REGENERON

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Regeneron to Discontinue Development of Suptavumab for Respiratory Syncytial Virus

TARRYTOWN, N.Y., Aug. 14, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that a Phase 3 study evaluating suptavumab (REGN2222), an antibody to respiratory syncytial virus (RSV), did not meet its primary endpoint of preventing medically-attended RSV infections in infants. Suptavumab did show signs of efficacy in a subgroup of patients. Adverse events were generally balanced between suptavumab and placebo. Regeneron plans to discontinue further clinical development of this antibody.

"We are disappointed in these results, as we had hoped suptavumab might offer a new option for the thousands of infants impacted by serious RSV infections every year," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "Regeneron has a robust pipeline across many serious diseases, and we look forward to important data readouts from other programs in the coming weeks and months."

The double-blind, placebo-controlled global Phase 3 NURSERY Pre-term study enrolled 1,149 healthy pre-term infants. Patients were randomized in a 1:1:1 ratio to one of three study groups: suptavumab 30 mg/kg as a single dose; suptavumab 30 mg/kg administered as two doses 8 weeks apart; or placebo. Assessment of the primary endpoint occurred through Day 150 of treatment. Patients were considered 'medically-attended' if they required hospitalization and/or sought medical care for a centrally-adjudicated RSV infection. Pre-term infants in the study had a gestational age of less than 36 weeks and were 6 months old or younger at the beginning of the study.

Data from the study will be presented at a future medical congress.

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 nearly 30 years by physician-scientists, our unique ability to consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates, 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 its proprietary *VelociSuite*[®] technologies, including *VelocImmune*[®] which yields optimized fully-human antibodies, 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 <u>www.regeneron.com</u> 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 nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may lead to therapeutic applications; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; 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; the ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; 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), 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 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 commercially 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 U.S. Securities and Exchange Commission, including its Form 10-K for the fiscal year ended December 31, 2016 and its Form 10-Q for the quarterly period ended June 30, 2017. 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 (<u>http://newsroom.regeneron.com</u>) and its Twitter feed (<u>http://twitter.com/regeneron</u>).

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