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Press Release

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Late-breaking ESMO presentation shows Libtayo® (cemiplimab) monotherapy increases overall survival in first-line advanced non-small cell lung cancer with PD-L1 expression of ≥50%

- In the overall trial population, Libtayo reduced risk of death by 32% compared to chemotherapy
- In a prespecified analysis of patients with confirmed PD-L1 expression of ≥50%, Libtayo reduced risk of death by 43%

PARIS and TARRYTOWN, N.Y. – September 21, 2020 - Positive pivotal trial data for the investigational use of PD-1 inhibitor Libtayo® (cemiplimab) in first-line locally advanced or metastatic non-small cell lung cancer (NSCLC) were shared in a presentation at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.

The trial compared Libtayo monotherapy to platinum-doublet chemotherapy in patients whose tumor cells expressed PD-L1, including those whose cancers had confirmed PD-L1 expression of ≥50%.These results form the basis of regulatory submissions, including in the U.S. and European Union.

> *"In new analyses presented at ESMO, Libtayo reduced the risk of death by 43% in patients whose cancer had confirmed PD-L1 expression of 50% or greater. This is notable given that nearly three-quarters of patients crossed over from chemotherapy following disease progression and 12% of patients had pretreated and stable brain metastases,"* said Ahmet Sezer, M.D., Associate Professor in the Department of Medical Oncology at Başkent University in Adana, Turkey and a trial investigator. *"These results support Libtayo as a potential new option for anti-PD-1 monotherapy in first-line advanced non-small cell lung cancer."*

The late-breaking ESMO presentation expands on topline results shared in April. In the overall trial population (n=710), the median follow-up was 13 months for both Libtayo (n=356; range: <1-32 months) and chemotherapy (n=354; range: <1-32 months). Among these patients, Libtayo demonstrated the following results compared to chemotherapy:

- **32% reduced risk of death** (hazard ratio [HR]=0.68; 95% confidence interval [CI]: 0.53-0.87; p=0.0022).
- **22-month median overall survival** (OS; 95% CI: 18 months to not yet evaluable) compared to 14 months (95% CI: 12-19 months).

- **41% reduced risk of disease progression** (HR=0.59; 95% CI: 0.49-0.72; p<0.0001). The median progression-free survival (PFS) was 6.2 months (95% CI: 4.5-8.3 months) compared to 5.6 months (95% CI: 4.5-6.1 months).
- **37% objective response rate** (ORR; 95% CI: 32-42%; 3% complete response [CR] and 33% partial response [PR] rate) compared to 21% ORR (95% CI: 17-25%; 1% CR and 20% PR rate).

A prespecified analysis of data from patients whose cancers had confirmed PD-L1 expression ≥50% (n=563) was also conducted. In this group, the median follow-up was 11 months for both Libtayo (n=283; range: <1-32 months) and chemotherapy (n=280; range: <1-30 months), and Libtayo demonstrated the following results compared to chemotherapy:

- **43% reduced risk of death** (HR=0.57; 95% CI: 0.42-0.77; p=0.0002).
- **Median OS was not yet reached** (95% CI: 18 months to not yet evaluable) compared to 14 months (95% CI: 11-18 months).
- **46% reduced risk of disease progression** (HR=0.54; 95% CI: 0.43-0.68; p<0.0001). The median PFS was 8 months (95% CI: 6-9 months) compared to 6 months (95% CI: 5-6 months).
- **39% ORR** (95% CI: 34-45%; 2% CR and 37% PR rate) compared to 20% ORR (95% CI: 16-26%; 1% CR and 19% PR rate).

The trial also found a direct correlation between tumor response and PD-L1 expression level in Libtayo-treated patients. The ORR was highest (46%; range: 36-56%) in tumors with ≥90% PD-L1 expression, with target tumors shrinking by more than 40% after 6 months of treatment on average (per last observation carried forward method). This correlation with PD-L1 expression level was not observed with chemotherapy.

In the overall trial population, the median duration of exposure to Libtayo was 27 weeks (range: <1-115 weeks) and 18 weeks for chemotherapy (range: <1-87 weeks). Overall adverse events (AEs) occurred in 88% of Libtayo patients and 94% of chemotherapy patients. Grade 3 or higher AEs occurred in 37% of Libtayo patients and 49% of chemotherapy patients. Immune-mediated AEs were reported in 17% of Libtayo patients and included hypothyroidism (6%), hyperthyroidism (4%), pneumonitis (2%), hepatitis (2%), skin adverse reaction (2%), arthritis, increased blood thyroid stimulating hormone, thyroiditis, colitis, nephritis and peripheral neuropathy (each 1%). Treatment discontinuation due to an AE occurred in 6% of Libtayo patients and 4% of chemotherapy patients. No new Libtayo safety signals were observed.

Libtayo is being jointly developed by Regeneron and Sanofi 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 investigated the first-line treatment of Libtayo monotherapy compared to platinum-doublet chemotherapy in squamous or non-squamous advanced NSCLC that tested positive for PD-L1 in ≥50% of tumor cells but not

ALK, EGFR or ROS1. PD-L1 expression was confirmed using the PD-L1 IHC 22C3 pharmDx kit. The trial included 712 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).

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 are OS and PFS, and secondary endpoints include 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: controlled hepatitis B, hepatitis C or HIV; pre-treated and stable brain metastases; and/or locally advanced disease that had progressed after definitive chemoradiation. Patients whose disease progressed in the trial were able to change their therapy: those in the chemotherapy arm were allowed to crossover into the Libtayo arm, while those in the Libtayo arm were allowed to combine Libtayo treatment with 4 to 6 cycles of chemotherapy.

A prespecified interim analysis was performed after 50% of OS events. Due to a highly significant improvement in OS at the interim analysis, the trial was modified to allow all patients to receive Libtayo based on an Independent Data Monitoring Committee recommendation.

About non-small cell lung cancer

Lung cancer is the leading cause of cancer death worldwide, with more than 2.2 million new cases expected globally in 2020. Approximately 85% 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. 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.

Libtayo is the first immunotherapy approved 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. 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 U.S. Food and Drug Administration. 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 in addition to a pivotal trial in advanced BCC. Libtayo is also being investigated in pivotal trials in NSCLC 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 seven 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 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

Sanofi Media Relations Contact
Sally Bain
Tel.: +1 (781) 264-1091
sally.bain@sanofi.com

Sanofi Investor Relations Contacts Paris
Eva Schaefer-Jansen
Arnaud Delepine
Yvonne Naughton

Sanofi Investor Relations Contacts North America
Felix Lauscher
Fara Berkowitz
Suzanne Greco

IR main line:
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.com

Regeneron Media Relations Contact
Daren Kwok
Tel.: +1 914 847 1328
daren.kwok@regeneron.com

Regeneron Investor Relations Contact
Vesna Tosic
Tel.: +1 914 847 5443
vesna.tosic@regeneron.com

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, 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 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 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 non-small cell lung cancer, basal cell carcinoma, adjuvant and neoadjuvant cutaneous squamous cell carcinoma, and cervical cancer (as well as in trials combining Libtayo with either conventional or novel therapeutic approaches for both solid tumors and blood cancers, as applicable); 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; safety issues resulting from the administration of Regeneron's Products (such as Libtayo) and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and 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 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 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 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 or collaboration 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 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 and other related proceedings relating to EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), and Praluent® (alirocumab)), 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, 2019 and its Form 10-Q for the quarterly period ended June 30, 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 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).