Dupixent® (dupilumab) Data Presented at ATS Reinforce Impact of Targeting Key Type 2 Inflammation Drivers to Improve Outcomes for Chronic Respiratory Diseases

May 1, 2025 at 9:00 AM EDT

24 abstracts, including 1 oral presentation and 4 late-breaking posters on Dupixent, to showcase new clinical and real-world analyses in chronic obstructive pulmonary disease (COPD) and asthma

COPD data from the landmark Phase 3 trials will highlight Dupixent impact on lung function and health-related quality of life across broad populations of patients with type 2 inflammation

Asthma abstracts include late-breaking data on mucus burden and the first presentation of efficacy results from a Phase 2 trial designed to study Dupixent in allergic bronchopulmonary aspergillosis (ABPA) in patients with asthma

TARRYTOWN, N.Y., May 01, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced 24 abstracts on Dupixent® (dupilumab) clinical data and real-world analyses in respiratory diseases will be presented at the American Thoracic Society (ATS) International Conference 2025 being held from May 18 to 21 in San Francisco, California. The abstracts, presented in collaboration with Sanofi, demonstrate the benefit of targeting IL-4 and IL-13 to address type 2 inflammation in chronic obstructive pulmonary disease (COPD) and asthma – chronic respiratory diseases that can impair lung function and impact daily life.

"The data presented at ATS demonstrate Regeneron's commitment to advancing the scientific understanding of type 2 inflammation across chronic respiratory diseases to ultimately transform care and quality of life for as many appropriate patients as possible," said Jennifer Maloney, M.D., Therapeutic Area Lead of Immune, Inflammation, and Infectious Disease Global Development at Regeneron. "Among our 24 abstracts at ATS are the latest results from the Dupixent COPD program, which include new analyses of its impact on critical disease measures such as lung function in broad patient populations with type 2 inflammation. We also look forward to sharing new asthma insights in both adult and pediatric populations."

COPD data assess Dupixent impact on lung function and exacerbations in COPD, including patients with or without emphysema

Notable abstracts in COPD will highlight new results from the pivotal landmark Phase 3 BOREAS and NOTUS trials, including analyses demonstrating Dupixent reduced exacerbations and improved lung function regardless of whether patients had emphysema. In the pivotal COPD trials, the majority of patients had chronic bronchitis (≥95%) and ≥30% had emphysema. Additional data being presented also demonstrate Dupixent improved multiple spirometry measures of lung function that were sustained through 52 weeks, compared to placebo.

Furthermore, a late-breaking poster of a win-ratio post-hoc analysis will assess the likelihood of avoiding a composite of events including death, hospitalization, worsening symptoms and lung function decline in the COPD pivotal trials by comparing each patient on Dupixent to each patient on placebo.

The safety results from BOREAS and NOTUS COPD trials were generally consistent with the known safety profile of Dupixent in its other approved indications. In pooled data from both trials, the most common adverse events (AEs; ≥2%) more frequently observed with Dupixent than placebo were viral infection, headache, nasopharyngitis, back pain, diarrhea, arthralgia, urinary tract infection, local administration reaction, rhinitis, eosinophilia, toothache and gastritis.

Asthma data reinforce impact of Dupixent on mucus burden, exacerbations and disease control

A late-breaking poster on the VESTIGE imaging trial will highlight that Dupixent reduced mucus burden, compared to placebo, as measured by mucus plug scores and volume regardless of fractional exhaled nitric oxide (FeNO) levels. An analysis of the VOYAGE trial also shows that, in children aged 6 to 11 years, Dupixent reduced exacerbations and improved disease control regardless of how long they had the disease.

The safety results in the asthma trials were generally consistent with the known safety profile of Dupixent in moderate-to-severe asthma, with the addition of helminth infections in the VOYAGE trial. In VOYAGE, the most common AEs more frequently observed with Dupixent than placebo were injection site reactions, viral upper respiratory tract infections and eosinophilia. In VESTIGE, the most common AEs (≥5%) more frequently observed with Dupixent than placebo included COVID-19 and injection site reactions.

Results will also be shared for the first time in an oral presentation from the Phase 2 AIRED trial evaluating the impact of Dupixent on lung function, exacerbations and health-related quality of life in adults and adolescents with allergic bronchopulmonary

aspergillosis (ABPA) and asthma. ABPA is a progressive lung disease caused by hypersensitivity to a fungal microorganism that can live in the airways of patients with breathing disorders like asthma.

