



## Libtayo® (cemiplimab) Receives Positive CHMP Opinion for the Treatment in Europe of Two Advanced Cancers

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**Libtayo recommended for approval in the first-line treatment of certain patients with advanced non-small cell lung cancer whose tumors have  $\geq 50\%$  PD-L1 expression**

**Libtayo also recommended for approval in patients with advanced basal cell carcinoma who have progressed on or are intolerant to a hedgehog pathway inhibitor**

**CHMP has now issued three positive opinions for Libtayo in advanced cancers**

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted positive opinions for Libtayo® (cemiplimab) as monotherapy in two advanced cancers.

The CHMP recommended the approval of Libtayo for the first-line treatment of adults with non-small cell lung cancer (NSCLC) expressing PD-L1 in  $\geq 50\%$  of tumor cells with no EGFR, ALK or ROS1 aberrations. Patients must have metastatic disease or locally advanced disease that is not a candidate for definitive chemoradiation. Libtayo was also recommended for approval in adults with locally advanced or metastatic basal cell carcinoma (BCC) who have progressed on or are intolerant to a hedgehog pathway inhibitor (HHI). The European Commission is expected to make a decision on both indications in the coming months.

The positive opinion for Libtayo in advanced NSCLC is based on results from a Phase 3 trial, which allowed for the enrollment of patients with disease characteristics frequently underrepresented in advanced NSCLC pivotal trials, including those with pre-treated and clinically stable brain metastases or locally advanced NSCLC and who were not candidates for definitive chemoradiation. Results from the pivotal trial were [published](#) in *The Lancet* in February 2021.

The positive opinion for Libtayo in locally advanced and metastatic BCC is based on results from the largest prospective clinical trial in these patients previously treated with an HHI to date, with data [presented](#) at the European Society for Medical Oncology Virtual Congress 2020 and recently published in *The Lancet Oncology*. Libtayo is the first immunotherapy to receive a positive CHMP opinion for this indication.

Libtayo is currently [approved](#) in the European Union (EU) and other countries for the treatment of certain patients with advanced cutaneous squamous cell carcinoma (CSCC).

### **About the Phase 3 Trial in Advanced NSCLC**

EMPOWER-Lung 1 was an open-label, randomized, multi-center Phase 3 trial designed to investigate Libtayo monotherapy compared to platinum-doublet chemotherapy as first-line treatment in patients with advanced NSCLC who tested positive for PD-L1 in  $\geq 50\%$  of tumor cells and had no EGFR, ALK or ROS1 aberrations. PD-L1 expression was confirmed using the Agilent Dako PD-L1 IHC 22C3 pharmDx kit. The primary endpoints were overall survival and progression-free survival, and secondary endpoints included objective response rate (ORR), duration of response (DOR) and quality of life. In 2020, the trial was [stopped](#) early due to significant improvement in overall survival.

The trial randomized 710 patients with either previously untreated metastatic NSCLC (stage IV) or locally advanced NSCLC (stage IIIB/C) who were not candidates for surgical resection or definitive chemoradiation or who had progressed after treatment with definitive chemoradiation. Among those enrolled, 12% had pre-treated and clinically stable brain metastases and 16% had locally advanced NSCLC that was not a candidate for definitive chemoradiation.

Patients whose disease progressed in the trial were able to change their therapy: those assigned to chemotherapy were allowed to crossover to Libtayo treatment, while those assigned to Libtayo monotherapy were allowed to continue Libtayo treatment and add four cycles of chemotherapy. There was a  $>70\%$  crossover rate to Libtayo following disease progression on chemotherapy.

### **About the Pivotal Trial in Advanced BCC**

EMPOWER-BCC 1 was an open-label, multi-center, non-randomized Phase 2 trial of patients with unresectable locally advanced or metastatic BCC (nodal or distant). Patients in both cohorts had either progressed on HHI therapy, had not had an objective response after nine months on HHI therapy, or were intolerant of prior HHI therapy. The primary efficacy endpoint was confirmed ORR and a key secondary endpoint was DOR, assessed by independent central review.

## 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 currently approved as the first systemic treatment in the U.S., EU and other countries for adults with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation. In the U.S., Libtayo is also approved as the first immunotherapy indicated for patients with advanced BCC previously treated with an HHI or for whom an HHI is not appropriate that is either locally advanced (full approval) or metastatic (accelerated approval), as well as for the first-line treatment of certain patients with advanced NSCLC with  $\geq 50\%$  PD-L1 expression and no EGFR, ALK or ROS1 aberrations.

The generic name for Libtayo in its approved U.S. indications is cemiplimab-rwlc, with rwlc as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the U.S. Food and Drug Administration (FDA).

The extensive clinical program for Libtayo is focused on difficult-to-treat cancers. Current clinical development programs include Libtayo in combination with chemotherapy for advanced NSCLC irrespective of PD-L1 expression and Libtayo monotherapy for advanced cervical cancer. Libtayo is also being investigated in combination 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.

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

## About Regeneron's *VelocImmune*<sup>®</sup> 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 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 approximately a quarter of all original, FDA-approved fully human monoclonal antibodies currently available. This includes REGEN-COV<sup>™</sup> (casirivimab with imdevimab), Dupixent<sup>®</sup> (dupilumab), Libtayo<sup>®</sup> (cemiplimab-rwlc), Praluent<sup>®</sup> (alirocumab), Kevzara<sup>®</sup> (sarilumab), Evkeeza<sup>®</sup> (evinacumab-dgnb) and Inmazeb<sup>™</sup> (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 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 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](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) for the treatment of non-small cell lung cancer ("NSCLC") and basal cell carcinoma ("BCC"); the impact of the opinions adopted by the European Medicines Agency's Committee for Medicinal Products for Human Use discussed in this press release on any approval by the European Commission of Libtayo for the treatment of NSCLC and/or BCC in the European Union and the timing of any such approval; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products (such as Libtayo) and Regeneron's Product Candidates; the 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 for NSCLC and/or BCC in the European Union discussed in this press release and possible regulatory approval of Libtayo in other jurisdictions and indications, including in combination with chemotherapy for advanced NSCLC irrespective of PD-L1 expression and as monotherapy for advanced cervical cancer (as well as in combination with either conventional or novel therapeutic approaches for both solid tumors and blood cancers); 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® (afibercept) Injection, Dupixent® (dupilumab), Praluent® (alirocumab), and REGEN-COV™ (casirivimab with imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2020 and its Form 10-Q for the quarterly period ended March 31, 2021. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.*

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

### **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, 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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