SANOFI

Press Release

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

Phase 3 trial of Libtayo® (cemiplimab) monotherapy in advanced cervical cancer stopped early for positive result on overall survival

- Libtayo is the first immunotherapy to demonstrate improved overall survival in patients with cervical cancer, reducing the risk of death by 31% compared to chemotherapy
- Trial enrolled patients with advanced cervical cancer regardless of PD-L1 status
- Fourth cancer type where Libtayo has positive pivotal data; regulatory submissions planned in 2021

PARIS and TARRYTOWN, N.Y. – March 15, 2021 – Positive results demonstrating an overall survival (OS) benefit from the Phase 3 trial investigating Sanofi and Regeneron's PD-1 inhibitor Libtayo® (cemiplimab) monotherapy compared to chemotherapy in patients previously treated with chemotherapy whose cervical cancer is recurrent or metastatic, were announced today. The trial will be stopped early based on a unanimous recommendation by the Independent Data Monitoring Committee (IDMC), and the data will form the basis of regulatory submissions in 2021.

> *"Libtayo monotherapy is the first medicine to demonstrate an improvement in overall survival in women with recurrent or metastatic cervical cancer following progression on platinum-based chemotherapy in a Phase 3 trial,"* said Krishnansu S. Tewari, M.D., Professor and Director of the Division of Gynecologic Oncology at the University of California, Irvine and a trial investigator. *"This landmark clinical achievement will bring hope to women with advanced cervical cancer who are often younger than patients with other cancers. This is reflected in the trial where the average age was 51."*

This is the largest Phase 3 randomized clinical trial in advanced cervical cancer and included women (median age: 51 years) with either squamous cell carcinoma or adenocarcinoma. Patients were randomized to receive Libtayo monotherapy (350 mg every three weeks) or an investigator's choice of commonly used chemotherapy (pemetrexed, vinorelbine, topotecan, irinotecan or gemcitabine). Compared to chemotherapy, patients receiving Libtayo experienced:

- **Total population:** 31% reduced risk of death
  - Median 12.0 months survival for Libtayo (n=304) compared to 8.5 months for chemotherapy (n=304); hazard ratio (HR): 0.69; 95% confidence interval (CI): 0.56-0.84 (p<0.001)

- **Squamous cell carcinoma:** 27% reduced risk of death
    - Median 11.1 months survival for Libtayo (n=239) compared to 8.8 months for chemotherapy (n=238); HR: 0.73; 95% CI: 0.58-0.91 (p=0.003)
- **Adenocarcinoma:** 44% reduced risk of death
    - Median 13.3 months survival for Libtayo (n=65) compared to 7.0 months for chemotherapy (n=66); HR: 0.56; 95% CI: 0.36-0.85 (p<0.005; not adjusted for multiplicity)

The primary endpoint for the trial was OS, analyzed first among patients with squamous cell carcinoma, then in the total population. Per a protocol-specified interim analysis, the IDMC reviewed OS data when approximately 85% of events had occurred among patients with squamous cell carcinoma. Based on the highly significant effect on OS among these patients, the IDMC recommended stopping the trial. Detailed results will be presented at an upcoming medical meeting. The use of Libtayo in cervical cancer is investigational and has not been fully reviewed by any regulatory authority.

No new Libtayo safety signals were observed. Safety was assessed in patients who received at least one dose of study treatment: 300 patients in the Libtayo group (median duration of exposure: 15 weeks; range: 1-101 weeks) and 290 patients in the chemotherapy group (median duration of exposure: 10 weeks; range: 1-82 weeks). Adverse events (AEs) were observed in 88% of Libtayo patients and 91% of chemotherapy patients, with serious AEs occurring in 30% of Libtayo patients and 27% of chemotherapy patients. The five most common AEs were anemia (25% Libtayo, 45% chemotherapy), nausea (18% Libtayo, 33% chemotherapy), fatigue (17% Libtayo, 16% chemotherapy), vomiting (16% Libtayo, 23% chemotherapy) and constipation (15% Libtayo, 20% chemotherapy). Other AEs that occurred more often in the Libtayo group and in at least 10% of patients were fatigue (17% Libtayo, 16% chemotherapy), urinary tract infections (12% Libtayo, 9% chemotherapy), back pain (11% Libtayo, 9% chemotherapy) and arthralgia (10% Libtayo, 3% chemotherapy). Discontinuations due to AEs occurred in 8% of Libtayo patients and 5% of chemotherapy patients.

