# Regeneron to Highlight Advances at ASCO with Phase 3 Adjuvant Libtayo® (cemiplimab) CSCC Updates and Promising Early Blood Cancer Data with Linvoseltamab Combination

May 1, 2025 at 9:30 AM EDT

**18 presentations across five cancer types include new insights on the potential of checkpoint inhibitors and bispecific antibodies**

TARRYTOWN, N.Y., May 01, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced new and updated data from its oncology and hematology portfolio will be shared at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place from May 30 to June 3 in Chicago, IL. Eighteen presentations will share the latest insights from ongoing research of approved and investigational treatment regimens across a range of difficult-to-treat cancers including non-melanoma and melanoma skin cancer, lung cancer, lymphoma and multiple myeloma.

"Our broad oncology and hematology programs are uniquely designed to investigate regimens that could provide meaningful impact for people living with difficult-to-treat cancers across all stages of the treatment paradigm," said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer at Regeneron. "Our PD-1 inhibitor Libtayo is the standard of care in advanced cutaneous squamous cell carcinoma, and in clinical trials, our investigational BCMAxCD3 bispecific antibody linvoseltamab has demonstrated a compelling profile in relapsed or refractory multiple myeloma. At ASCO, our presentations showcase how we are seeking to further transform the treatment of these diseases with updates from two key programs – our Phase 3 trial exploring adjuvant Libtayo in high-risk cutaneous squamous cell carcinoma and early data from investigational combinations of linvoseltamab and different proteasome inhibitors in third-line or higher multiple myeloma."

Notable presentations at ASCO on Regeneron's oncology pipeline include detailed efficacy and safety findings from the Phase 3 C-POST trial evaluating the adjuvant use of the PD-1 inhibitor Libtayo in post-surgical high-risk cutaneous squamous cell carcinoma (CSCC). The results will be presented in an oral session on Saturday, May 31.

In hematology, Regeneron will debut results from two cohorts of the LINKER-MM2 trial, which is exploring combinations of linvoseltamab, Regeneron's investigational BCMAxCD3 bispecific antibody. These include combinations of linvoseltamab with carfilzomib or bortezomib in relapsed/refractory (R/R) multiple myeloma (MM) after at least two lines of therapy, which will be featured in two rapid oral presentations on Monday, June 2.

In addition, the results of a cooperative group study reporting on the primary analysis of a randomized Phase 2 trial of vidutolimod in combination with an anti-PD-1 versus anti-PD-1 as neoadjuvant therapy in stage 3 resectable melanoma will be presented in an oral session on Tuesday, June 3. Vidutolimod is a toll like receptor 9 antagonist that was acquired by Regeneron in 2022.

The full list of Regeneron presentations at ASCO includes:

| Medicine | Abstract title | Abstract and Session | Lead author | Presentation date/time (all CDT) |
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| **Skin Cancer** | | | | |
| Libtayo | Phase 3 trial of adjuvant cemiplimab (cemi) versus placebo (pbo) for high-risk cutaneous squamous cell carcinoma (CSCC) | #6001<br><br>Oral Abstract Session – Head and Neck Cancer | Danny Rischin | Saturday, May 31<br><br>1:15 p.m. – 4:15 p.m. |
| Libtayo | Patient-reported outcomes (PROs) in the C-POST trial of adjuvant cemiplimab (cemi) vs placebo (pbo) for high-risk cutaneous squamous cell carcinoma (CSCC) | #6065<br><br>Poster Session – Head and Neck Cancer | Annette M. Lim | Monday, June 2<br><br>9:00 a.m. – 12:00 p.m. |

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| Libtayo | CemiplimAb-rwlc Survivorship and Epidemiology (CASE): Interim results from a prospective study of the safety and effectiveness of cemiplimab in patients with advanced cutaneous squamous cell carcinoma (CSCC) in a real-world setting | #9533<br><br>Poster Session – Melanoma/Skin Cancers | Soo J. Park | Sunday, June 1<br><br>9:00 a.m. – 12:00 p.m. |
| Libtayo | A Phase 3 randomized study of low-dose intralesional cemiplimab versus primary surgery for patients with early-stage cutaneous squamous cell carcinoma (CLEAR CSCC) | #TPS9612<br><br>Poster Session – Melanoma/Skin Cancers | Michael Migden | Sunday, June 1<br><br>9:00 a.m. – 12:00 p.m. |
| Fianlimab, Libtayo | A randomized phase 2 peri-operative (neoadjuvant plus adjuvant) study of fianlimab (anti–LAG-3) plus cemiplimab (anti–PD-1) versus anti–PD-1 alone in patients with resectable stage III and IV melanoma | #TPS9596<br><br>Poster Session – Melanoma/Skin Cancers | Rodabe N. Amaria | Sunday, June 1<br><br>9:00 a.m. – 12:00 p.m. |
| Libtayo | Utilizing EORTC Item Library to develop a tailored patient-reported outcome measure (CSCC-NAAP-32) to evaluate quality of life in resectable advanced (RA) cutaneous squamous cell carcinoma (CSCC) | #e18014<br><br>Publication-Only Abstract: Head and Neck Cancer | Neil Gross | N/A |
| Vidutolimod | A phase 2 randomized study of neoadjuvant pembrolizumab (P) alone or in combination with vidutolimod (V) in high-risk resectable melanoma: ECOG-ACRIN 6194 | #LBA9505<br><br>Oral Abstract Session – Melanoma/Skin Cancers | Ahmad Tarhini | Tuesday, June 3<br><br>9:45 a.m. – 12:45 p.m. |
| **Multiple Myeloma** | | | | |
| Linvoseltamab | Linvoseltamab (LINVO) + carfilzomib (CFZ) in patients (pts) with relapsed/refractory | #7513<br><br>Rapid Oral Abstract Session – Hematologic | Salomon Manier | Monday, June 2<br><br>8:00 a.m. – 9:30 a.m. |

