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Press Release

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

The Lancet publishes Libtayo® (cemiplimab) data showing extended overall survival in patients with first-line advanced non-small cell lung cancer with PD-L1 expression of ≥50%

- Libtayo was superior in extending overall survival compared to chemotherapy even with a high crossover rate
- Data are the basis for multiple ongoing regulatory submissions, including in the U.S. and European Union

PARIS and TARRYTOWN, N.Y. – February 12, 2021 – *The Lancet* today published results from a pivotal trial designed to evaluate the investigational use of the PD-1 inhibitor Libtayo® (cemiplimab) compared to platinum-doublet chemotherapy in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with ≥50% PD-L1 expression in tumor cells.

The data were shared during a late-breaking presentation at the 2020 European Society for Medical Oncology (ESMO) Virtual Congress and formed the basis of regulatory submissions in the U.S. and European Union (EU). The U.S. Food and Drug Administration (FDA) granted a Priority Review with a target action date of February 28, 2021. A European Commission decision is expected by mid-2021.

> *"These clinical results published in The Lancet support regulatory submissions for Libtayo as a potential new treatment option for patients with advanced NSCLC with PD-L1 expression of ≥50%," said Ahmet Sezer, M.D., Professor in the Department of Medical Oncology at Başkent University in Adana, Turkey and a trial investigator. "Libtayo was superior in extending overall survival compared to chemotherapy, even with 74% of patients crossing over to the Libtayo arm following progression on chemotherapy. Libtayo reduced the risk of death by 32% in all patients in the pivotal trial and by 43% among those with confirmed PD-L1 expression of 50% or higher. In addition, the data included more advanced patient populations usually underrepresented in advanced NSCLC trials – including 12% with pretreated and stable brain metastases and 16% with locally advanced NSCLC who were not candidates for definitive chemoradiation. As a result, the medical community now has valuable new clinical evidence that could enhance our understanding of how to treat this deadly cancer."*

The safety of Libtayo in the trial was generally consistent with previous Libtayo pivotal trials, and according to the publication, consistent with the safety profiles of other PD-1 or PD-L1 inhibitors in NSCLC and other tumor types. Grade 3 or 4 adverse events occurred in 28% and 39% of patients in the Libtayo and chemotherapy arms, respectively. Immune-mediated AEs were reported in 17% of patients in the Libtayo arm, compared to

2% in the chemotherapy arm, and included hypothyroidism (6% versus 0%), hyperthyroidism (4% versus <1%), pneumonitis (2% versus 0%), hepatitis (2% versus 0%), skin adverse reaction (2% versus <1%), colitis (1% versus <1%), nephritis (<1% versus <1%), arthritis, increased blood thyroid stimulating hormone, thyroiditis, and peripheral neuropathy (all <1% versus 0%).

Libtayo is currently approved as the first systemic treatment in the U.S., EU and other countries for adults with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Libtayo is also approved in the U.S. as the first immunotherapy treatment indicated for patients with advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate, and is under regulatory review in the EU for the treatment of locally advanced BCC previously treated with an HHI.

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

The use of Libtayo to treat advanced NSCLC is investigational and has not been fully evaluated by any regulatory authority.

About the Phase 3 Trial

The open-label, randomized, multi-center Phase 3 trial, called EMPOWER-Lung 1, was designed to investigate the first-line treatment of Libtayo monotherapy compared to platinum-doublet chemotherapy in patients with squamous or non-squamous advanced NSCLC that tested positive for PD-L1 in ≥50% of tumor cells, but not for ALK, EGFR or ROS1. PD-L1 expression was confirmed using the PD-L1 IHC 22C3 pharmDx kit. The trial randomized 710 patients with either locally advanced NSCLC (stage IIIB/C) who were not candidates for surgical resection or definitive chemoradiation or had progressed after treatment with definitive chemoradiation, or previously untreated metastatic NSCLC (stage IV). Of the 710 patients randomized to receive treatment, 563 patients had confirmed PD-L1 expression of ≥50%.

Patients were randomized 1:1 to receive either Libtayo 350 mg administered intravenously every three weeks for up to 108 weeks or an investigator-selected, standard-of-care, platinum-based, doublet chemotherapy regimen for 4 to 6 cycles (with or without histology relevant maintenance pemetrexed chemotherapy). The co-primary endpoints were overall survival and progression-free survival, and secondary endpoints included overall response rate, duration of response and quality of life.

The trial was designed to reflect current and emerging treatment paradigms. Inclusion criteria allowed patients with NSCLC who had: pre-treated and stable brain metastases; locally advanced disease that was not a candidate for, or which had progressed after, definitive chemoradiation; or controlled hepatitis B, hepatitis C or HIV. Patients whose disease progressed in the trial were able to change their therapy: those in the chemotherapy arm were allowed to cross over into the Libtayo arm following disease

progression on chemotherapy; and those in the Libtayo arm were allowed to combine Libtayo treatment with 4 to 6 cycles of chemotherapy.

About Non-small Cell Lung Cancer

Lung cancer is the leading cause of cancer death worldwide. In 2020, an estimated 2.2 million and 225,000 new cases were diagnosed worldwide and in the U.S, respectively. Approximately 84% of all lung cancers are NSCLC, and an estimated 25% to 30% of these cases are expected to test positive for PD-L1 in ≥50% of tumor cells. Additionally, an estimated 75% of patients are diagnosed with advanced NSCLC and have a poor survival prognosis. While immunotherapies have transformed advanced NSCLC treatment in recent years, there remains an unmet need to optimize the identification and treatment of patients with high PD-L1 expression and offer additional treatment options.

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., the generic name for Libtayo in its approved indication 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.

The extensive clinical program for Libtayo is focused on difficult-to-treat cancers. In skin cancer, this includes trials in adjuvant and neoadjuvant CSCC. Libtayo is also being investigated in pivotal trials in NSCLC (in combination with chemotherapy) and cervical cancer, 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.

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 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, 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, 2019. 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); 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 locally advanced or metastatic non-small cell lung cancer, locally advanced basal cell carcinoma previously treated with a hedgehog pathway inhibitor (in the European Union and other potential jurisdictions), adjuvant and neoadjuvant cutaneous squamous cell carcinoma, and cervical cancer (as well as in combination with either conventional or novel therapeutic approaches for both solid tumors and blood cancers); 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 study discussed in this press release, on the commercial success of Regeneron's Products and Regeneron's 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; 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).