New Dupixent® (dupilumab) Analyses at Two Upcoming Dermatology Congresses Reinforce Long-term Safety and Efficacy Profile in Patients with Atopic Dermatitis as Young as 6 Years

April 23, 2021

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Nearly 30 data presentations at AAD and ESPD highlight the impact of Dupixent on disease measures including rapid itch relief and sustained improvement in disease severity, as well as quality of life in clinical and real-world settings

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that new analyses of Dupixent® (dupilumab) in patients as young as 6 years with moderate-to-severe atopic dermatitis will be presented at the American Academy of Dermatology Annual Meeting (AAD VMX 2021) from April 23-25, and at the 20th European Society for Pediatric Dermatology Annual Meeting (ESPD 2021) from May 12-14.

"Atopic dermatitis is a debilitating disease that spares no age group and is associated with persistent itch and painful lesions that can impair quality of life, affecting the entire family," said Bola Akinlade, M.D., Vice President, Clinical Sciences, Immunology and Inflammation, at Regeneron. "The depth and breadth of our data being presented at AAD and ESPD show the rapid and long-term effect of Dupixent in adults, adolescents and children, addressing the key disease measures that are top of mind for patients and treating physicians. Further, our data continue to support the established safety profile of Dupixent, which can be one of the most important factors impacting treatment decisions for this chronic disease."

Regeneron and Sanofi will present results from clinical and real-world settings including long-term data from Dupixent open-label extension (OLE) trials, up to three years in adults and up to one year in adolescents (aged 12 to 17 years) and children (aged 6 to 11 years) with moderate-to-severe atopic dermatitis. In the adult analysis, a lower rate of overall infections was observed in the Dupixent long-term treatment group compared to the placebo group in the one-year CHRONOS trial. Additional long-term analyses on laboratory blood measures further reinforce that patients 6 years and older who take Dupixent do not require ongoing laboratory blood monitoring. Across age groups, researchers evaluated the response rates across a broad patient population, as well as the impact of Dupixent on disease extent and severity, quality of life and itch.

Dupixent 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. It was invented using Regeneron's proprietary *VelocImmune*® technology. IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP) and eosinophilic esophagitis.

Abstracts to be presented at AAD VMX 2021
Abstracts presenting research on Dupixent and evaluation of efficacy, safety and impact on health-related quality of life include:

Pediatric efficacy and quality of life data

- **Abstract #27350:** Dupilumab Improves Eczema Area and Severity Index Regional Scores Across All Anatomical Regions in Children Aged 6–11 Years with Severe Atopic Dermatitis (AD), Amy S. Paller
- **Abstract #27375:** Dupilumab Provides Early and Sustained Improvement of Sleep Disturbance in Children ≥ 6 Years With Severe Atopic Dermatitis (AD) and Adolescents With Moderate-to-Severe AD, Amy S. Paller
- **Abstract #27389:** Rapid and Sustained Improvement in Itch in Children Aged 6–11 Years With Severe Atopic Dermatitis (AD) Treated With Dupilumab: Analysis From the LIBERTY AD PEDS Phase 3 Trial, Amy S. Paller
- **Abstract #27394:** Dupilumab Provides Clinically Meaningful Improvement in Atopic Dermatitis (AD) Signs, Symptoms, and Quality of Life in Children With Severe AD: Results From the LIBERTY AD PEDS Phase 3 Clinical Trial, Amy S. Paller
- **Abstract #27406:** Dupilumab Improves Signs and Symptoms of Severe Atopic Dermatitis in Children Aged 6–11 Years With and Without Comorbid Asthma, Mark Boguniewicz
- **Abstract #27431:** Dupilumab Treatment Improves Health-Related Quality of Life in Children Aged ≥6 to <12 Years With Severe Atopic Dermatitis, Alan Irvine

Adult efficacy data

- **Abstract #26839:** Dupilumab With Topical Corticosteroids Results in Rapid and Sustained Improvement in Adults with Moderate-to-Severe Atopic Dermatitis Across All Anatomic Regions Over 52 Weeks, Andrew Blauvelt
- **Abstract #27571:** Dupilumab Provides Clinically Meaningful Responses in Adults With Moderate-To-Severe Atopic Dermatitis (AD): Results From LIBERTY AD CHRONOS Study, Jonathan I. Silverberg