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| | multiple myeloma (RRMM): Initial results from the LINKER-MM2 trial | Malignancies—Plasma Cell Dyscrasia | | |
| Linvoseltamab | Linvoseltamab (LINVO) + bortezomib (BTZ) in patients (pts) with relapsed/refractory multiple myeloma (RRMM): First results from the LINKER-MM2 trial | #7510<br><br>Rapid Oral Abstract Session – Hematologic Malignancies—Plasma Cell Dyscrasia | Paula Rodríguez-Otero | Monday, June 2<br><br>8:00 a.m. – 9:30 a.m. |
| Linvoseltamab | Indirect comparison of linvoseltamab versus elranatamab for triple-class exposed (TCE) relapsed/refractory multiple myeloma (RRMM) | #7531<br><br>Poster Session – Hematologic Malignancies—Plasma Cell Dyscrasia | Sundar Jagannath | Sunday, June 1<br><br>9:00 a.m. – 12:00 p.m. |
| Linvoseltamab | Second primary malignancy (SPM) in patients (pts) with multiple myeloma (MM) receiving chimeric antigen receptor T-cell (CAR T) therapy or other systemic anticancer therapy (SACT): A comparative study using a real-world database | #7519<br><br>Poster Session – Hematologic Malignancies—Plasma Cell Dyscrasia | Attaya Suvannasankha | Sunday, June 1<br><br>9:00 a.m. – 12:00 p.m. |
| Linvoseltamab | Concordance between blinded independent central review committee and physician-assessed responses: Analyses based on a real-world external control arm in relapsed/refractory multiple myeloma using International Myeloma Working Group data | #e19521<br><br>Publication-Only Abstract: Hematologic Malignancies—Plasma Cell Dyscrasia | Brian G. Durie | N/A |
| **Lung Cancer** | | | | |
| REGN7075, Libtayo | A randomized study of neoadjuvant REGN7075 + cemiplimab + chemotherapy (chemo) vs cemiplimab + chemo in patients (pts) with resectable non-small cell lung cancer (NSCLC) | #TPS8116<br><br>Poster Session –Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers | Ardy Davarifar | Saturday, May 31<br><br>1:30 p.m. – 4:30 p.m. |
| Fianlimab, Libtayo | Phase 2 peri-operative study of fianlimab + cemiplimab + | #TPS8117<br><br>Poster Session – Lung Cancer | Ekaterine Arkania | Saturday, May 31<br><br>1:30 p.m. – |

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| | chemotherapy versus cemiplimab + chemotherapy in resectable early-stage non-small cell lung cancer (NSCLC) | Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers | | 4:30 p.m. |
| Libtayo | Evaluation of current programmed death-ligand 1 (PD-L1) testing trends for metastatic non-small cell lung cancer (mNSCLC): Insights from a large network of US community oncology practices | #e23294<br><br>Publication-Only Abstract: Quality Care/Health Services Research | Kathleen M. Aguilar | N/A |
| Libtayo | Evaluating the safety and effectiveness of cemiplimab in combination with platinum-doublet chemotherapy by demographic characteristics in first-line treatment of advanced non-small cell lung cancer: An ongoing multi-database real world evidence study in US patients | #e20572<br><br>Publication-Only Abstract: Lung Cancer—Non-Small Cell Metastatic | Alexi Archambault | N/A |
| **Head and Neck Cancer** | | | | |
| Fianlimab, Libtayo | A Phase 2 study of fianlimab (anti-LAG-3) plus cemiplimab (anti-PD-1) versus cemiplimab plus placebo in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) with positive PD-L1 expression | #TPS6112<br><br>Poster Session – Head and Neck Cancer | Danny Rischin | Monday, June 2<br><br>9:00 a.m. – 12:00 p.m. |
| **Lymphoma** | | | | |
| Odronextamab | Long-term follow-up of the phase 2 ELM-2 study: Odronextamab for patients (pts) with relapsed/refractory (R/R) follicular lymphoma (FL) | #7049<br><br>Poster Session – Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia | Deepa Jagadeesh | Sunday, June 1<br><br>9:00 a.m. – 12:00 p.m. |
| Odronextamab | Second primary malignancy in patients with diffuse large B-cell lymphoma (DLBCL) receiving chimeric antigen receptor T-cell (CAR T) therapy | #7080<br><br>Poster Session – Hematologic Malignancies—Lymphoma and Chronic Lymphocytic | Matthew Lunning | Sunday, June 1<br><br>9:00 a.m. – 12:00 p.m. |

