



## Libtayo® (cemiplimab-rwlc) Presentations at ASCO Highlight Expanding Clinical Data in Diverse Cancers

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**Presentations include first positive clinical data for the fianlimab (LAG-3 inhibitor) and Libtayo combination in advanced melanoma**

**Regeneron will host an investor webcast on Monday, June 7 to provide further updates across its oncology portfolio**

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced the company will share a range of presentations for its PD-1 inhibitor Libtayo® (cemiplimab-rwlc) and broader oncology portfolio at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting from June 4-8, taking place virtually. Presentations include new clinical data and in-depth analyses on the impact of Libtayo in several advanced cancers, including non-small cell lung cancer (NSCLC), cutaneous squamous cell carcinoma (CSCC), basal cell carcinoma (BCC) and melanoma.

"Following our presentation of updated, positive cervical data at the ESMO Virtual Plenary, we look forward to providing an overview of the maturing experience with Libtayo across a range of cancers at ASCO," said Israel Lowy, M.D., Ph.D., Senior Vice President, Translational and Clinical Sciences, Oncology, at Regeneron. "Presentations include a new post-hoc analysis of our pivotal Libtayo trial for advanced non-small cell lung cancer in a subset of patients with brain metastases, as well as new data from a prospective real-world trial in immunocompromised or immunosuppressed patients with advanced cutaneous squamous cell carcinoma. We will also share presentations showing the impact of Libtayo on quality of life in multiple cancers, and for the first time, positive results for Libtayo in combination with our investigational LAG-3 inhibitor fianlimab in advanced melanoma."

Investigator-assessed results from two expansion cohorts of a Phase 1 trial investigating fianlimab (REGN3767) and Libtayo in advanced melanoma were published by ASCO today. Efficacy was greatest in PD-1 inhibitor naïve patients, who experienced a 64% objective response rate (21 of 33 patients; 3 complete responses, 18 partial responses), and the median progression-free survival and median duration of response had not yet been reached.

Among 48 patients receiving the fianlimab and Libtayo combination, the most common adverse events (AEs) were fatigue (n=15; 31%) and rash (n=11; 23%). Grade 3 or higher AEs occurred in 35% (n=17) of patients, with 23% (n=11) of these events classified as serious. Treatment discontinuations due to an AE occurred in 8% (n=4) of patients. Updated efficacy and safety data will be presented during a poster discussion session available on-demand starting Friday, June 4 at 9:00 a.m. ET (Abstract 9515).

Earlier this year, Libtayo monotherapy was [approved](#) in the U.S. for certain patients with NSCLC whose tumors have high PD-L1 expression and no EGFR, ALK or ROS1 aberrations. The FDA also recently [approved](#) the use of Libtayo as the first immunotherapy indicated for patients with 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 CSCC. Libtayo is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

### Investor Webcast Information

Regeneron will host a conference call and simultaneous webcast to share updates on the Company's oncology portfolio on Monday, June 7 at 4:30 p.m. ET. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International), conference ID 7569618. A link to the webcast may be accessed from the 'Investors and Media' page of Regeneron's website at <http://investor.regeneron.com/events.cfm>. A replay of the conference call and webcast will be archived on the Company's website for at least 30 days.

### Libtayo joint presentations with Sanofi at ASCO NSCLC

- Cemiplimab monotherapy as first-line (1L) treatment of patients with brain metastases from advanced non-small cell lung cancer (NSCLC) with programmed cell death-ligand 1 (PD-L1)  $\geq 50\%$ ; EMPOWER-Lung 1 subgroup analysis (Abstract 9085; Mustafa Özgüroğlu, M.D.; Poster Session)
- Patient-reported symptoms, functioning, and quality of life (QoL) in patients treated with cemiplimab monotherapy for first-line treatment of advanced NSCLC with PD-L1  $\geq 50\%$ : Results from EMPOWER-Lung 1 study (Abstract 9078; Mahmut Gümüş, M.D.; Poster Session)
- Network meta-analysis (NMA) of immuno-oncology (IO) monotherapy (mono) as first-line (1L) treatments (txs) for advanced non-small cell lung cancer (NSCLC) with PD-L1 expression  $\geq 50\%$  (Abstract e21091; Nick Freemantle, Ph.D.; Online