The full list of Regeneron and Sanofi presentations at ATS includes:

Abstract Title	Presentation Number	Presenting Author	Presentation Date and Time (PT)
COPD			
Stability of Blood Eosinophil Counts in Patients With Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation in the BOREAS and NOTUS Trials	#P660 Late-Breaking Poster Presentation	Bafadhel, M.	Tuesday, May 20 11:30 AM-1:15 PM
Use of Systemic Corticosteroids and Antibiotics in Patients with Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation Receiving Dupilumab	#P659 Late-Breaking Poster Presentation	Bafadhel, M.	Tuesday, May 20 11:30 AM-1:15 PM
Win Ratio Analysis of BOREAS and NOTUS: Faster Trials, Clearer Wins for Patients with Chronic Obstructive Pulmonary Disease With Type 2 Inflammation	#P1017 Late-Breaking Poster Presentation	Ramakrishnan, S.	Sunday, May 18 11:30 AM-1:15 PM
Impact of Dupilumab Treatment on Lung Function in Patients with Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation	#P946 Poster Presentation	Bafadhel, M.	Monday, May 19 11:30-1:15 PM
Assessing the Risks of Exacerbations and Mortality Among COPD Patients in the Global Initiative for Chronic Obstructive Lung Disease Category E Based on Blood Eosinophils Level and Smoking Status	#P617 Poster Presentation	Bhatt, S.P.	Monday, May 19 9:15-11:15 AM
Dupilumab Efficacy in Patients with Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation With and Without Emphysema	#P1420 Poster Presentation	Bhatt, S.P.	Sunday, May 18 11:30 AM-1:15 PM
Dupilumab Efficacy in Patients with Chronic Obstructive Pulmonary Disease (COPD) with Type 2 Inflammation Across Baseline Eosinophil Counts	#P1419 Poster Presentation	Christenson, S.A.	Sunday, May 18 11:30 AM-1:15 PM
Reduction of Exacerbations According to Type 2 Inflammatory Biomarkers With	#P1418 Poster Presentation	Couillard, S.	Sunday, May 18 11:30 AM-1:15 PM

Dupilumab Treatment in Patients with Chronic Obstructive Pulmonary Disease (COPD)			
Dupilumab Improves Lung Function in Patients with Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation: A Pooled Analysis from The Phase 3 NOTUS and BOREAS Trials	#P1411 Poster Presentation	Han, M.K.	Sunday, May 18 11:30 AM-1:15 PM
Dupilumab Efficacy on Chronic Obstructive Pulmonary Disease (COPD) Exacerbations and Lung Function by Cough and Sputum Score: Pooled Results from Phase 3 BOREAS and NOTUS	#P1018 Poster Presentation	Hanania, N.A.	Monday, May 19 2:15-4:15 PM
Assessment of Symptom Burden and Related Quality of Life in GOLD E COPD Patients in the United States via a Real-world Cross-sectional Survey	#P955 Poster Presentation	Herrera, E.M.	Monday, May 19 11:30 AM-1:15 PM
Symptom Burden and COPD Quality of Life by Smoking Status and Eosinophil Level: A United States Cross-Sectional Survey	#P956 Poster Presentation	Herrera, E.M.	Monday, May 19 11:30 AM-1:15 PM
Variability of Eosinophil Levels Over Time in Chronic Obstructive Pulmonary Disease Patients Within an Integrated Healthcare Delivery System	#P261 Poster Presentation	Mularski, R.A.	Monday, May 19 11:30 AM-1:15 PM
Type 2 Inflammatory Biomarkers and Lung Function Improvement in Patients with Chronic Obstructive Pulmonary Disease (COPD) Receiving Placebo Therapy	#P1533 Poster Presentation	Ramakrishnan, S.	Sunday, May 18 11:30 AM-1:15 PM
Dupilumab Efficacy in Patients With Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation by Evaluating Respiratory Symptoms in COPD (E-RS:COPD) Breathlessness And St. George's Respiratory Questionnaire (SGRQ) Activity Scores	#P949 Poster Presentation	Singh, D.	Monday, May 19 11:30 AM-1:15 PM
Impact of Dupilumab on Type 2 Inflammatory Biomarkers in Patients	#P1532 Poster Presentation	Singh, D.	Sunday, May 18 11:30 AM-1:15 PM

