



Regeneron and Sanofi Share First Positive Clinical Data for Cemiplimab in Advanced Non-small Cell Lung Cancer at ASCO

May 16, 2018

TARRYTOWN, N.Y. and BRIDGEWATER, N.J., May 16, 2018 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the first positive Phase 1 clinical data assessing cemiplimab as a potential treatment for advanced non-small cell lung cancer (NSCLC) will be shared at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. Cemiplimab is an investigational human monoclonal antibody targeting the immune checkpoint PD-1 (programmed cell death protein 1).

As published online in advance of ASCO, interim results from the Phase 1 dose-escalation phase and expansion cohort of patients with advanced NSCLC showed that cemiplimab monotherapy resulted in an overall response rate (ORR) of 29 percent (six of 21 patients, all of which were partial responses or non-complete responses or non-progressive disease) and a disease control rate of 57 percent (12 of 21 patients, including ORR and six stable disease or non-complete responses or non-progressive disease) as of the data cut-off date. The duration of response exceeded eight months in five of six patients. In the trial, patients received either a 1 mg/kg dose (one patient) or 200 mg flat dose (20 patients) of cemiplimab, each given every two weeks. The most common treatment-related adverse events were asthenia, pneumonitis and rash (three patients each, 14 percent).

The NSCLC expansion cohort enrolled patients whose disease had worsened after initial improvement (relapsed) or not responded (refractory) after at least one course of chemotherapy. NSCLC patients in the Phase 1 trial had failed, on average, 2.14 previous chemotherapy regimens.

"Cemiplimab is the foundation of our broader immuno-oncology program, and the clinical profile we've seen to date has encouraged us to explore the potential of this anti-PD-1 in multiple malignancies," said Israel Lowy, M.D., Ph.D., Vice President of Global Clinical Development and Head of Translational Science and Clinical Oncology, Regeneron. "In NSCLC, there remains a high unmet need despite recent advances. The positive Phase 1 results in advanced NSCLC support our strategy to advance cemiplimab in multiple Phase 3 trials exploring a number of treatment settings for this disease."

Cemiplimab being investigated in patients with NSCLC in different settings

The Regeneron and Sanofi clinical development program in NSCLC encompasses several Phase 2 and 3 trials investigating cemiplimab treatment of tumors with different PD-L1 (programmed death-ligand 1) expression levels and as a monotherapy or part of doublet or triplet combinations in the first- and second-line treatment settings. This includes a Phase 3 NSCLC trial investigating cemiplimab combination therapy versus pembrolizumab in certain first-line patients.

"The cemiplimab development program is an example of our ability to rapidly translate scientific innovation into potential treatment breakthroughs in oncology," added Joanne Lager, M.D., Head of Oncology Development, Sanofi. "The data shared at ASCO will provide an important foundation for evaluating cemiplimab in new combination regimens, with the goal of helping patients who may not benefit from existing therapies."

Additional results for cemiplimab will also be presented at ASCO

In addition to the Phase 1 advanced NSCLC data, updated results from pivotal clinical trials investigating cemiplimab in advanced cutaneous squamous cell carcinoma (CSCC) will be presented at ASCO. Additional accepted abstracts include an assessment of treatment patterns and costs in CSCC as well as overviews of clinical trials in progress for cemiplimab in cervical cancer and for REGN3767, an investigational human monoclonal antibody targeting the immune checkpoint LAG-3 (lymphocyte-activation gene 3), as either a monotherapy or in combination with cemiplimab in solid tumors and lymphoma.

Cemiplimab is currently being reviewed by the U.S. Food and Drug Administration and European Medicines Agency as a potential new treatment for patients with metastatic CSCC or patients with locally advanced CSCC who are not candidates for surgery. In addition to CSCC and NSCLC, cemiplimab is also being investigated in potentially pivotal/pivotal trials as a monotherapy for 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 and REGN3767 are being jointly developed by Regeneron and Sanofi under a global collaboration agreement and were invented by Regeneron using the company's proprietary *VelocImmune*[®] technology that yields optimized fully-human antibodies.

Cemiplimab and REGN3767 are currently under clinical development, and their safety and efficacy have 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 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 non-small cell lung cancer ("NSCLC"), advanced cutaneous squamous cell carcinoma ("CSCC"), 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 NSCLC, advanced CSCC, 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 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, to complete related transactions 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, 2017. 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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