Regeneron Announces Evinacumab has Received FDA Breakthrough Therapy Designation for Homozygous Familial Hypercholesterolemia (HoFH)

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TARRYTOWN, N.Y., April 6, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation status to evinacumab for the treatment of hypercholesterolemia in patients with Homozygous Familial Hypercholesterolemia (HoFH), an inherited disorder that can lead to premature cardiovascular disease due to very high levels of LDL cholesterol. Evinacumab is an investigational monoclonal antibody to angiopoietin-like protein 3 (ANGPTL3). ANGPTL3 acts as an inhibitor of lipoprotein lipase and endothelial lipase, and appears to play a central role in lipoprotein metabolism.

Regeneron previously reported positive interim phase 2 results for evinacumab in HoFH patients and is currently planning a phase 3 trial.

HoFH is the most severe form of hypercholesterolemia. While rare, occurring in approximately one to two people per million, untreated patients can have LDL cholesterol levels ranging from 500 to 1000 mg/dL, compared to normal LDL cholesterol levels of less than 130 mg/dL. Due to these high levels of LDL cholesterol, patients with HoFH are at an extreme risk of premature cardiovascular disease. Without treatment, patients typically present with signs and symptoms of atherosclerotic cardiovascular disease before the age of 20.

Breakthrough Therapy designation was created to expedite the development and review of drugs that target serious or life-threatening conditions. A Breakthrough Therapy drug must show preliminary clinical evidence of a substantial improvement on a clinically significant endpoint over available therapies, or over placebo if there is no available therapy.

About Regeneron Pharmaceuticals, Inc.
Regeneron (NASDAQ: REGN) is a leading science-based biopharmaceutical company that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, high LDL-cholesterol, atopic dermatitis and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, asthma, pain, cancer and infectious diseases. 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 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 evinacumab (REGN1500); 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, such as evinacumab for the treatment of hypercholesterolemia in patients with Homozygous Familial Hypercholesterolemia and other potential indications; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including without limitation evinacumab; serious complications or side effects in connection with the use of Regeneron's products and product candidates (such as evinacumab) in clinical trials; 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 evinacumab; 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, 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 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 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. 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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