REGENERON

May 31, 2018

Regeneron's Investigational Ebola Treatment Shipping to Democratic Republic of the Congo for Use in Current Outbreak

TARRYTOWN, New York, May 31, 2018 /PRNewswire/ --

Regeneron working with World Health Organization, U.S. Food and Drug Administration and Democratic Republic of the Congo authorities to ensure appropriate and timely access

Data published today in Journal of Infectious Diseases show promising efficacy of REGN-EB3 (REGN3470-3471-3479) in animal models; Phase 1 results have demonstrated safety in healthy human volunteers

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that REGN-EB3 (also known as REGN3470-3471-3479), its investigational therapy that combines three fully-human monoclonal antibodies, is being shipped to the Democratic Republic of the Congo for use in the current Ebola virus infection outbreak. REGN-EB3 is one of several investigational therapeutics evaluated for use by a panel of independent scientific experts convened by the World Health Organization (WHO) and selected for inclusion in a potential WHO-coordinated clinical trial. Regeneron's Ebola and other infectious disease programs utilize the company's proprietary *VelociSuite*® technologies that facilitate rapid identification, validation and development of suitable antibody candidates to address urgent public health needs by moving from preclinical to clinical research in a matter of months instead of years.

"The unfortunate reemergence of Ebola has created an urgent need to deliver and administer investigational treatments with promising data, such as REGN-EB3," said Neil Stahl, Ph.D., Executive Vice President of Research and Development at Regeneron. "In addition to preclinical demonstrations of efficacy in animals that were symptomatic post-infection and positive safety data in humans, we believe our antibodies have certain beneficial attributes for outbreak situations. For instance, our investigational treatment can be administered in a single dose and its stability means that it does not have to be stored frozen - very practical qualities in countries where these outbreaks have previously occurred."

A new publication from the *Journal of Infectious Diseases* describes development of REGN-EB3 and efficacy results at different doses in animal models. In three preclinical studies, REGN-EB3 was seen to treat advanced Ebola virus disease and prevent mortality of infected non-human primates. REGN-EB3 also demonstrated efficacy in symptomatic non-human primates with a single dose when given as late as Day 5 after infection with Ebola virus.

Regeneron worked with the WHO and U.S. Food and Drug Administration (FDA) to develop an Expanded Access Program protocol to support use of this treatment in the most recent outbreak in the Congo. Similarly, the treatment will be provided in-line with the WHO ethical framework known as Monitored Emergency Use of Unregistered Interventions (MEURI), which establishes certain criteria for access to investigational therapeutics outside of clinical trials. Regeneron has secured various regulatory approvals, country approvals and import licenses and has hundreds of doses of REGN-EB3 ready to ship beyond the initial shipment currently in process. Additional drug substance is also available, should resupply be necessary.

REGN-EB3 has received orphan drug designation from both the FDA and European Medicines Agency. It is currently under clinical development, and its safety and efficacy have not been fully evaluated by any regulatory authority. Additional preclinical research and human safety data collection is ongoing to support future regulatory applications. REGN-EB3 is being developed, tested and manufactured as part of an agreement established in 2015 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). HHS has provided funding to support preclinical development and antibody manufacturing, as well as the recently completed Phase 1 safety study in healthy volunteers that is currently pending publication.

Regeneron and BARDA have several ongoing research collaborations in addition to the Ebola program, including a collaboration to develop treatments for Middle Eastern Respiratory Syndrome (MERS) and a collaboration for the discovery, research, development and manufacturing of a portfolio of antibodies targeting up to 10 pathogens that pose significant risk to public health. The National Institute of Allergy and Infectious Diseases recently initiated an NIH-sponsored Phase 1 clinical trial of the MERS Spike-protein blocking antibody identified and validated by Regeneron.

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 for 30 years by physician-scientists, our unique ability to repeatedly and consistently

translate science into medicine has led to six 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 disease, heart disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*® which produces optimized fully-human antibodies, and 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 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, (REGN-EB3 or REGN3470-3471-3479) and Middle East Respiratory Syndrome (MERS); 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 and MERS; 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 and MERS) 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 and MERS; 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 referenced 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 proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of such litigation proceedings, 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, 2017 and its Form 10-Q for the quarterly period ended March 31, 2018. 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).

Regeneron Investor Relations
Manisha Narasimhan, Ph.D.
Tel: +1 (914) 847-5126
Manisha.narasimhan@regeneron.com

Regeneron Media Relations

Alexandra Bowie
Tel: +1 (914) 847-3407
alexandra.bowie@regeneron.com

View original content:http://www.prnewswire.com/news-releases/regenerons-investigational-ebola-treatment-shipping-to-democratic-republic-of-the-congo-for-use-in-current-outbreak-300657516.html

SOURCE Regeneron Pharmaceuticals, Inc.