SANOFI

Media Update

Positive Phase 3 Libtayo® (cemiplimab) results in advanced cervical cancer presented at ESMO Virtual Plenary

- Libtayo is the first immunotherapy to demonstrate an improvement in overall survival in advanced cervical cancer, as well as progression-free survival and objective response rate, compared to chemotherapy
- Improvements in overall survival were seen in the overall population and both squamous cell carcinoma and adenocarcinoma subgroups
- Additionally, the Phase 3 trial found significant differences in patient-reported outcomes favoring Libtayo over chemotherapy

May 12, 2021

Positive results from the Phase 3 trial investigating Sanofi and Regeneron's PD-1 inhibitor Libtayo® (cemiplimab) in patients with recurrent or metastatic cervical cancer who had previously progressed on chemotherapy were shared today as part of a European Society for Medical Oncology (ESMO) Virtual Plenary. Results add to previously reported data showing an improvement in overall survival (OS) with Libtayo compared to chemotherapy, and will form the basis of regulatory submissions in 2021.

> *"In this Phase 3 trial, Libtayo demonstrated a significant improvement in overall survival in women with advanced cervical cancer after progression on chemotherapy, reducing the risk of death by 31% compared to chemotherapy in the overall population," 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. "Improvements in progression-free survival and objective response rate were also demonstrated in the overall population compared to chemotherapy. Taken together, this landmark trial – which enrolled patients regardless of PD-L1 expression status - helps support the use of Libtayo as a potential new second-line treatment for women with advanced cervical cancer who face a poor prognosis and limited treatment options."*

In the overall population, those treated with Libtayo (n=304) experienced significant improvements in OS, progression-free survival (PFS) and objective response rate (ORR), compared to chemotherapy (n=304), including a:

- **31% reduction in the risk of death** (hazard ratio [HR]: 0.69; 95% confidence interval [CI]: 0.56-0.84; one-sided p=0.00011).
- **25% reduction in the risk of disease progression** (HR: 0.75; 95% CI: 0.63-0.89; one-sided p=0.00048).
- **16% ORR** (50 patients; 95% CI: 13-21%; one-sided p=0.00004), compared to 6% with chemotherapy (19 patients). Median duration of response was 16 months with

Libtayo (95% CI: 12 months to not yet evaluable) and 7 months with chemotherapy (95% CI: 5-8 months), per Kaplan-Meier estimates.

In the trial, 78% of patients had advanced cervical cancer that was classified as squamous cell carcinoma (SCC). In this patient subgroup, significant improvements were also seen with Libtayo (n=239), compared to chemotherapy (n=238), including a:

- **27% reduction in the risk of death** (HR: 0.73; 95% CI: 0.58-0.91; one-sided p=0.00306).
- **29% reduction in the risk of disease progression** (HR: 0.71; 95% CI: 0.58-0.86; one-sided p=0.00026).
- **18% ORR** (42 patients; 95% CI: 13-23%), compared to 7% with chemotherapy (16 patients; 95% CI: 4-11%).

While assessment of the adenocarcinoma was not a pre-specified endpoint, a post-hoc analysis demonstrated the following outcomes for Libtayo-treated patients (n=65) compared to chemotherapy (n=66), including a:

- **44% reduction in the risk of death** (HR: 0.56; 95% CI: 0.36-0.85; nominal one-sided p<0.005).
- **9% reduction in the risk of disease progression** (HR: 0.91; 95% CI: 0.62-1.34).
- **12% ORR** (8 patients; 95% CI: 6-23%), compared to 5% with chemotherapy (3 patients; 95% CI: 1-13%).

Additionally, the Phase 3 trial found Libtayo-treated patients were able to generally improve or maintain their baseline Global Health Status/Quality of Life (GHS/QOL) over time, while those treated with chemotherapy experienced a deterioration that became clinically meaningful starting at cycle 8, per the EORTC QLQ-C30 (overall estimated mean change [95% CI]: improvement of 1.01 [-2.033, 4.047] for Libtayo, worsening of -6.81 [-10.977, -2.637] for chemotherapy; difference: 7.81; one-sided nominal p=0.00040).

No new Libtayo safety signals were observed. Safety was assessed in patients who received at least 1 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 those occurring in 15% or more Libtayo patients being anemia (25% Libtayo, 45% chemotherapy), nausea (18% Libtayo, 33% chemotherapy), fatigue (17% Libtayo, 16% chemotherapy), vomiting (16% Libtayo, 23% chemotherapy), decreased appetite (15% Libtayo, 16% chemotherapy) and constipation (15% Libtayo, 20% chemotherapy). Grade 3 or higher AEs occurred in 45% of Libtayo patients and 53% of chemotherapy patients. Among AEs in 15% or more patients, Grade 3 or higher AEs that occurred more often in the Libtayo group included asthenia (2% Libtayo, 1% chemotherapy) and pyrexia (less than 1% Libtayo, 0% chemotherapy). Immune-related AEs were observed in 16% of Libtayo patients and less than 1% of chemotherapy patients,

with 6% and less than 1% being Grade 3 or higher, respectively. Discontinuations due to AEs occurred in 8% of Libtayo patients and 5% of chemotherapy patients.

The use of Libtayo in advanced cervical cancer is investigational and has not been fully reviewed by any regulatory authority.

About the Phase 3 Trial

The Phase 3, open-label, multi-center trial is the largest randomized clinical trial in advanced cervical cancer, and 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, with 78% of patients having SCC and 22% having adenocarcinoma or adenosquamous carcinoma. 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.

Patients (median age: 51 years) 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). The primary endpoint for the trial was OS, analyzed first among patients with SCC, then in the total population.

In March, the trial was stopped early based on the highly significant effect of Libtayo on OS among SCC patients and following a unanimous recommendation by the Independent Data Monitoring Committee.

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 SCC (arising from cells lining the bottom of the cervix) and the remainder being 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, with deaths exceeding 250,000. In the U.S. there are 14,500 new patients 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 cutaneous squamous cell carcinoma (CSCC), basal cell carcinoma (BCC) and non-small cell lung cancer (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 UK 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 U.S. Food and Drug Administration (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 advanced BCC following treatment with a hedgehog pathway inhibitor (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, 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.

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 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) for the treatment of patients with recurrent or metastatic cervical cancer who had previously progressed on chemotherapy; 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 and adjuvant and neoadjuvant cutaneous squamous cell carcinoma (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 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 or any potential regulatory approval of Regeneron's Products (such as Libtayo) and Regeneron's 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; 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 with 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 and its

Form 10-Q for the quarterly period ended March 31, 2021. 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).