Regeneron Provides Business Updates and Highlights from Broad Clinical Pipeline at the 43rd Annual J.P. Morgan Healthcare Conference

January 13, 2025 at 6:30 AM EST

Dupixent® is now used to treat over a million patients globally, with continued growth and expansion in multiple indications for diseases in which type 2 inflammation plays a role

EYLEA HD® and EYLEA® remained the U.S. anti-VEGF category leader in 2024; aggregate U.S. net product sales were $6 billion for full-year 2024, up 1% based on preliminary (unaudited) results

EYLEA HD pre-filled syringe (PFS) submission completed; launch expected by mid-2025

Libtayo® exceeded $1 billion in 2024 annual net sales, and becomes the first and only immunotherapy to show a statistically significant clinical benefit as adjuvant therapy in high-risk cutaneous squamous cell carcinoma (CSCC)

Linvoseltamab Biologics License Application (BLA) resubmitted following resolution of third-party manufacturing issues; launch anticipated mid-2025

Approximately 40 investigational candidates in industry-leading pipeline cover dozens of disease states with expansive market potential

Regeneron collaborates with Truveta and leading American health systems to massively extend its DNA sequence-linked healthcare database to further advance scientific innovation and healthcare delivery

TARRYTOWN, N.Y., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today will share corporate progress and highlights from the Company's broad and diverse investigational pipeline while presenting at the annual J.P. Morgan Healthcare Conference. The presentation is scheduled for 2:15 p.m. Pacific Time (5:15 p.m. Eastern Time) and may be accessed from the "Investors & Media" page of Regeneron's website.

"The Regeneron name is synonymous with innovation, brought to life through proprietary technologies and world-class science that produce medicines that make a meaningful impact on patients' lives," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "Thanks to our long-term and consistent R&D investment, we have – in addition to our four blockbuster medicines – one of the industry's largest, most promising and most diverse clinical pipelines. Our therapeutic candidates tackle a myriad of diseases, with the most advanced programs addressing an aggregate commercial market opportunity expected to exceed $220 billion by 2030. We are well positioned for future growth and more confident than ever in the power of Regeneron's science."

Marketed Products

Dupixent Updates

- Dupixent® (dupilumab) is now used to treat over a million patients globally. The recent approval and launch in chronic obstructive pulmonary disease (COPD) has had a successful start, with coverage secured from the top commercial and Medicare payers and Dupixent now well positioned to address approximately 300,000 patients in the U.S.
- There is continued growth potential in existing and additional indications for diseases in which type 2 inflammation may play a role, including chronic spontaneous urticaria (CSU) with an expected U.S. Food and Drug Administration (FDA) decision by April 18, 2025, and bullous pemphigoid, for which a supplemental Biologics License Application (sBLA) was submitted in the fourth quarter of 2024.

EYLEA HD and EYLEA Updates

- On a combined basis, EYLEA HD® (aflibercept) Injection 8 mg and EYLEA® (aflibercept) Injection 2 mg remained the U.S. anti-VEGF category leader in 2024. Based on preliminary (unaudited) results, the products achieved 1% year-over-year growth by reaching $6 billion in aggregate U.S. net product sales for the year and $1.5 billion in aggregate U.S. net product sales for the fourth quarter of 2024, despite increasing competition. EYLEA HD U.S. net product sales were $305 million in the fourth quarter of 2024. EYLEA U.S. net product sales were $1.19 billion in the fourth quarter of 2024.
- Combined EYLEA HD and EYLEA U.S. net product sales for the fourth quarter of 2024 were favorably impacted by

approximately $85 million as a result of higher wholesaler inventory levels for EYLEA, partially offset by lower wholesaler inventory levels for EYLEA HD.
- The Company filed an application with the FDA for use of the EYLEA HD pre-filled syringe (PFS) with U.S. approval and launch expected by mid-2025.
- Longer term data in wet age-related macular degeneration (wAMD) and diabetic macular edema (DME) are under FDA review with a PDUFA date of April 20, 2025 to potentially extend dosing intervals for EYLEA HD up to every-24 weeks.
- The Company plans to submit a sBLA for EYLEA HD for every four-week dosing and for retinal vein occlusion (RVO) in the first quarter of 2025 to potentially maximize dosing flexibility and address more retinal diseases.

