



New England Journal of Medicine Publishes Pivotal Cemiplimab Trials Showing Positive Results in Advanced Cutaneous Squamous Cell Carcinoma

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TARRYTOWN, N.Y. and PARIS, June 4, 2018 /PRNewswire/ --

Patients treated with cemiplimab experienced robust anti-tumor effects

Data also presented today at the 2018 ASCO Annual Meeting

Cemiplimab applications under review by regulatory authorities in the U.S. and the EU; if approved, would be the third anti-PD-1 available

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi announced that pivotal data from two trials evaluating cemiplimab in advanced cutaneous squamous cell carcinoma (CSCC) were published today in the *New England Journal of Medicine* (NEJM) and presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. Advanced CSCC, the deadliest nonmelanoma skin cancer, encompasses both patients with metastatic CSCC and those with locally advanced CSCC who are not candidates for surgery; there is currently no approved treatment for these patients. Cemiplimab is an investigational human monoclonal antibody targeting the immune checkpoint PD-1 (programmed cell death protein 1).

"The strong results seen with cemiplimab are noteworthy given that advanced CSCC is a very serious condition that currently has no approved treatments once surgery is no longer an option," said Michael R. Migden, M.D., co-lead author and Associate Professor in the Departments of Dermatology and Head and Neck Surgery at The University of Texas MD Anderson Cancer Center. "Advanced CSCC tumors were shown to be responsive to cemiplimab in both metastatic and locally advanced patients, with the results being clinically meaningful and consistent between the Phase 1 and Phase 2 trials."

Data published in NEJM and/or presented at ASCO, and confirmed by independent central review, include:

- Phase 2 EMPOWER-CSCC-1 trial:
 - Cemiplimab-treated patients had a 47.5 percent response rate (28 of 59 patients, including 4 complete responses and 24 partial responses [PRs]) with a median observed time to response of 2 months as of the data cut-off date. The durable disease control rate (DCR) was 61 percent (36 of 59 patients) and was defined as the proportion of patients without progressive disease for at least 105 days.
 - The median duration of response (DOR), median progression free survival, and median overall survival have not been reached as of the data cut-off date (median follow-up for all patients: 8 months). Of the responding patients, 82 percent remained in response and continued on cemiplimab. The estimated progression-free probability at 12 months was 52.5 percent, and the estimated probability of survival at 12 months was 81 percent.
 - The most common treatment-emergent adverse events were diarrhea (27 percent), fatigue (24 percent), nausea (17 percent), constipation and rash (each 15 percent). Grade 3 or higher adverse events regardless of attribution were reported in 25 patients (42 percent), of whom seven (12 percent) were considered related to treatment. Three patients (5 percent) had adverse events with the outcome of death; however, none were considered related to treatment.
 - Data are from 59 metastatic CSCC patients who received cemiplimab (3 mg/kg every 2 weeks) for up to 96 weeks.
- CSCC expansion cohorts of Phase 1 trial:
 - Cemiplimab-treated patients had a response rate of 50 percent (13 of 26 patients, all of which were PRs) with a median observed time to response of 2 months as of the data cut-off date. The durable DCR was 65 percent (17 of 26 patients). The median DOR has not been reached as of the data cut-off date (median follow-up for all patients: 11 months).
 - The most common treatment-emergent adverse events of any grade were fatigue (27 percent), constipation, decreased appetite, diarrhea, hypercalcemia, hypophosphatemia, nausea and urinary tract infection (each 15 percent). Grade 3 or higher adverse events regardless of attribution were reported in 12 patients (46 percent), of which five (19 percent) were considered related to treatment. Two patients (8 percent) had adverse events related to treatment that led to treatment discontinuation.
 - Data are from 26 advanced CSCC patients who participated in two Phase 1 expansion cohorts and received cemiplimab (3 mg/kg every 2 weeks) for up to 48 weeks. Patients either had metastatic CSCC or locally advanced CSCC who were not candidates for surgery.

These findings formed part of the data set used for regulatory applications for cemiplimab as a potential treatment for advanced CSCC. These applications were accepted earlier this year for priority review by the U.S. Food and Drug Administration (FDA) and review by the European Medicines Agency (EMA). The FDA target action date is October 28, 2018, and the EMA review process is expected to be complete by the first half of 2019.

Regulatory applications in additional countries are also being considered for submission later in 2018. There are currently no FDA- or EMA-approved treatments for patients with metastatic CSCC or patients with locally advanced CSCC who are not candidates for surgery.

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. In addition to CSCC, cemiplimab is also being investigated in potentially pivotal/pivotal trials in non-small cell lung cancer, basal cell carcinoma and cervical cancer alongside exploratory trials in squamous cell carcinoma of the head and neck, melanoma, colorectal cancer, prostate cancer, multiple myeloma, Hodgkin lymphoma and non-Hodgkin lymphoma.

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

About CSCC

CSCC is the second most common type of skin cancer in the U.S., accounting for approximately 20 percent of all skin cancers and with the number of newly diagnosed cases expected to rise annually. Although CSCC has a good prognosis when caught early, the cancer can prove especially difficult to treat effectively when it is advanced, and patients can experience reduced quality of life due to the impact of the disease as it progresses. Advanced CSCC is the deadliest non-melanoma skin cancer. While estimates vary, sources suggest that between 4,000 to 8,000 people in the U.S. die annually of advanced CSCC.

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 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and numerous 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, such as *VelocImmune*[®] which produces optimized fully-human antibodies, and ambitious research initiatives such as the Regeneron Genetics Center, which is conducting 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 for the treatment of patients with advanced cutaneous squamous cell carcinoma ("CSCC"), non-small cell lung cancer ("NSCLC"), basal cell carcinoma, cervical cancer, squamous cell carcinoma of the head and neck, melanoma, colorectal cancer, prostate cancer, multiple myeloma, Hodgkin lymphoma, Non-Hodgkin lymphoma, or other potential indications; 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, NSCLC, basal cell carcinoma, cervical cancer, squamous cell carcinoma of the head and neck, melanoma, colorectal cancer, prostate cancer, multiple myeloma, Hodgkin lymphoma, Non-Hodgkin lymphoma, 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, such as cemiplimab; 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, 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, 2017 and its Form 10-Q for the quarterly period ended March 31, 2018. 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 potential marketing approvals for the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans", "will 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, including future clinical data relating to the product, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve 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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Sanofi Contacts:

Media Relations

Ashleigh Koss
Tel: +1 (908) 981-8745
mr@sanofi.com

Investor Relations

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


Regeneron Contacts:

Media Relations

Daren Kwok
Tel: +1 (914) 847-1328
daren.kwok@regeneron.com

Investor Relations

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

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