



## Phase 3 Trial of Libtayo® (cemiplimab) Monotherapy in Advanced Cervical Cancer Stopped Early for Positive Result on Overall Survival

March 15, 2021 at 2:00 AM EDT

TARRYTOWN, N.Y. and PARIS, March 15, 2021 /PRNewswire/ --

**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; first-in-class survival results in cervical cancer follow first-in-class pivotal results in advanced BCC and advanced CSCC**

**Regulatory submissions planned in 2021**

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced positive results demonstrating an overall survival (OS) benefit from the Phase 3 trial investigating the PD-1 inhibitor Libtayo® (cemiplimab) monotherapy compared to chemotherapy, in patients previously treated with chemotherapy whose cervical cancer is recurrent or metastatic. 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 this 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 3 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 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 serious AEs occurring in 30% of Libtayo patients and 27% of chemotherapy patients. The 5 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.

"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."

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).

"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."

### **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 with 78% of patients having squamous cell carcinoma and 22% having 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 there are approximately 570,000 women diagnosed with cervical cancer worldwide each year. 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 CSCC, BCC and NSCLC with  $\geq 50\%$  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 Regeneron's *VelocImmune*<sup>®</sup> Technology**

Libtayo was invented using Regeneron's *VelocImmune*<sup>®</sup> technology that utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's co-Founder, 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*<sup>®</sup> technologies. Dr. Yancopoulos and his team have used *VelocImmune* technology to create multiple antibodies including Libtayo<sup>®</sup> (cemiplimab-rwlc), Dupixent<sup>®</sup> (dupilumab), Praluent<sup>®</sup> (alirocumab), Kevzara<sup>®</sup> (sarilumab), Evkeeza<sup>™</sup> (evinacumab-dgnb), Inmazeb<sup>™</sup> (atoltivimab, maftivimab, and odesivimab-ebgn), and Regeneron's antibody cocktail for COVID-19, which was [recently](#) granted Emergency Use Authorization (EUA) in the U.S.

### **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  $\geq 50\%$  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.

## 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 an 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 a hedgehog pathway inhibitor (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 accompanying 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, 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](http://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

### **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 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® (afibercept) 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>).

### **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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