Libtayo Updates

- Libtayo® (cemiplimab) exceeded $1 billion in sales for 2024 and remains foundational to Regeneron's oncology portfolio.
- As announced this morning, a Phase 3 study demonstrated that Libtayo is the only immunotherapy to show a statistically significant and clinically meaningful benefit in high-risk cutaneous squamous cell carcinoma (CSCC) in the adjuvant setting; a recent Phase 3 trial with Keytruda® failed in the same setting.[1] Specifically, adjuvant Libtayo demonstrated a 68% reduction in the risk of disease recurrence or death, compared to placebo (hazard ratio: 0.32; 95% confidence interval: 0.20-0.51; p<0.0001). Grade ≥3 adverse events occurred in 24% (n = 49 of 205) and 14% (n = 29 of 204) of patients in the Libtayo arm and the placebo arm, respectively. Detailed results will be presented at an upcoming medical meeting and will be shared with regulatory authorities with a plan for FDA submission in the first half of 2025.

Phase 3 and Other Major Pipeline Opportunities

Regeneron is progressing numerous promising drug candidates across diverse disease states, with advanced programs that together have a total addressable commercial market expected to exceed $220 billion by 2030. Some near-term highlights include:

- **Itepekimab (IL-33) for COPD:** Based on genetic data linking IL-33 with increased risk of COPD and Phase 2 results, Regeneron's next innovation in COPD offers potential for benefit in a broader population, including former smokers, non-cystic fibrosis bronchiectasis and other indications. Results are expected from the Phase 3 AERIFY study in the second half of 2025, with a potential BLA submission to follow.

- **Fianlimab (LAG3) for melanoma**: Combining fianlimab and Libtayo, two potentially best-in-class checkpoint inhibitors, has the potential for differentiated efficacy and safety versus the current standard-of-care. Results from the first Phase 3 study in first-line metastatic melanoma are expected in the second half of 2025, with a potential BLA submission to follow.

- **Linvoseltamab (BCMAxCD3) for multiple myeloma:** Linvoseltamab has potential to be the best-in-class BCMAxCD3 bispecific with its differentiated clinical profile, dosing regimen and administration method. The linvoseltamab BLA has been resubmitted following resolution of third-party manufacturing issues, with launch anticipated in mid-2025. Phase 3 programs in earlier lines of therapy using linvoseltamab monotherapy and novel combinations are also underway.

- **Odronextamab (CD20xCD3) for lymphoma:** Ordspono ™(odronextamab) has been approved in the European Union for relapsed/refractory follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy, and enrollment is underway for a confirmatory study to support resubmission of the BLA for FL to the FDA in the first quarter of 2025. A broad and differentiated Phase 3 program is also underway to investigate odronextamab in earlier lines of FL and DLBCL. As reported at the American Society of Hematology annual meeting, odronextamab monotherapy showed complete responses in 12 out of 12 evaluable patients with first-line FL in the safety lead-in portion of the Phase 3 program.

- **Factor XI for anticoagulation:** Regeneron's two-pronged approach to anticoagulation is being evaluated for its potential to control thombosis while minimizing bleeding risk in a variety of patient populations and clinical settings. Two Factor XI antibodies, REGN7508 (catalytic domain) and REGN9933 (A2 domain), will advance to pivotal trials in 2025 on the basis of positive proof-of-concept data announced in December 2024. Current standards of care for thrombosis disorders have challenges including elevated risk of bleeding resulting in underutilization, presenting an unmet need for more specific inhibition of the intrinsic coagulation pathway.

- **Multiple approaches to obesity:** Regeneron is studying various combinations with GLP-based therapies to potentially improve quality of weight loss by preserving lean muscle, as well as improve maintenance of weight loss following GLP-1/GIP discontinuations. A Phase 2 study of trevogrumab and semaglutide with and without garetosmab is now fully enrolled and a Phase 2 study testing combinations of tirzepatide and mibavademab is ongoing, with initial data expected from both in the second half of 2025.

