ESMO Late-breaking Data Show Libtayo® (cemiplimab) and Chemotherapy First-line Treatment Combination Significantly Improved Overall Survival in Patients with Advanced NSCLC

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Phase 3 trial met its primary and key secondary endpoints

Libtayo is one of two PD-(L)1 inhibitors to demonstrate positive Phase 3 results in first-line advanced NSCLC irrespective of histology both as monotherapy and in combination with chemotherapy

Trial enrolled patients with varied baseline characteristics, including squamous and non-squamous histologies and all PD-L1 expression levels; 84% had an ECOG 1 performance status (reduced daily functioning)

Regeneron will host investor webcast on Monday, September 20 to discuss results and broader oncology portfolio

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi announced positive Phase 3 results for a Libtayo® (cemiplimab) combination treatment were presented today during a late-breaking session at the European Society for Medical Oncology Virtual Congress 2021. The trial, which met its primary overall survival (OS) endpoint and all key secondary endpoints, assessed the investigational use of PD-1 inhibitor Libtayo in combination with a physician's choice of platinum-doublet chemotherapy (Libtayo combination) in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) irrespective of histology and across all PD-L1 expression levels, compared to chemotherapy alone. These results were also achieved in a patient population with varied baseline characteristics and will form the basis of regulatory submissions, including in the U.S. and European Union (EU).

"Libtayo added to chemotherapy significantly improved patient outcomes, extending median overall survival to 22 months and median progression-free survival to 8 months," said Miranda Gogishvili, M.D., an oncologist at the High Technology Medical Center University Clinic, in Tbilisi, Georgia and a trial investigator. "Exploratory analyses showed that survival improvements were seen across squamous and non-squamous histologies and in patients with reduced daily functioning, with 43% of patients having squamous disease and 84% having an ECOG 1 performance status. Furthermore, in another exploratory analysis, the Libtayo combination helped delay deterioration in patient-reported quality of life and pain symptoms."

In the overall population, patients treated with the Libtayo combination (n=312) experienced significant improvements compared to those receiving chemotherapy alone (n=154), including a:

- **22-month median OS** compared to 13 months for chemotherapy, representing **a 29% relative reduction in the risk of death** (hazard ratio [HR]: 0.71; 95% confidence interval [CI]: 0.53 to 0.93; p=0.014). The 12-month probability of survival was 66% for the Libtayo combination and 56% for chemotherapy.
- **8-month median progression-free survival (PFS)** compared to 5 months for chemotherapy, representing **a 46% relative reduction in the risk of disease progression** (HR: 0.56; 95% CI: 0.44 to 0.70; p<0.0001). The 12-month probability of PFS was 38% for the Libtayo combination and 16% for chemotherapy.
- **43% objective response rate (ORR)** compared to 23% for chemotherapy.
- **16-month median duration of response (DOR)** compared to 7 months for chemotherapy.

Favorable patient-reported outcomes were also observed. Specifically, the Libtayo combination delayed deterioration in pain symptoms (HR: 0.39; 95% CI: 0.26 to 0.60; nominal p<0.0001) and showed a trend towards delayed deterioration in global health status/quality of life (HR: 0.78; 95% CI: 0.51 to 1.19; nominal p=0.248), compared to chemotherapy. The Libtayo combination also improved pain symptoms, compared to chemotherapy (-4.98 difference in baseline changes between treatment groups; 95% CI: -8.36 to -1.60; nominal p=0.004).

No new Libtayo safety signals were identified. The median duration of exposure was 38 weeks for the Libtayo combination (n=312) and 21 weeks for chemotherapy (n=153). Adverse events (AEs) of any grade occurred in 96% of patients receiving the Libtayo combination and 94% of patients receiving chemotherapy alone, with 19% and 0% being immune-mediated, respectively. For the Libtayo combination and chemotherapy groups, the most common AEs were anemia (44%, 40%), alopecia (37%, 43%) and nausea (25%, 16%); grade ≥3 AEs occurring in ≥5% of patients were anemia (10%, 7%) and neutropenia (both 6%). Treatment discontinuation due to AEs occurred in 5% of patients receiving the Libtayo combination and 3% receiving chemotherapy.

"This Phase 3 trial was stopped early because Libtayo significantly improved overall survival compared to chemotherapy, a milestone also achieved by our Phase 3 trial for Libtayo monotherapy as a first-line treatment for advanced non-small cell lung cancer with high PD-L1 expression," said Israel Lowy, M.D., Ph.D., Senior Vice President, Translational and Clinical Sciences, Oncology at Regeneron. "Both trials were designed to reflect everyday clinical practice by allowing for the enrollment of patients with difficult-to-treat disease characteristics. And this is the second Libtayo trial to demonstrate significant improvement in its primary and key secondary endpoints for these patient populations, compared to chemotherapy."

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.

"These data add to the growing body of evidence supporting the use of Libtayo in patients with advanced non-small cell lung cancer," said Peter C. Adamson, M.D., Global Development Head, Oncology and Pediatric Innovation at Sanofi. "With additional trials underway investigating Libtayo as the backbone in combinations with conventional and novel therapeutic approaches, we are encouraged by the potential to further improve outcomes for patients with difficult-to-treat cancers."

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

Investor Webcast Information
Regeneron will host a conference call and simultaneous webcast to share updates on Regeneron's oncology portfolio on Monday, September 20 at 8:30 a.m. ET. To access this call, dial 888 660 6127 (U.S.) or +1 973 890 8355 (International). A link to the webcast may be accessed from the "Investors and Media" page of Regeneron's website at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website and will be available for at least 30 days.