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| and other systemic anti-cancer therapy: A real-world data analysis | Leukemia |

The potential uses of Libtayo in adjuvant CSCC, fianlimab, REGN7075, vidutolimod, and the combinations with linvoseltamab described above are investigational, and their safety and efficacy in these uses have not been fully evaluated by any regulatory authority. Fianlimab, REGN7075 and vidutolimod are not currently approved for use in any indication. Odronextamab is conditionally approved as Ordspono™ in the European Union for the treatment of R/R follicular lymphoma (FL) or diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy, although its safety and efficacy have not been fully evaluated by any other regulatory authority. Linvoseltamab is conditionally approved as Lynozyfic™ in the European Union for the treatment of adult patients with R/R multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody, and have demonstrated disease progression on the last therapy, although its safety and efficacy have not been fully evaluated by any other regulatory authority. The U.S. Food and Drug Administration (FDA) accepted for review the Biologics License Applications for linvoseltamab and odronextamab with respective target action dates for FDA decisions of July 10, 2025 and July 30, 2025.

**About Regeneron in Cancer**
We aspire to turn revolutionary discoveries into medicines that can transform the lives of those impacted by cancer. Our team around the world is driven to solve the needs and challenges of those affected by one of the most serious diseases of our time.

Backed by our legacy of scientific innovation and a deep understanding of biology, genetics and the immune system, we're pursuing potential therapies across more than 30 types of solid tumors and blood cancers. Our cancer strategy is powered by cutting-edge technologies and therapies that can be flexibly combined to investigate potentially transformative treatments for patients. Oncology assets in clinical development comprise nearly half of Regeneron's pipeline, and include checkpoint inhibitors, bispecific antibodies and costimulatory bispecific antibodies. Our approved PD-1 inhibitor Libtayo serves as the backbone of many of our investigational combinations.

To complement our extensive in-house capabilities, we collaborate with patients, healthcare providers, governments, biopharma companies and each other to further our shared goals. Together, we are united in the mission to serve as a beacon of transformation in cancer care.

**Libtayo U.S. FDA-approved Indications**
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.
- People with a type of skin cancer called basal cell carcinoma (BCC) when your BCC cannot be removed by surgery (locally advanced BCC) or when it has spread (metastatic BCC) and have received treatment with a hedgehog pathway inhibitor (HHI), or cannot receive treatment with a HHI.
- Adults with a type of lung cancer called non-small cell lung cancer (NSCLC).
    - LIBTAYO may be used in combination with chemotherapy that contains a platinum medicine 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 does not have an abnormal "EGFR," "ALK," or "ROS1" gene.
    - LIBTAYO may be used alone 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.

**IMPORTANT SAFETY INFORMATION FOR U.S. PATIENTS**

**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 or life-threatening.** Signs and symptoms of infusion reactions may include: nausea, vomiting, 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 received radiation treatment to your chest area
- 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 to 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 when used alone include tiredness, muscle or bone pain, rash, diarrhea, and low levels of red blood cells (anemia). The most common side effects of LIBTAYO when used in combination with platinum-containing chemotherapy include hair loss, muscle or bone pain, nausea, tiredness, numbness, pain, tingling, or burning in your hands or feet, and decreased appetite. 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 at 1-877-542-8296.

**Please see full Prescribing Information, including Medication Guide.**

**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 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 a substantial proportion of all original, FDA-approved or authorized fully human

monoclonal antibodies. This includes Dupixent® (dupilumab), Libtayo, Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb), Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) and Veopoz® (pozelimab-bbfg). In addition, REGEN-COV® (casirivimab and imdevimab) had been authorized by the FDA during the COVID-19 pandemic until 2024.

**About Regeneron**
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite*®, which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook or X.

**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 nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Libtayo® (cemiplimab) and Regeneron's Product Candidates discussed or referenced in this press release (such as linvoseltamab, REGN7075, fianlimab, and odronextamab); 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 adjuvant Libtayo in high-risk cutaneous squamous cell carcinoma, linvoseltamab (as a monotherapy or in combination with other cancer treatments discussed or referenced in this press release) in relapsed/refractory ("R/R") multiple myeloma, REGN7075 in combination with Libtayo and chemotherapy in non-small cell lung cancer ("NSCLC"), fianlimab in combination with Libtayo in perioperative melanoma or NSCLC, odronextamab in R/R follicular lymphoma, and the other clinical programs discussed or referenced in the press release; 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 and Regeneron's Product Candidates (such as those referenced above); the ability of Regeneron's collaborators, licensees, 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 manage supply chains for multiple products and product candidates and risks associated with tariffs and other trade restrictions; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates (such as those referenced above) 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 or copay assistance for Regeneron's Products from third-party payors and other third parties, 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 payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees 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 and Bayer (or their respective affiliated companies, as applicable) to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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), 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, 2024 and its Form 10-Q for the quarterly period ended March 31, 2025. 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 (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).*

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