- **BCMAxCD3/Dupixent in severe allergy**: Combining linvoseltamab and Dupixent has the potential to eliminate immunoglobulin E (IgE), the key driver of allergic reactions, and thus potentially reverse severe allergies. A trial in patients with severe food allergies is ongoing, with initial clinical data shared in today's presentation showing profound reduction of IgE in the first patient treated with this two-drug approach.

- **C5 Combo (pozelimab and cemdisiran) in complement-mediated diseases:** Regeneron's differentiated siRNA and antibody combination approach has the potential to address multiple complement-mediated diseases, such as generalized myasthenia gravis (Phase 3 results expected in the second half of 2025), paroyxsmal noctural hemoglobinuria (Phase 3 registrational data expected in 2026+) and geographic atrophy, an advanced form of dry AMD (Phase 3 pivotal program underway).

DNA Sequence-Linked Healthcare Database

Regeneron continues to grow its leadership in genetics-driven drug discovery and is building the world's largest DNA sequence-linked healthcare database, designed to unlock profound insights into how genetics impact health and aid in the development new genetic-based therapies and optimized healthcare services.

- The Regeneron Genetics Center® has sequenced nearly three million people to date, all with deidentified linked healthcare records.
- A newly announced strategic collaboration with Truveta, Inc. is expected to dramatically expand the size of this database, with sequencing and linked Electronic Health Records for up to 10 million additional individuals from Truveta's network of leading U.S. health systems.
- On the basis of its industry-leading capabilities, Regeneron Genetics Center was selected by UK BioBank consortium members to complete proteomic assay data generation for the recently announced UK Biobank Pharma Proteomics Project.

"Regeneron continues to diversify our commercial, clinical and research portfolios by relentlessly pushing the boundaries of innovation and technology," said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, President and Chief Scientific Officer of Regeneron. "In 2025, we will progress dozens of promising new assets and expand the reach of our important established medicines to help even more patients in need. We remain at the forefront of biotechnology's most remarkable era of drug discovery, striving to change the practice of medicine with approaches spanning antibodies, bispecifics, gene editing, gene silencing, gene therapy and cell therapy supported by DNA sequence- and proteomics-linked healthcare database."

The unapproved uses of EYLEA, EYLEA HD, Dupixent, Libtayo and pozelimab noted here are investigational and have not been fully evaluated by any regulatory authority. Cemdisiran, itepekimab, fianlimab, linvoseltamab, REGN7508, REGN9933, trevogrumab and garetosmab are investigational and have also not been fully evaluated by any regulatory authority. Odronextamab is approved in the European Union as Ordspono™ to treat R/R FL or DLBCL after two or more lines of systemic therapy, but the safety and efficacy of odronextamab has not been fully evaluated by any other regulatory authority.

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.

DUPIXENT IMPORTANT SAFETY INFORMATION AND U.S. INDICATIONS

DUPIXENT® (dupilumab) is a prescription medicine used:

- to treat adults and children 6 months of age and older with moderate-to-severe eczema (atopic dermatitis or AD) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children with atopic dermatitis under 6 months of age.
- with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent

asthma in adults and children 6 years of age and older whose asthma is not controlled with their current asthma medicines. DUPIXENT helps prevent severe asthma attacks (exacerbations) and can improve your breathing. DUPIXENT may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. It is not known if DUPIXENT is safe and effective in children with asthma under 6 years of age.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adults and children 12 years of age and older whose disease is not controlled. It is not known if DUPIXENT is safe and effective in children with chronic rhinosinusitis with nasal polyps under 12 years of age.
- to treat adults and children 1 year of age and older with eosinophilic esophagitis (EoE), who weigh at least 33 pounds (15 kg). It is not known if DUPIXENT is safe and effective in children with eosinophilic esophagitis under 1 year of age, or who weigh less than 33 pounds (15 kg).
- to treat adults with prurigo nodularis (PN). It is not known if DUPIXENT is safe and effective in children with prurigo nodularis under 18 years of age.
- with other medicines for the maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and a high number of blood eosinophils (a type of white blood cell that may contribute to your COPD). DUPIXENT is used to reduce the number of flare-ups (the worsening of your COPD symptoms for several days) and can improve your breathing. It is not known if DUPIXENT is safe and effective in children with chronic obstructive pulmonary disease under 18 years of age.

