

## **New Dupixent® (dupilumab) data in patients as young as 6 years old with moderate-to-severe atopic dermatitis to be presented at WCPD and EADV**

- \* More than 30 presentations reinforce the role of Dupixent in targeting IL-4 and IL-13, key drivers of the type 2 inflammation underlying atopic dermatitis in children, adolescents, and adults
- \* Results provide insight into the clinical and real-world experience of Dupixent on key disease measures including itch, disease severity, sleep and anxiety
- \* Dupixent presentations include longest duration of data for any biologic medicine in adults with moderate-to-severe atopic dermatitis, with results up to 3.5 years

**PARIS and TARRYTOWN, N.Y. – September 21, 2021** - New Dupixent® (dupilumab) analyses in patients as young as 6 years old with moderate-to-severe atopic dermatitis will be presented at the 14<sup>th</sup> World Congress of Pediatric Dermatology Annual Congress (WCPD) from September 22-25 and the 30<sup>th</sup> European Academy of Dermatology and Venereology Congress (EADV) from September 29-October 2.

*“The extensive portfolio of Dupixent data being showcased at these global congresses addresses the impact of Dupixent on the signs, symptoms and quality of life in patients as young as six years old with moderate-to-severe atopic dermatitis and reinforces the need for studying the long-term safety and efficacy of treatments targeting type 2 inflammation,”* said Naimish Patel, M.D. Head of Global Development in Immunology and Inflammation at Sanofi. *“In addition, we look forward to presenting key findings from our global Atopic Dermatitis-GAP survey and Quality of Care Report, which demonstrate our commitment to disease education and fostering new conversations about best practices for patient care within the atopic dermatitis community”*

Notable Dupixent presentations include long-term efficacy and safety data showing the impact of Dupixent on signs and symptoms of moderate-to-severe atopic dermatitis in children, adolescents and adults. More than 30 presentations include Dupixent results on skin lesions, itch and skin infections as well as sleep and health-related quality of life for patients and their families, including in adults with a history of mental health disorders and in children with anxiety and depression. Real-world evidence will be also presented from observational registries and claims databases across multiple geographies.

Notable disease burden data to be presented at EADV include results from the Atopic Dermatitis Global Adolescent and Pediatric Survey on how patients, caregivers, and physicians view the full impact of moderate-to-severe atopic dermatitis based on findings from more than 3,900 people across 13 countries. Data will also be shared from the *Quality of Care in AD Initiative*, which documents best practices from 32 atopic dermatitis centers across the world, focused on the value of patient education and communication.

## **Data to be presented at WCPD 2021**

### **Clinical Efficacy and Safety of Dupixent in Atopic Dermatitis**

- Oral presentation (September 24, 3:40-3:50 pm BST):
  - #SP42 Long-Term Efficacy and Safety Data for Dupilumab in a Phase 3, Open-Label Extension Trial (LIBERTY AD PED-OLE) in Patients Aged  $\geq 6$  to  $< 12$  Years With Uncontrolled, Moderate-to-Severe Atopic Dermatitis (AD), Michael Cork
- Poster #P22: Efficacy and Safety of Dupilumab for up to 1 Year in a Phase 3 Open-Label Extension Trial (LIBERTY AD PED-OLE) in Adolescents With Uncontrolled, Moderate-to-Severe Atopic Dermatitis (AD), Andrew Blauvelt
- Poster #P23: 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 Cork
- Poster #P33: Dupilumab Improved Itch in Children Aged 6–11 Years With Severe Atopic Dermatitis: Analysis From the LIBERTY AD PEDS Trial, Gil Yosipovitch
- Poster #P35: IGAXBSA: An Alternative to EASI in Assessing Disease Severity and Response in Pediatric Patients With Moderate-to-Severe Atopic Dermatitis, Amy Paller
- Poster #P36: Dupilumab Induces Rapid and Sustained Improvement in Clinical Signs in Children With Severe Atopic Dermatitis, Amy Paller
- Poster #P38: Dupilumab Significantly Improves All POEM Components in Children Aged  $\geq 6$  to  $< 12$  Years With Severe Atopic Dermatitis, Andreas Wollenberg
- Poster #P40: Efficacy and Safety of Dupilumab in Children Aged  $\geq 6$  to  $< 18$  Years With a History of Infection (LIBERTY AD PEDS, LIBERTY AD ADOL), Michael Cork
- Poster #P41: Dupilumab in Children Aged  $\geq 6$  to  $< 12$  Years Significantly Improves Global Clinical Signs of Atopic Dermatitis (LIBERTY AD PEDS), Amy Paller
- Poster #P44: Dupilumab in Children Aged  $\geq 6$ – $< 12$  Years Significantly Improves Signs and Symptoms of Atopic Dermatitis Assessed by SCORAD, Sébastien Barbarot

