



Regeneron and Sanofi Announce Positive Topline Pivotal Results for PD-1 Antibody Cemiplimab in Advanced Cutaneous Squamous Cell Carcinoma

December 13, 2017 at 1:01 AM EST

TARRYTOWN, N.Y. and PARIS, Dec. 13, 2017 /PRNewswire/ -- [Regeneron Pharmaceuticals, Inc.](#) (NASDAQ: **REGN**) and [Sanofi](#) today announced positive topline results from a pivotal Phase 2 clinical study of cemiplimab in 82 patients with advanced cutaneous squamous cell carcinoma (CSCC), the second deadliest skin cancer after melanoma. Cemiplimab, an investigational human antibody targeting PD-1 (programmed cell death protein 1), demonstrated an overall response rate (ORR) of 46.3%, as determined by independent review. The median duration of response (DOR) had not yet been reached at the data cut-off point (32 of 38 responses are ongoing). At the time of this analysis, all patients had a minimum follow up of 6 months. The safety profile in the study was generally consistent with approved anti-PD-1 agents.

These pivotal data will form the basis of a rolling Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA), which has been initiated and is expected to be completed in the first quarter of 2018. A rolling BLA submission allows for portions of the regulatory application to be submitted to the FDA as they are completed. A submission to the European Medicines Agency (EMA) is also expected to be completed in the first quarter of 2018. These data confirm the positive Phase 1 clinical trial expansion cohort results [reported at the 2017 American Society of Clinical Oncology \(ASCO\) Annual Meeting](#), which led to a Breakthrough Therapy Designation for cemiplimab in advanced CSCC in September 2017.

"For patients with CSCC that cannot be cured by surgery or radiation, there are no FDA-approved treatment options, and advanced CSCC is responsible for 3,900 to 8,800 deaths per year in the U.S.," said Israel Lowy, MD, PhD, Vice President of Global Clinical Development and Head of Translational Science and Clinical Oncology, Regeneron. "This is the largest prospective study ever conducted in this disease, and we are pleased that many patients were able to achieve deep and durable responses with cemiplimab monotherapy. The high and durable response rates seen in this study are particularly notable given that the study enrolled patients regardless of biomarker status."

The efficacy data reported today include results from 82 patients in the Phase 2 EMPOWER-CSCC 1 study. Approximately two-thirds of patients had progressed after prior systemic chemotherapy or radiation.

"EMPOWER-CSCC 1 was initiated in 2016 and has enrolled rapidly, underscoring the serious unmet need in advanced CSCC," said Elias Zerhouni, MD, President, Global R&D, Sanofi. "We look forward to working with regulatory agencies globally to bring this important therapy to advanced CSCC patients as quickly as possible. We continue to rapidly advance a broad development program to evaluate cemiplimab both as monotherapy and combination across a number of solid tumor and blood cancers."

EMPOWER-CSCC 1 is a single-arm, open-label clinical trial and remains active. Enrollment is complete in the study arm of patients with metastatic CSCC receiving a 3 mg/kg dose of cemiplimab every two weeks. Enrollment continues in the remaining two study arms of patients with metastatic CSCC receiving a 350 mg flat dose of cemiplimab every three weeks and patients with locally advanced and unresectable CSCC receiving a 3 mg/kg dose of cemiplimab every two weeks.

Updated results from both the EMPOWER-CSCC 1 and the Phase 1 clinical trial will be submitted for presentation at a 2018 medical congress.

Cemiplimab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement, and was invented by Regeneron using the company's proprietary VelocImmune® technology that yields optimized fully-human antibodies. Cemiplimab is currently under clinical development, and its safety and efficacy has not been fully evaluated by any regulatory authority.

About Cutaneous Squamous Cell Carcinoma (CSCC)

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. CSCC is the second deadliest skin cancer after melanoma and is responsible for the most deaths among non-melanoma skin cancer patients.

About Regeneron

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 repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen 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, including VelocImmune® to yield 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 is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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 advanced 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 for the treatment of patients with advanced CSCC and other potential indications (including the impact (if any) of the Breakthrough Therapy designation status granted to cemiplimab for the treatment of patients with advanced CSCC by the U.S. Food and Drug Administration); 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; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs (such as the clinical programs 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 proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of any 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, 2016 and its Form 10-Q for the quarterly period ended September 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 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.

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