with Chronic Obstructive Pulmonary Disease (COPD)			
ABPA and Asthma			
Dupilumab Improves Lung Function, Asthma Control and Exacerbation Frequency in Allergic Bronchopulmonary Aspergillosis - Results from the Phase 2 LIBERTY ABPA AIRED Study	Session C14 Mini Symposium Oral Presentation	Bourdin, A.	Tuesday, May 20 9:15-9:27 AM
Asthma			
Association Between Baseline Fractional Exhaled Nitric Oxide and Mucus Response in Patients With Uncontrolled Moderate-To-Severe Asthma Treated With Dupilumab in the Vestige Study	#P665 Late-Breaking Poster Presentation	Bourdin, A.	Tuesday, May 20 11:30 AM-1:15 PM
Characteristics of Patients with Severe Asthma Initiating Dupilumab in a Real-World Setting: The REVEAL Registry	#P1436 Poster Presentation	Al-Ahmad, M.S.	Sunday, May 18 11:30 AM-1:15 PM
Impact of Dupilumab on Type 2 Inflammatory Biomarkers in Asthma by Clinical Remission Status	#P1024 Poster Presentation	Brusselle, G.G.	Monday, May 19 2:15-4:15 PM
Association Between Improvements in Mucus Score and Volume and Changes in Type 2 Biomarkers in Patients with Moderate-To-Severe Asthma Receiving Dupilumab in the Vestige Study	#P1428 Poster Presentation	Castro, M.	Sunday, May 18 11:30 AM-1:15 PM
Dupilumab Improves Health-related Quality of Life and Asthma Control in Patients With and Without Coexisting Type 2 Conditions: Results from the RAPID Study	#P1441 Poster Presentation	Côté, A.	Sunday, May 18 11:30 AM-1:15 PM
Dupilumab Reduces Exacerbations and Improves Asthma Control in Children Regardless of Asthma Duration	#P1416 Poster Presentation	Phipatanakul, W.	Sunday, May 18 11:30 AM-1:15 PM
Safety and Efficacy of Dupilumab in Adults and Adolescents with Asthma in the RAPID Registry	#P1412 Poster Presentation	Lugogo, N.L.	Sunday, May 18 11:30 AM-1:15 PM

About Dupixent

Dupixent, which was invented using Regeneron's proprietary *VelocImmune*® technology, is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways and is not an immunosuppressant. The Dupixent development program has shown significant clinical benefit and a decrease in type 2 inflammation in Phase 3 trials,

establishing that IL-4 and IL-13 are two of the key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic esophagitis (EoE), prurigo nodularis, chronic spontaneous urticaria (CSU) and chronic obstructive pulmonary disease (COPD) in different age populations. More than 1,000,000 patients are being treated with Dupixent globally.[1]

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 fully human monoclonal antibodies. This includes Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), 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.

Dupilumab Development Program
Dupilumab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement. To date, dupilumab has been studied across more than 60 clinical trials involving more than 10,000 patients with various chronic diseases driven in part by type 2 inflammation.

In addition to the currently approved indications, Regeneron and Sanofi are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes in Phase 3 trials, including chronic pruritus of unknown origin, bullous pemphigoid and lichen simplex chronicus. These potential uses of dupilumab are currently under clinical investigation, and the safety and efficacy in these conditions have not been fully evaluated by any regulatory authority.

U.S. INDICATIONS
DUPIXENT 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.
- to treat adults and children 12 years of age and older with chronic spontaneous urticaria (CSU) who continue to have hives that are not controlled with H1 antihistamine treatment. It is not known if DUPIXENT is safe and effective in children with chronic spontaneous urticaria under 12 years of age, or who weigh less than 66 pounds (30 kg).

DUPIXENT is not used to relieve sudden breathing problems and will not replace an inhaled rescue medicine.

DUPIXENT is not used to treat any other forms of hives (urticaria).

IMPORTANT SAFETY INFORMATION

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, chronic obstructive pulmonary disease, or chronic spontaneous urticaria, 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. Tell your healthcare provider right away if you have: rash, chest pain, worsening shortness of breath, brown or dark colored urine, persistent fever, or a feeling of pins and needles or numbness of your arms or legs.
- **Psoriasis.** This can happen in people with atopic dermatitis and asthma who receive DUPIXENT. Tell your healthcare provider about any new skin symptoms. Your healthcare provider may send you to a dermatologist for an examination if needed.
- **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 site 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.
- **Chronic Spontaneous Urticaria**: injection site reactions.

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.

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.

Regeneron Forward-Looking Statements and Use of Digital Media
This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the 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) for the treatment of chronic obstructive pulmonary disease and asthma as 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; 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 Dupixent for the treatment of chronic pruritus of unknown origin, bullous pemphigoid, lichen simplex chronicus, and other potential indications; 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 (such as Dupixent) 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; changes in laws, regulations, and policies affecting the healthcare industry; risks associated with tariffs and other trade restrictions; 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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[1] Data on File

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Source: Regeneron Pharmaceuticals, Inc.