Regeneron and Sanofi Present Positive Study Results for Investigational PD-1 Antibody REGN2810 at American Society of Clinical Oncology (ASCO) Annual Meeting

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Oral presentation provides first REGN2810 data in patients with advanced cutaneous squamous cell carcinoma (CSCC)

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced positive preliminary results with investigational REGN2810, a checkpoint inhibitor targeting PD-1 (programmed death 1), in patients with advanced cutaneous squamous cell carcinoma (CSCC)**.** The data, pooled from two expansion cohorts of the REGN2810 Phase 1 trial, will be presented today at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago during an oral presentation (Abstract #9503). REGN2810 is also being investigated in EMPOWER-CSCC 1, an ongoing Phase 2 potentially pivotal, single-arm, open label clinical trial that is currently enrolling advanced CSCC patients.

Treatment with REGN2810 led to an investigator-assessed overall response rate (ORR) of 46.2 percent (12 of 26 patients, including 2 complete responses, 9 partial responses and 1 unconfirmed partial response) and a disease control rate (DCR) of 69.2 percent (18 of 26 patients, including 12 ORR and 6 stable disease). The median progression free survival and overall survival were not reached at the data cutoff date with a median follow up of 6.9 months (range: 1.1 to 13.8 months; ongoing). One patient experienced progressive disease during treatment with REGN2810 after the initial response, and two patients were not evaluable due to death, which was considered unrelated to REGN2810. Ten patients remain in response as of the data cutoff date (range: 8 to 40 weeks duration of response).

The most common treatment-related adverse event of any grade was fatigue (23.1 percent). All grade 3 or higher adverse events occurred once and included arthralgia (3.8 percent), maculopapular rash (3.8 percent), asthenia (3.8 percent), aspartate aminotransferase (AST) elevation (3.8 percent) and alanine aminotransferase (ALT) elevation (3.8 percent).

"Cutaneous squamous cell carcinoma or CSCC is the second deadliest skin cancer after melanoma, according to the most recent data available," said Kyriakos P. Papadopoulos, M.D., Senior Clinical Investigator at South Texas Accelerated Research Therapeutics (START) and the study presenter. "There are limited treatments and no established standards of care for advanced stages of this disease. CSCC has one of the highest mutation rates reported for any cancers, likely contributing to the study findings, which represent a high responder rate to a PD-1 antibody in a solid tumor cancer. These results are promising and suggest the PD-1 pathway is an important therapeutic target in these patients."

No apparent association between the objective response and level of PD-L1 (programmed death ligand 1) expression was found. PD-L1 expression by immunohistochemistry (22C3 clone, Dako) was performed in tumor cells for 21 expansion cohort patients, with 81 percent of patients (17 of 21) having greater than or equal to 1 percent positive PD-L1 expression. Additional correlative studies are in process.

This Phase 1 study was designed with an initial dose-escalation portion followed by multiple expansion cohorts that were opened to investigate safety and antitumor activity in specific patient populations. These results are from 10 patients with distantly metastatic CSCC who were enrolled in one expansion cohort (Cohort 7) and 16 patients with inoperable (unresectable) locally or regionally advanced CSCC who were enrolled in a second expansion cohort (Cohort 8). All expansion cohort patients were treated with 3 mg/kg doses of REGN2810 by intravenous infusion over 30 minutes every two weeks for up to 48 weeks.

REGN2810 is a human, monoclonal antibody targeting the checkpoint inhibitor PD-1 and is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. REGN2810 is currently being explored as a monotherapy for multiple cancers - including cutaneous squamous cell carcinoma (CSCC), basal cell carcinoma (BCC) and non-small cell lung cancer (NSCLC) - as well as in combination with REGN3767, another investigational immunotherapy targeting the checkpoint inhibitor LAG-3 (lymphocyte-activation gene 3).

REGN2810 and REGN3767 are currently under clinical development, and their safety and efficacy have not been fully evaluated by any regulatory authority.

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

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).

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. All Regeneron commercialized medicines were discovered and developed by our own scientists, including therapies for eye diseases, high LDL cholesterol, atopic dermatitis, rheumatoid arthritis, and a rare inflammatory condition. Regeneron also has product candidates in development in other areas of high unmet medical need, including asthma, pain, cancer and infectious diseases.

Regeneron invented the leading VelociSuite® technologies, which are a suite of complementary genetics-based technologies that accelerate, improve and disrupt the traditional drug discovery and development process and established the Regeneron Genetics Center, one of the largest genetic sequencing efforts in the world. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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 and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" 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, 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 any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those 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.

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 Regeneron's immuno-oncology program, REGN2810 (an investigational antibody targeting the checkpoint inhibitor PD-1 (programmed death 1) that is being jointly developed by Regeneron and Sanofi), REGN3767 (an investigational antibody targeting the checkpoint inhibitor LAG-3 (lymphocyte-activation gene 3) that is being jointly developed by Regeneron and Sanofi), and the combination therapy involving REGN2810 and REGN3767 (the "PD-1/LAG-3 Combination Therapy"); 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 REGN2810, REGN3767, and the PD-1/LAG-3 Combination Therapy; 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; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs (such as the clinical programs 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 March 31, 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).

Contacts Sanofi:	**Contacts Regeneron:**
Media Relations	***Media Relations***
Ashleigh Koss	Daren Kwok
Tel: +1 (908) 981-8745	Tel: +1 (914) 847-1328

ashleigh.koss@sanofi.com daren.kwok@regeneron.com

Investor Relations
George Grofik
Tel: +33 (0)1 53 77 45 45
ir@sanofi.com

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