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Regeneron and Sanofi Announce Cemiplimab (REGN2810) Has Received FDA Breakthrough Therapy Designation for Advanced Cutaneous Squamous Cell Carcinoma

TARRYTOWN, N.Y. and PARIS, Sept. 8, 2017 /PRNewswire/ -- [Regeneron Pharmaceuticals, Inc.](#) (NASDAQ: REGN) and [Sanofi](#) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation status to cemiplimab (REGN2810) for the treatment of adults with metastatic cutaneous squamous cell carcinoma (CSCC) and adults with locally advanced and unresectable CSCC, the second deadliest skin cancer after melanoma. Cemiplimab is an investigational human, monoclonal antibody targeting PD-1.

Regeneron and Sanofi [previously reported](#) positive, preliminary results for cemiplimab from two expansion cohorts involving 26 advanced CSCC patients in a Phase 1 study of nearly 400 patients, at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2017. EMPOWER-CSCC 1, a Phase 2, potentially pivotal, single-arm, open-label clinical trial of cemiplimab is currently enrolling patients with metastatic CSCC and locally advanced and unresectable CSCC. Cemiplimab was discovered using Regeneron's proprietary VelocImmune® technology that yields optimized fully-human antibodies, and is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. Pending data results, the companies anticipate submitting a biologics license application for cemiplimab with the FDA in the first quarter of 2018.

CSCC is the second most common type of skin cancer in the United States. Although CSCC has a good prognosis when caught early, it can prove especially difficult to treat when it progresses to advanced stages. Patients at this stage can be disfigured due to multiple surgeries to remove CSCC tumors on the head, neck and other parts of the body.¹ CSCC is responsible for the most deaths among non-melanoma skin cancer patients.

Breakthrough Therapy designation serves to expedite the development and review of drugs that target serious or life-threatening conditions. Drugs qualifying for this designation must show credible evidence of a substantial improvement on a clinically significant endpoint over available therapies, or over placebo if there is no available therapy. The designation includes all of the Fast Track program features, as well as more intensive FDA guidance and discussion. The Breakthrough Therapy designation is distinct from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met.

Cemiplimab is currently under clinical development, and its safety and efficacy has not been fully evaluated by any regulatory authority.

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 www.regeneron.com or follow @Regeneron on Twitter.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families.

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 cemiplimab (REGN2810) for the treatment of patients with metastatic or locally advanced and unresectable cutaneous squamous cell carcinoma (CSCC) or other potential indications; 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, such as cemiplimab; 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; 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 cemiplimab, including the impact (if any) of the Breakthrough Therapy designation status granted to cemiplimab for the treatment of patients with metastatic or locally advanced and unresectable CSCC by the U.S. Food and Drug Administration; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs (such as the clinical program relating to cemiplimab referenced in this news release), and business, including those relating to patient privacy; 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'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; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; 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 HealthCare LLC, 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 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>).

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates regarding the clinical development of and potential marketing approvals for the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans", "would be" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development of the product, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve the product or biological application that may be filed for the product as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of the product, the absence of guarantee that the product if approved will be commercially successful, risks associated with intellectual property, future litigation, the future approval and commercial success of therapeutic alternatives, and volatile economic conditions, as well as those risks discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any

forward-looking information or statements.

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¹ Medscape. Cutaneous Squamous Cell Carcinoma. Available at: <http://emedicine.medscape.com/article/1965430-overview>.
Last Accessed: August 2, 2017.

View original content:<http://www.prnewswire.com/news-releases/regeneron-and-sanofi-announce-cemiplimab-regn2810-has-received-fda-breakthrough-therapy-designation-for-advanced-cutaneous-squamous-cell-carcinoma-300516208.html>

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