> *"We are committed to developing therapies for cancers with high unmet needs including patients with advanced cervical cancer,"* said Peter C. Adamson, M.D., Global Development Head, Oncology and Pediatric Innovation at Sanofi. *"Combined with data from our non-melanoma skin cancer and lung cancer studies, these data contribute to the growing evidence demonstrating the significant potential of Libtayo to treat a spectrum of difficult-to-treat cancers."*

Today's announcement follows the recent U.S. approval of Libtayo monotherapy for certain patients with advanced non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression. The FDA also recently authorized the use of Libtayo as the first immunotherapy indicated for patients with basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate, whose cancer is either locally advanced (full approval) or metastatic (accelerated approval). In 2018, Libtayo was approved as the first systemic treatment for certain patients with advanced cutaneous squamous cell carcinoma (CSCC).

"Recurrent or metastatic cervical cancer is notoriously difficult to treat and has no approved standard of care after first-line chemotherapy," said Israel Lowy, M.D., Ph.D., Senior Vice President, Translational and Clinical Sciences, Oncology, at Regeneron. "This trial, which enrolled patients regardless of their PD-L1 status, demonstrated that Libtayo helped patients with recurrent or metastatic cervical cancer live longer after progression on prior chemotherapy. This is the fourth patient population in which Libtayo has shown clinical benefit and we look forward to submitting the results to regulatory authorities later this year."

About the Phase 3 Trial

This open-label, randomized, multi-center, Phase 3 trial investigated Libtayo monotherapy versus an investigator's choice of chemotherapy in patients with recurrent or metastatic cervical cancer that has progressed on platinum-based chemotherapy. Patients were allowed to enroll regardless of PD-L1 expression status, and 78% of patients had squamous cell carcinoma and 22% had adenocarcinoma. The trial included women from 14 countries: the U.S., Japan, Taiwan, South Korea, Canada, Russia, Poland, Spain, Brazil, Australia, the UK, Italy, Greece and Belgium.

About Cervical Cancer

Cervical cancer is the fourth leading cause of cancer death in women worldwide and is most frequently diagnosed in women between the ages of 35 and 44. Almost all cases are caused by human papillomavirus (HPV) infection, with approximately 80% classified as squamous cell carcinoma (arising from cells lining the bottom of the cervix) and the remainder largely adenocarcinomas (arising from glandular cells in the upper cervix). Cervical cancer is often curable when detected early and effectively managed, but treatment options are more limited in advanced stages.

It is estimated that approximately 570,000 women are diagnosed with cervical cancer worldwide each year. In the U.S. 14,500 new patients are diagnosed annually, and approximately 4,000 women die each year.

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.

In the U.S., Libtayo is approved for certain patients with advanced stages of CSCC, BCC and NSCLC with ≥50% PD-L1 expression. Outside of the U.S., Libtayo is approved for certain patients with advanced CSCC in the European Union and six other countries, including Australia, Brazil, the United Kingdom and Canada.

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 FDA. Outside of the U.S., the generic name for Libtayo in its approved indication is cemiplimab.

About the Libtayo Development Program

The extensive clinical program for Libtayo is focused on difficult-to-treat cancers. The European Medicines Agency is assessing regulatory submissions for Libtayo monotherapy in advanced NSCLC with ≥50% PD-L1 expression and locally advanced BCC following treatment with an HHI, with European Commission decisions expected by mid-2021.

Libtayo monotherapy is being investigated in trials in adjuvant CSCC and neoadjuvant CSCC, as well as in trials combining Libtayo with either conventional or novel therapeutic approaches for both solid tumors and blood cancers. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

Libtayo is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

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, hematology, 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.

Sanofi, Empowering Life

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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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, 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

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 patients previously treated with chemotherapy whose cervical cancer is recurrent or metastatic; uncertainty of market acceptance and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on the commercial success of Regeneron's Products (such as Libtayo) and Regeneron's Product Candidates; 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 Libtayo for the treatment of cervical cancer, adjuvant and neoadjuvant cutaneous squamous cell carcinoma, and advanced non-small cell lung cancer (as first-line treatment or in combination with chemotherapy) (as well as in combination with either conventional or novel therapeutic approaches for both solid tumors and blood cancers); 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; 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; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; 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; 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, including its Form 10-K for the year ended December 31, 2020. 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).