or side effects in connection with the use of Regeneron's products and product candidates (such as Regeneron's potential antibody therapies for the treatment of Ebola, Influenza, Middle East Respiratory Syndrome, and other emerging pathogens) in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; 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, such as Regeneron's potential antibody therapies for the treatment of Ebola, Influenza, Middle East Respiratory Syndrome, and other emerging pathogens; competing drugs and product candidates that may be superior to 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 ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other 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 discussed in this news 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 relating to Praluent[®] (alirocumab) Injection, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, 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 United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2016 and its Form 10-Q for the quarterly period ended June 30, 2017. 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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