SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Phase 3 trial of Libtayo® (cemiplimab) combined with chemotherapy stopped early due to significant improvement in overall survival in patients with first-line advanced non-small cell lung cancer

- Libtayo combined with chemotherapy increased median overall survival from 13 to 22 months, leading to a 29% reduction in the risk of death
- Trial enrolled patients with locally advanced and metastatic disease with squamous or non-squamous histology, and across all PD-L1 expression levels
- Libtayo has now demonstrated improved overall survival as a monotherapy or in combination with chemotherapy in first-line advanced non-small cell lung cancer

PARIS and TARRYTOWN, NY – August 5, 2021 - The Phase 3 trial of Sanofi and Regeneron's PD-1 inhibitor Libtayo in combination with platinum-doublet chemotherapy was stopped early after meeting its overall survival (OS) primary endpoint in patients with advanced non-small cell lung cancer (NSCLC). Adding Libtayo to chemotherapy significantly improved OS, compared to chemotherapy alone, in the trial that enrolled patients with metastatic or locally advanced disease and tumors with either squamous or non-squamous histology and across all PD-L1 expression levels. These data are planned to form the basis of regulatory submissions in the U.S. and European Union.

> *"Libtayo in combination with chemotherapy increased median overall survival to 22 months in patients with advanced non-small cell lung cancer, compared to 13 months with chemotherapy alone,"* said Miranda Gogishvili, M.D., an oncologist at the High Technology Medical Center, University Clinic, in Tbilisi, Georgia and a trial investigator. *"Notably, the Phase 3 trial enrolled patients with a variety of challenging-to-treat disease characteristics, as well as those with locally advanced disease. These data add to the growing body of evidence supporting Libtayo in advanced non-small cell lung cancer, which also include the pivotal results for Libtayo monotherapy in cases of high PD-L1 expression."*

The decision to stop the trial early was based on a recommendation by the Independent Data Monitoring Committee (IDMC) during a protocol-specified interim analysis. In this top-line initial analysis of 466 patients, combining Libtayo with chemotherapy reduced the risk of death by 29% compared to chemotherapy alone (hazard ratio: 0.71; 95% confidence interval [CI]: 0.53-0.93; p=0.014). Median OS was 22 months (95% CI: 16 months to not evaluable) for Libtayo and chemotherapy, and 13 months (95% CI: 12 to 16 months) for chemotherapy alone. No new Libtayo safety signals were identified in the IDMC analysis, and additional detailed efficacy and safety data will be presented at an upcoming medical meeting.

Lung cancer is the leading cause of cancer death worldwide. In 2020, an estimated 2.2 million and 225,000 new cases were diagnosed globally and in the U.S., respectively. Approximately 84% of all lung cancers are NSCLC, with 75% of these cases diagnosed in advanced stages. While PD-1 inhibitor monotherapy has primarily advanced the treatment of NSCLC with ≥50% PD-L1 expression, approximately 70% of all NSCLC cases will have <50% PD-L1 expression, making it the most common treatment setting.

The use of Libtayo in combination with chemotherapy for advanced NSCLC is currently under clinical investigation, and its safety and efficacy have not been fully evaluated by any regulatory authority.

About the Phase 3 Trial

The randomized, multicenter Phase 3 trial, called EMPOWER-Lung 3, investigated a first-line combination treatment of Libtayo and platinum-doublet chemotherapy, compared to platinum-doublet chemotherapy alone, in squamous or non-squamous advanced NSCLC irrespective of PD-L1 expression. Specifically, the trial included 466 patients who tested negative for ALK, EGFR and ROS1 mutations and had either previously untreated metastatic NSCLC (stage IV) or locally advanced NSCLC (stage IIIB/C) and were not candidates for definitive chemoradiation.

Patients were randomized 2:1 to receive either Libtayo 350 mg (n=312) or placebo (n=154) administered intravenously every three weeks for 108 weeks, plus platinum-doublet chemotherapy administered every three weeks for four cycles. The co-primary endpoints were OS and progression-free survival, and key secondary endpoints included objective response rate and best overall response.

Among trial patients, 30% (n=139) had tumors with <1% PD-L1 expression, 38% (n=175) had tumors with 1% to 49% PD-L1 expression, and 33% (n=152) had tumors with ≥50% PD-L1 expression.

About Libtayo

Libtayo is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T-cells. By binding to PD-1, Libtayo has been shown to block cancer cells from using the PD-1 pathway to suppress T-cell activation.

The generic name for Libtayo in its approved U.S. indications is cemiplimab-rwlc, with rwlc as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the U.S. FDA. Libtayo is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

The extensive clinical program for Libtayo is focused on difficult-to-treat cancers. Libtayo is currently being investigated in advanced cervical cancer, as well as in trials combining Libtayo with either conventional or novel therapeutic approaches for other solid tumors and blood cancers. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous product candidates in development, almost all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, infectious diseases and rare diseases

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through 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.

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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 fact that product candidates if approved may not 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 and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties 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, 2020. 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 press 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Libtayo® (cemiplimab) in combination with chemotherapy for the treatment of patients with advanced non-small cell lung cancer ("NSCLC"); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, such as possible regulatory approval of Libtayo in combination with chemotherapy for NSCLC and as monotherapy for advanced cervical cancer (as well as in combination with either conventional or novel therapeutic approaches for both solid tumors and blood cancers); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products (such as Libtayo) and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the study discussed in this press release, on any of the foregoing; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products (such as Libtayo) and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; 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 Regeneron's Product Candidates, including without limitation Libtayo; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), Praluent® (alirocumab), and REGEN-COV™ (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, 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 U.S. Securities and Exchange Commission. 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 or otherwise) 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).