Long-term data

- **Abstract #26313:** Efficacy and Safety of Dupilumab for up to 1 Year in a Phase 3 Open-Label Extension (OLE) Trial (LIBERTY AD PED-OLE) in Adolescents With Uncontrolled, Moderate-To-Severe Atopic Dermatitis (AD), Andrew Blauvelt
- **Abstract #26875:** 52-Week Laboratory Safety Findings From an Open-Label Extension (OLE) Study of Dupilumab in Adolescent Patients With Atopic Dermatitis (LIBERTY AD PED-OLE), Michael J. Cork

- **Abstract #26880:** Long-Term Efficacy and Safety Data for Dupilumab in a Phase 3, Open-Label Extension Trial (LIBERTY AD PED-OLE) in Patients Aged ≥6 to <12 Years With Uncontrolled, Moderate-to-Severe Atopic Dermatitis (AD), Michael J. Cork
- **Abstract #27419:** Laboratory Safety of Long-Term Dupilumab Treatment in Adults With Moderate-to-Severe Atopic Dermatitis: Open-Label Extension (OLE) Study, Andrew Blauvelt
- **Abstract #27424:** Infections in Adults with Moderate-to-Severe Atopic Dermatitis Treated with Dupilumab: Long-Term Data from an Open-Label Extension (OLE) Study, Andrew Blauvelt

Real-world data

- **Abstract #27434:** Early Trends of Disease Improvement in Adult Patients With Atopic Dermatitis Treated With Dupilumab: Real-World Data From the PROSE Registry, Jerry Bagel

Abstracts presenting research on the burden, impact and care of atopic dermatitis include:

- **Abstract #27430:** Worldwide Survey Shows That Atopic Dermatitis Is Associated with a High Disease Burden in Children, Stephan Weidinger
- **Abstract #27473:** Worldwide Survey Shows That Atopic Dermatitis in Children is Associated with a Negative Impact on Their Families, Sebastien Barbarot
- **Abstract #28081:** Strategies to Improve Quality of Atopic Dermatitis Care in the North America: Results from the Atopic Dermatitis Quality of Care (ADQoC) Initiative, Peter Lio

Abstracts to be presented at ESPD 2021

Abstracts related to the research for Dupixent and evaluation of efficacy, safety and impact on health-related quality of life include:

Efficacy data

- **ESPD21-0326**: Dupilumab Provides Clinically Meaningful Improvement in Atopic Dermatitis (AD) Signs, Symptoms, and Quality of Life in Children With Severe AD, Stephan Weidinger
- **ESPD21-0330**: Dupilumab Improves EASI Regional Scores Across All Anatomical Regions in Children Aged ≥6–<12 Years With Severe Atopic Dermatitis, Michael J. Cork
- **ESPD21-0331**: Rapid Itch Improvement in Children With Severe Atopic Dermatitis Treated With Dupilumab: A Phase 3 Subset Analysis, Gil Yosipovitch
- **ESPD21-0332**: Dupilumab Significantly Improves Signs and Symptoms of Atopic Dermatitis Assessed by SCORAD in Children Aged ≥6 to <12 Years, Sebastien Barbarot
- **ESPD21-0334**: Dupilumab Treatment Improves Health-Related Quality of Life in Children Aged ≥6 to <12 Years With Severe Atopic Dermatitis, Alan Irvine
- **ESPD21-0340**: Dupilumab Improved Itch in Children Aged 6–11 Years With Severe Atopic Dermatitis: Analysis from the LIBERTY AD PEDS Trial, Amy S. Paller
- **ESPD21-0341**: Dupilumab Treatment Improves Sleep in Children Aged ≥6 to <12 Years With Severe Atopic Dermatitis, Amy S. Paller

Long-term data

- **ESPD21-0335**: Long-Term Efficacy and Safety of Dupilumab in a Phase 3, Open-Label Extension Trial in Children With Uncontrolled, Moderate-to-Severe Atopic Dermatitis, Michael J. Cork

Safety data

- **ESPD21-0200**: Increased Incidence of Conjunctivitis With Dupilumab Treatment in Adolescents Appears to be Specific to Atopic Dermatitis, Marjolein De Bruin-Weller
- **ESPD21-0308**: Laboratory Safety of Dupilumab in Children Aged ≥6–<12 Years With Severe Atopic Dermatitis: Results From a Phase 3 Trial, Andreas Wollenberg

Results from a qualitative survey on the impact of atopic dermatitis

- **ESPD21-0322**: AD-GAP: A Global, Cross-sectional, Qualitative Survey of Children/Adolescents Aged 6−17 Years With Moderate-to-Severe Atopic Dermatitis, Their Carers, and Physicians, Stephan Weidinger

About Dupixent

Dupixent is approved in the U.S. to treat patients aged 6 years and older with moderate-to-severe atopic dermatitis that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies; for use with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in patients aged 12 years and older whose asthma is not controlled with their current asthma medicines; and for use with other medicines for the maintenance treatment of CRSwNP in adults whose disease is not controlled.