### **Quality of Life Data in Atopic Dermatitis for Dupixent**

- Poster #P30: Dupilumab Induces Clinically Meaningful Improvement in Symptoms of Anxiety and Depression in Children With Severe Atopic Dermatitis, Elaine Siegfried

- Poster #P37: Dupilumab Treatment Improves Sleep in Children Aged  $\geq 6$  to  $< 12$  Years With Severe Atopic Dermatitis, Danielle Marcoux
- Poster #P46: Dupilumab Improves Family Quality of Life in Children Aged 6–11 Years With Severe Atopic Dermatitis (LIBERTY AD PEDS), Amy Paller

### **Dupixent Use and Vaccination**

- Poster #P120: Dupilumab and Live-Attenuated Vaccines: Experience With Prior Dupilumab Use and Yellow Fever Vaccine in Patients With Severe Asthma From Brazil, Michael Wechsler

### **Abstracts presenting research on the burden of atopic dermatitis include:**

- Poster #P29: Children With Atopic Dermatitis (AD) Have a High Burden of Atopic Comorbidities: Results From a Large Worldwide Survey, Jonathan Silverberg

### **Data to be presented at EADV 2021**

#### **Long-Term Efficacy and Safety of Dupixent in Atopic Dermatitis**

- Oral Presentation (September 30, 10:00-11:00 am CEST):
  - #2008 Long-Term Efficacy of Dupilumab in Adults With Moderate-to-Severe Atopic Dermatitis: Results From an Open-Label Extension Trial up to 172 Weeks, Lisa Beck
- Poster #P0258: Dupilumab Provides Long-Term Improvement in Pruritus in Children With Severe Atopic Dermatitis, and Adolescents and Adults With Moderate-to-Severe Atopic Dermatitis, Amy Paller
- Poster #P0723: Patient Well-Being and Perception of Treatment Effect With Long-Term Dupilumab Monotherapy in Adults With Moderate-to-Severe Atopic Dermatitis, Eric Simpson
- Poster #P0726: Safety of Long-Term Dupilumab Treatment in Adults With Moderate-to-Severe Atopic Dermatitis: Results From an Open-Label Extension Trial up to 172 Weeks, Andreas Wollenberg
- Poster #P0727: Dupilumab Provides Long-Term Efficacy Over 2.5 Years in Adults With Moderate-to-Severe Atopic Dermatitis, Lisa Beck
- Poster #P0729: Dupilumab Monotherapy Provides Long-Term Control and Prevents Flares in Adults With Moderate-to-Severe Atopic Dermatitis Optimally Responding at Week 16, Andreas Wollenberg

#### **Quality of Life Data for Dupixent in Atopic Dermatitis**

- Poster #P0239: Dupilumab Improves Family Quality of Life in Children Aged 6-11 Years With Severe Atopic Dermatitis: An Analysis From the Phase 3 LIBERTY AD PEDS Trial, Amy Paller
- Poster #P0252: Dupilumab Provides Long-Term Improvement of Sleep Loss in Children, Adolescents, and Adults With Atopic Dermatitis, Lisa Beck
- Poster #P0722: Dupilumab Monotherapy Provides Long-Term Improvement in Quality of Life in Adults With Moderate-to-Severe Atopic Dermatitis Optimally Responding at Week 16, Carlos Ferrándiz