Publication)

- Budget impact (BI) analysis of cemiplimab for first-line (1L) advanced non-small cell lung cancer (NSCLC) with programmed cell death-ligand 1 (PD-L1)  $\geq 50\%$  in the United States (Abstract e18817; Andreas Kuznik, Ph.D.; Online Publication)

## BCC

- Health-related quality of life (HRQoL) in patients (pts) with locally advanced basal cell carcinoma (laBCC) treated with cemiplimab: analysis of a phase II, open-label clinical trial (Abstract 9566; Alexander J. Stratigos, M.D.; Poster Session)
- Frequency, characteristics, and subsequent treatment (Tx) of real-world patients (pts) who discontinue hedgehog inhibitors (HHI) as first-line (1L) systemic Tx for advanced basal cell carcinoma (aBCC) (Abstract e18740; C. Lance Cowey, M.D.; Online Publication)
- Outcomes in patients (pts) with advanced basal cell carcinoma (aBCC) who discontinued hedgehog inhibitors (HHI) as first-line (1L) systemic treatment (Tx) in a US community oncology setting: A retrospective observational study (Abstract e18742; C. Lance Cowey, M.D.; Online Publication)
- Budget impact (BI) analysis of cemiplimab-rwlc for advanced basal cell carcinoma (BCC) after hedgehog inhibitor (HHI) therapy in the United States (Abstract e18830; Eleanor Paul; Online Publication)

## CSCC

- Checkpoint inhibition in immunosuppressed or immunocompromised patients with advanced cutaneous squamous cell carcinoma (CSCC): Data from prospective CemiplimAb-rwlc Survivorship and Epidemiology (C.A.S.E.) study (Abstract 9547; Guilherme Rabinowits, M.D.; Poster Session)

## Additional Regeneron presentations at ASCO

### *Libtayo in combination with fianlimab*

- Clinical activity of fianlimab (REGN3767), a human anti-LAG-3 monoclonal antibody, combined with cemiplimab (anti-PD-1) in patients (pts) with advanced melanoma (Abstract 9515; Omid Hamid, M.D.; Poster Discussion)

### *REGN5668 (MUC16xCD28)*

- A Phase I/II, multicenter, open-label study of REGN5668 (mucin [MUC]16 x CD28 bispecific antibody [bsAb]) with cemiplimab (programmed death [PD]-1 Ab) or REGN4018 (MUC16 x CD3 bsAb) in recurrent ovarian cancer (rOVCA) (Abstract TPS5602; Ira Winer, M.D., Ph.D.; Trial-in-progress Poster)

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

## About Regeneron in Oncology

At Regeneron, we're applying more than three decades of scientific innovation to develop paradigm-changing therapies for patients with cancer. Fusing our deep expertise in biology with our proprietary *VelociSuite*<sup>®</sup> technologies, we have contributed landmark cancer research to the field and are pioneering first-in-class investigational treatments through a growing pipeline of more than 10 cancer therapies.

Our oncology portfolio is built around two foundational approaches – our approved PD-1 inhibitor Libtayo and bispecific antibodies – which are being investigated both as monotherapies and in combination with emerging therapeutic modalities. Together, they provide us with unique combinatorial flexibility to develop customized and potentially synergistic treatments for a wide range of solid tumors and blood cancers.

For more information on our clinical programs, visit [www.regeneron.com/pipeline](http://www.regeneron.com/pipeline).

## 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, and 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 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.

### **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* 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™ (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 Inmazed™ (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 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, 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.

**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"), cutaneous squamous cell carcinoma, basal cell carcinoma, and melanoma (in combination with fianlimab (REGN3767)), as well as REGN5668 and REGN4018; 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 (such as fianlimab (REGN3767), REGN5668, and REGN4018); 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 in combination with chemotherapy for advanced NSCLC irrespective of PD-L1 expression and Libtayo 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® (aflibercept) 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>).*

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