Outside of the U.S., Dupixent is approved for specific patients with moderate-to-severe atopic dermatitis and certain patients with asthma in a number of other countries around the world, including those in the EU and Japan. Dupixent is also approved in the EU and Japan to treat certain adults with severe CRSwNP. Across all approved indications globally, more than 260,000 patients have been treated with Dupixent.

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 approximately a quarter of all original, FDA-approved fully human monoclonal antibodies currently available. This includes REGEN-COV™ (casirivimab with imdevimab), Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza™ (evinacumab-dgnb) and Inmazeb™ (atoltivimab, maftivimab and odesivimab-ebgn).

Dupilumab Development Program
To date, dupilumab has been studied in more than 10,000 patients across 50 clinical trials in various chronic diseases driven 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, including pediatric asthma (6 to 11 years of age, Phase 3), chronic obstructive pulmonary disease with evidence of type 2 inflammation (Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 3), eosinophilic esophagitis (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), chronic inducible urticaria-cold (Phase 3), chronic rhinosinusitis without nasal polyposis (Phase 3), allergic fungal rhinosinusitis (Phase 3) and food allergies (Phase 2). These potential uses are under clinical investigation, and the safety and efficacy of dupilumab in these conditions have not been fully evaluated by any regulatory authority. Dupilumab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

U.S. INDICATIONS

DUPIXENT is a prescription medicine used:

- to treat people aged 6 years and older with moderate-to-severe atopic dermatitis (eczema) 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 years of age.
- with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in people aged 12 years 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. DUPIXENT is not used to treat sudden breathing problems. It is not known if DUPIXENT is safe and effective in children with asthma under 12 years of age.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled. It is not known if DUPIXENT is safe and effective in children with chronic rhinosinusitis with nasal polyposis under 18 years of age.

IMPORTANT SAFETY INFORMATION FOR U.S. PATIENTS

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" if you are treated with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
    - There is a pregnancy exposure registry for women who take DUPIXENT during pregnancy to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself. To get more information about the registry 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 or CRSwNP, and also have asthma. **Do not** change or stop your corticosteroid medicine or other asthma medicine without talking to your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine or other asthma medicine to come back.

DUPIXENT can cause serious side effects, including:

- **Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis.** Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following symptoms: breathing

problems, fever, general ill feeling, swollen lymph nodes, swelling of the face, mouth and tongue, hives, itching, fainting, dizziness, feeling lightheaded (low blood pressure), joint pain, or skin rash.
- **Eye problems**. Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision.
- **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, shortness of breath, persistent fever, chest pain, or a feeling of pins and needles or numbness of your arms or legs.

The most common side effects by indication are as follows:

- **Atopic dermatitis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, and cold sores in your mouth or on your lips.
- **Asthma:** injection site reactions, pain in the throat (oropharyngeal pain), and high count of a certain white blood cell (eosinophilia).
- **Chronic rhinosinusitis with nasal polyposis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, high count of a certain white blood cell (eosinophilia), trouble sleeping (insomnia), toothache, gastritis, and joint pain (arthralgia).

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. Your healthcare provider will tell you how much DUPIXENT to inject and how often to inject it. DUPIXENT is an injection given under the skin (subcutaneous injection). If your healthcare provider decides that you or a caregiver can give DUPIXENT injections, you or your caregiver should receive training on the right way to prepare and inject DUPIXENT. Do not try to inject DUPIXENT until you have been shown the right way by your healthcare provider. In children 12 years of age and older, it is recommended that DUPIXENT be administered by or under supervision of an adult. In children younger 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 life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous product candidates in development, almost all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite* technologies, such as *VelocImmune,* which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Regeneron Forward-Looking Statements and Use of Digital Media
This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab); uncertainty of 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 in this press release, on the commercial success of Regeneron's Products (such as Dupixent) and Regeneron's Product Candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, such dupilumab for the treatment of pediatric atopic dermatitis, pediatric asthma, chronic obstructive pulmonary disease, eosinophilic esophagitis, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, chronic inducible urticaria-cold, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, food and environmental allergies, and other potential indications; 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; competing drugs and product candidates that may be superior to, or more

cost effective than, Regeneron's Products and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (aflibercept) Injection, Dupixent, Praluent® (alirocumab), and REGEN-COV™ (casirivimab with imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2020. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

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

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