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. The trial enrolled 466 patients with locally advanced or metastatic NSCLC, as well as squamous or non-squamous histologies across all PD-L1 expression levels and with no ALK, EGFR and ROS1 aberrations.

Patients were randomized 2:1 to receive either Libtayo 350 mg (n=312) or placebo (n=154) administered intravenously every 3 weeks for 108 weeks, plus platinum-doublet chemotherapy administered every 3 weeks for 4 cycles. The primary endpoint was OS, and key secondary endpoints were PFS and ORR. The probability of survival and PFS at 12 months were calculated according to Kaplan-Meier estimates.

Notably, patients in the trial had a variety of baseline characteristics commonly considered difficult-to-treat. Among those enrolled, 43% had tumors with squamous histology, 67% had tumors with <50% PD-L1 expression, 15% had inoperable locally advanced disease not eligible for definitive chemoradiation, and 7% had pretreated and clinically stable brain metastases. Additionally, 84% of patients had an ECOG 1 performance status. ECOG performance status assesses patient ability to conduct daily living activities and prognosis on a scale of increasing severity ranging from 0 (no symptoms) to 5 (death).

About Libtayo
Libtayo is a fully human monoclonal antibody targeting the PD-1 immune checkpoint receptor 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's *VelocImmune*® Technology
Regeneron's *VelocImmune* technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's President and Chief Scientific Officer George D. Yancopoulos was a graduate student with his mentor Frederick W. Alt in 1985, they were the first to envision making such a genetically humanized mouse, and Regeneron has spent decades inventing and developing *VelocImmune* and related *VelociSuite*® technologies. Dr. Yancopoulos and his team have used *VelocImmune* technology to create approximately a quarter of all original, FDA-approved and authorized fully human monoclonal antibodies currently available. This includes REGEN–COV™ (casirivimab with imdevimab), Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb) and Inmazeb™ (atoltivimab, maftivimab and odesivimab-ebgn).

IMPORTANT SAFETY INFORMATION AND INDICATION FOR U.S. PATIENTS

What is Libtayo?
Libtayo is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation.

Libtayo is a prescription medicine used to treat people with a type of skin cancer called basal cell carcinoma that cannot be removed by surgery (locally advanced BCC) and have received treatment with a hedgehog inhibitor (HHI), or cannot receive treatment with an HHI.

Libtayo is a prescription medicine used to treat people with a type of skin cancer called basal cell carcinoma that has spread (metastatic BCC) and have received treatment with an HHI, or cannot receive treatment with an HHI. This use is approved based on how many patients responded to treatment and how long they responded. Studies are ongoing to provide additional information about clinical benefit.

Libtayo is a prescription medicine used to treat people with a type of lung cancer called non-small cell lung cancer (NSCLC). Libtayo may be used as your first treatment when your lung cancer has not spread outside your chest (locally advanced lung cancer) and you cannot have surgery or chemotherapy with radiation, or your lung cancer has spread to other areas of your body (metastatic lung cancer), and your tumor tests positive for high "PD-L1" and your tumor does not have an abnormal "EGFR"," ALK "or "ROS1" gene.

It is not known if Libtayo is safe and effective in children.

What is the most important information I should know about Libtayo?
Libtayo is a medicine that may treat certain cancers by working with your immune system. Libtayo can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- **Lung problems:** cough, shortness of breath, or chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual, stools that are black, tarry, sticky or have blood or mucus, or severe stomach area (abdomen) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), or bleeding or bruising more easily than normal
- **Hormone gland problems:** headache that will not go away or unusual headaches, eye sensitivity to light, eye problems, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, feeling more hungry or thirsty than usual, urinating more often than usual, hair loss, feeling cold, constipation, your voice gets deeper, dizziness or fainting, or changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in your amount of urine, blood in your urine, swelling of your ankles, or loss of appetite
- **Skin problems:** rash, itching, skin blistering or peeling, painful sores or ulcers in mouth or nose, throat, or genital area, fever or flu-like symptoms, or swollen lymph nodes
- Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with Libtayo. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include: chest pain, irregular heartbeat, shortness of breath or swelling of ankles, confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs, double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight, persistent or severe muscle pain or weakness, muscle cramps, low red blood cells, or bruising
- **Infusion reactions that can sometimes be severe.** Signs and symptoms of infusion reactions may include: nausea, chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, back or neck pain, or facial swelling.
- **Rejection of a transplanted organ.** Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.
- **Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with Libtayo. Your healthcare provider will monitor you for these complications.

Getting medical treatment right away may help keep these problems from becoming more serious.
Your healthcare provider will check you for these problems during your treatment with Libtayo. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with Libtayo if you have severe side effects.

Before you receive Libtayo, tell your healthcare provider about all your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome are pregnant or

plan to become pregnant. Libtayo can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment.
- You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of Libtayo. Talk with your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Libtayo.

- are breastfeeding or plan to breastfeed. It is not known if Libtayo passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of Libtayo.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of Libtayo include muscle or bone pain, tiredness, rash, and diarrhea. These are not all the possible side effects of Libtayo. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Regeneron Pharmaceuticals and Sanofi at 1-877-542-8296.

Please see full Prescribing Information, including Medication Guide.

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.

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 locally advanced or metastatic 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 the treatment of NSCLC as well as Libtayo (as a monotherapy or in combination with conventional or novel therapeutic approaches, as applicable) for the treatment of cervical cancer and other potential indications; 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, including its Form 10-K for the year ended December 31, 2020 and its Form 10-Q for the quarterly period ended June 30, 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).

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.

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