Do not use if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

Before using DUPIXENT, tell your healthcare provider about all your medical conditions, including if you:

- have eye problems.
- have a parasitic (helminth) infection.
- are scheduled to receive any vaccinations. You should not receive a “live vaccine” right before and during treatment with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
    - A pregnancy registry for women who take DUPIXENT during pregnancy collects information about the health of you and your baby. To enroll or get more information call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/.
- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT passes into your breast milk.

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

Especially tell your healthcare provider if you are taking oral, topical, or inhaled corticosteroid medicines; have asthma and use an asthma medicine; or have atopic dermatitis, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, or chronic obstructive pulmonary disease and also have asthma. **Do not** change or stop your other medicines, including corticosteroid medicine or other asthma medicine, without talking to your healthcare provider. This may cause other symptoms that were controlled by those medicines to come back.

DUPIXENT can cause serious side effects, including:

- **Allergic reactions. DUPIXENT can cause allergic reactions that can sometimes be severe.** Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following signs or symptoms: breathing problems or wheezing, swelling of the face, lips, mouth, tongue or throat, fainting, dizziness, feeling lightheaded, fast pulse, fever, hives, joint pain, general ill feeling, itching, skin rash, swollen lymph nodes, nausea or vomiting, or cramps in your stomach-area.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision, such as blurred vision. Your healthcare provider may send you to an ophthalmologist for an exam if needed.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive DUPIXENT. This may happen in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by DUPIXENT. Tell your healthcare provider right away if you have: rash, chest pain, worsening shortness of breath, a feeling of pins and needles or numbness of your arms or legs, or persistent fever.
- **Joint aches and pain.** Some people who use DUPIXENT have had trouble walking or moving due to their joint symptoms, and in some cases needed to be hospitalized. Tell your healthcare provider about any new or worsening joint symptoms. Your healthcare provider may stop DUPIXENT if you develop joint symptoms.

The most common side effects include:

- **Eczema:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, dry eye, cold sores in your mouth or on your lips, and high count of a certain white blood cell (eosinophilia).
- **Asthma:** injection site reactions, high count of a certain white blood cell (eosinophilia), pain in the throat (oropharyngeal pain), and parasitic (helminth) infections.
- **Chronic Rhinosinusitis with Nasal Polyps:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, high count of a certain white blood cell (eosinophilia), gastritis, joint pain (arthralgia), trouble sleeping (insomnia), and toothache.

- **Eosinophilic Esophagitis:** injection site reactions, upper respiratory tract infections, cold sores in your mouth or on your lips, and joint pain (arthralgia).
- **Prurigo Nodularis:** eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision, herpes virus infections, common cold symptoms (nasopharyngitis), dizziness, muscle pain, and diarrhea.
- **Chronic Obstructive Pulmonary Disease:** injection sites reactions, common cold symptoms (nasopharyngitis), high count of a certain white blood cell (eosinophilia), viral infection, back pain, inflammation inside the nose (rhinitis), diarrhea, gastritis, joint pain (arthralgia), toothache, headache, and urinary tract infection.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed by your healthcare provider. It's an injection given under the skin (subcutaneous injection). Your healthcare provider will decide if you or your caregiver can inject DUPIXENT. **Do not** try to prepare and inject DUPIXENT until you or your caregiver have been trained by your healthcare provider. In children 12 years of age and older, it's recommended DUPIXENT be administered by or under supervision of an adult. In children 6 months to less than 12 years of age, DUPIXENT should be given by a caregiver.

Please see accompanying full Prescribing Information including Patient Information.

EYLEA AND EYLEA HD IMPORTANT SAFETY INFORMATION AND U.S. INDICATIONS

INDICATIONS
EYLEA HD® (aflibercept) Injection 8 mg is a prescription medicine approved for the treatment of patients with Wet Age-Related Macular Degeneration (AMD), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

EYLEA® (aflibercept) Injection 2 mg is a prescription medicine approved for the treatment of patients with Wet Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Retinopathy of Prematurity (ROP) (0.4 mg).