### **Additional Efficacy and Safety Analyses of Dupixent in Atopic Dermatitis**

- Poster #P0230: Dupilumab Treatment in Adult Patients Is Efficacious Regardless of Age at Atopic Dermatitis Onset, Jonathan Silverberg
- Poster #P0231: Dupilumab in Children Aged  $\geq 6$  to  $< 12$  Years Promotes Rapid Improvement in Clinical Signs of Atopic Dermatitis, Amy Paller
- Poster #P0251: Infections in Dupilumab Pediatric Clinical Trials in Atopic Dermatitis — A Pooled Analysis, Amy Paller
- Poster #P0255: Dupilumab Significantly Improves Treatment Response in Children With Severe Atopic Dermatitis From the Patient's Perspective and by Clinical Assessments of Signs, Symptoms, and Quality of Life: Results From the LIBERTY AD PEDS Phase 3 Clinical Trial, Stephan Weidinger
- Poster #P0256: Dupilumab Treatment Is Efficacious in Adult Atopic Dermatitis Patients Independent of History of Mental Health Disorders: A Post Hoc Analysis of Pooled Phase 3 Trials, Jonathan Silverberg
- Poster #P0260: Dupilumab Treatment Is Efficacious in Adult Atopic Dermatitis Patients Regardless of History of Infection: A Pooled Analysis of Four Phase 3 Trials, Andreas Wollenberg
- Poster #P0733: Dupilumab Monotherapy Provides 1 Year Sustained Response in Adults With Moderate-to-Severe Atopic Dermatitis Optimally Responding at Week 16, With No Need of Concomitant Topical Steroids, Margitta Worm

### **Real-World Analyses**

- Poster #P0257: Improvement in Disease Severity and Quality of Life in Patients With Atopic Dermatitis Treated With Dupilumab for up to 18 Months: Real-World Data From the PROSE Registry, Jerry Bagel
- Poster #P0259: Use of Systemic Therapies in Adults With Atopic Dermatitis: 18-Month Results From the European Prospective Observational Study in Patients Eligible for Systemic Therapy for Atopic Dermatitis (EUROSTAD), Marjolein De Bruin-Weller
- Poster #P0272: Real-World Use of Dupilumab Among Adults With Atopic Dermatitis and Its Impact on Healthcare Utilization in Japan, Ken Igawa

### **Abstracts presenting research on patient education, health-related quality of life and burden of disease in atopic dermatitis include:**

- Poster #P0208: The Importance of Patient Education and Communication: Results from the Atopic Dermatitis Quality of Care Initiative, Eric Simpson
- Poster #P0254: Relative Importance of Distinct Aspects of Quality of Life for Patients Aged 6–11 and 12–17 Years Old With Atopic Dermatitis, Caregivers, and Physicians (AD-GAP), Stephan Weidinger
- Poster #P0271: Prevalence and Characteristics of Prurigo Nodules in Adults With Moderate-to-Severe Atopic Dermatitis in Japan: Results From a 2-Year Observational Study, Yoko Kataoka

## About Dupixent

Dupixent is a fully human monoclonal antibody that inhibits the signalling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways. Dupixent is not an immunosuppressant and does not require lab monitoring. IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP).

Dupixent is currently approved in the U.S., Europe, Japan and other countries around the world for use in specific patients with moderate-to-severe atopic dermatitis, as well as certain patients with asthma or CRSwNP in different age populations. Dupixent is also approved in one or more of these indications in more than 60 countries around the world and more than 300,000 patients have been treated globally.

## Dupilumab Development Program

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

Sanofi and Regeneron 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), allergic bronchopulmonary aspergillosis (Phase 3) and peanut allergy (Phase 2). 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.

## About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

## About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability

to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous product candidates in development, almost all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, infectious diseases and rare diseases.

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

For additional information about the company, please visit [www.regeneron.com](http://www.regeneron.com) or follow @Regeneron on Twitter.

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### **Sanofi Forward-Looking Statements**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates regarding the marketing and other potential of the product, or regarding potential future revenues from the product. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks*

*and uncertainties include among other things, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

### **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); 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 pediatric asthma, chronic obstructive pulmonary disease with evidence of type 2 inflammation, pediatric atopic dermatitis, eosinophilic esophagitis, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, chronic inducible urticaria-cold, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis, peanut allergy, and other potential indications; 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; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to 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, including without limitation Dupixent; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs*

*such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (afibercept) Injection, Dupixent, Praluent® (alirocumab), and REGEN-COVTM (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2020 and its Form 10-Q for the quarterly period ended June 30, 2021. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.*

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