IMPORTANT SAFETY INFORMATION

- EYLEA HD and EYLEA are administered by injection into the eye. You should not use EYLEA HD or EYLEA if you have an infection in or around the eye, eye pain or redness, or known allergies to any of the ingredients in EYLEA HD or EYLEA, including aflibercept.
- Injections into the eye with EYLEA HD or EYLEA can result in an infection in the eye, retinal detachment (separation of retina from back of the eye) and, more rarely, serious inflammation of blood vessels in the retina that may include blockage. Call your doctor right away if you or your baby (if being treated with EYLEA for Retinopathy of Prematurity) experience eye pain or redness, light sensitivity, or a change in vision after an injection.
- In some patients, injections with EYLEA HD or EYLEA may cause a temporary increase in eye pressure within 1 hour of the injection. Sustained increases in eye pressure have been reported with repeated injections, and your doctor may monitor this after each injection.
- In infants with Retinopathy of Prematurity (ROP), treatment with EYLEA will need extended periods of ROP monitoring.
- There is a potential but rare risk of serious and sometimes fatal side effects, related to blood clots, leading to heart attack or stroke in patients receiving EYLEA HD or EYLEA.
- The most common side effects reported in patients receiving EYLEA HD were cataract, increased redness in the eye, increased pressure in the eye, eye discomfort, pain, or irritation, blurred vision, vitreous (gel-like substance) floaters, vitreous detachment, injury to the outer layer of the eye, and bleeding in the back of the eye.
- The most common side effects reported in patients receiving EYLEA were increased redness in the eye, eye pain, cataract, vitreous detachment, vitreous floaters, moving spots in the field of vision, and increased pressure in the eye.
- The most common side effects reported in pre-term infants with ROP receiving EYLEA were separation of the retina from the back of the eye, increased redness in the eye, and increased pressure in the eye. Side effects that occurred in adults are considered applicable to pre-term infants with ROP, though not all were seen in clinical studies.
- You may experience temporary visual changes after an EYLEA HD or EYLEA injection and associated eye exams; do not drive or use machinery until your vision recovers sufficiently.
- For additional safety information, please talk to your doctor and see the full Prescribing Information for EYLEA HD and EYLEA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information for EYLEA HD and EYLEA.

LIBTAYO IMPORTANT SAFETY INFORMATION AND U.S. INDICATIONS

LIBTAYO® (cemiplimab-rwlc) 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.

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 Dupixent® (dupilumab), EYLEA HD® (aflibercept) Injection 8 mg, EYLEA® (aflibercept) Injection, Libtayo® (cemiplimab), Ordspono™ (odronextamab), itepekimab, linvoseltamab, fianlimab, pozelimab in combination with cemdisiran, REGN7508, REGN9933, other of Regeneron's Product Candidates discussed or referenced in this press release, and the use of human genetics in Regeneron's research programs; the likelihood and timing of achieving any of the anticipated milestones discussed or referenced in this press release; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including those listed above and/or otherwise discussed in this 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; Regeneron’s expectations with respect to commercialization of Regeneron’s Products (including Dupixent, EYLEA HD, EYLEA, and Libtayo), competitive and other relevant developments affecting the market share of Regeneron’s Products, and other relevant factors (whether within or without Regeneron’s control) impacting the degree to which commercialization of Regeneron’s marketed products is successful, as well as the impact of any of the foregoing on Regeneron’s results of operations; 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; safety issues resulting from the administration of Regeneron’s Products 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 (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 (such as those that may result from the strategic collaboration with Truveta, Inc. discussed in this press release) 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), as well as the collaboration with Truveta, Inc. discussed in this press release, to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business; 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), other 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), 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, 2023 and its Form 10-Q for the quarterly period ended September 30, 2024. 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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[1] Data not yet published. https://www.merck.com/news/merck-provides-update-on-phase-3-keynote-867-and-keynote-630-trials/. All trademarks used are the property of their respective owners. The studies had differences in trial design specifics and no head-to-head comparisons have been conducted.

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Source: Regeneron Pharmaceuticals, Inc.