

# *Dupixent® (dupilumab) late-breaking data at AAD show significant improvements in signs and symptoms of moderate-to-severe atopic hand and foot dermatitis*

- \* More than twice as many patients on Dupixent achieved clear or almost clear skin compared to placebo at 16 weeks
- \* Nearly four times as many patients on Dupixent saw a clinically meaningful reduction of itch, with improvements seen as early as one week

**Paris and Tarrytown, N.Y. March 18, 2023.** Positive results from the clinical trial assessing Dupixent® (dupilumab) in adults and adolescents with uncontrolled moderate-to-severe atopic hand and foot dermatitis were presented today. The trial, the first evaluating a biologic for this difficult-to-treat population, met its primary and key secondary endpoints. The results were featured in a late-breaking session, one of more than 20 Dupixent scientific presentations, at the American Academy of Dermatology (AAD) 2023 Annual Meeting.

### ***Eric L. Simpson, M.D.***

Frances J. Storrs Professor of Medical Dermatology at the Oregon Health and Science University and principal investigator of this trial

*“Atopic hand and foot dermatitis can extensively disrupt the lives of patients, given the intense itch and painful skin lesions it causes on essential body areas. In this trial, Dupixent significantly improved disease signs, symptoms and quality of life measures for this particularly difficult-to-treat subset of atopic dermatitis patients, with itch improvement seen as early as one week after the first dose. While the efficacy and safety profile of Dupixent is well-established for atopic dermatitis more broadly, these positive results are the first demonstrating the impact on specific and heavily used areas of the body.”*

In the trial, patients received Dupixent (n=67) every two weeks (adults 300 mg, adolescents 200 mg or 300 mg based on body weight) or placebo (n=66). At 16 weeks, patients treated with Dupixent experienced the following:

- 40% achieved clear or almost clear skin on hands and feet compared to 17% with placebo ( $p \leq 0.01$ ), the primary endpoint.
- 52% saw a clinically meaningful reduction in itch on hands and feet compared to 14% with placebo ( $p < 0.0001$ ), the key secondary endpoint.
- 69% average reduction in signs of hand and foot lesions from baseline compared to 31% with placebo ( $p < 0.0001$ ).
- 75% average improvement in hand eczema disease severity from baseline compared to 40% with placebo ( $p < 0.0001$ ).
- There were significant improvements in measures of hand and foot skin pain, sleep and hand eczema-related quality of life.

The trial demonstrated similar safety results to the known safety profile of Dupixent in atopic dermatitis. Overall rates of adverse events (AEs) were 66% for Dupixent and 74% for placebo. AEs more commonly observed with Dupixent ( $\geq 5\%$ ) compared to placebo included nasopharyngitis (16% Dupixent, 11% placebo), upper respiratory tract infection (9% Dupixent, 5% placebo), conjunctivitis (6% Dupixent, 2% placebo), herpes viral infections (6% Dupixent, 3% placebo) and increased blood creatine phosphokinase (6% Dupixent, 0% placebo). Additionally, 3% of patients taking Dupixent used at least one rescue medication compared to 21% of patients on placebo.

There are 23 Dupixent scientific abstracts being presented across three dermatological diseases with underlying type 2 inflammation at the AAD 2023 Annual Meeting. These include oral

presentations on long-term Dupixent use in children as young as 6 months with atopic dermatitis; the impact of Dupixent treatment on health-related quality of life, skin pain and sleep in prurigo nodularis; and the investigational use of Dupixent on signs, symptoms and health-related quality of life in chronic spontaneous urticaria.

The potential use of Dupixent in chronic spontaneous urticaria is currently under clinical development, and the safety and efficacy have not been fully evaluated by any regulatory authority.

### **About the Dupixent Trial**

The Phase 3 double-blind, placebo-controlled trial evaluated the efficacy and safety of Dupixent in 133 adolescents and adults with moderate-to-severe atopic hand and foot dermatitis who had an inadequate response or intolerance to topical corticosteroids. Patients with hand and foot disease predominantly driven by allergic or irritant contact dermatitis were excluded from the trial.

The primary endpoint evaluated the proportion of patients with clear or almost clear skin of hand and feet eczema at 16 weeks (measured by a score of 0 or 1 on the Investigator Global Assessment Scale). The key secondary endpoint measured the proportion of patients with improvement in itch on hands and feet from baseline (measured by a  $\geq 4$ -point reduction in Peak-Pruritis Numeric Rating Scale [PP-NRS] on a 0-10 scale) at 16 weeks. Lesion sign reduction was assessed by change from baseline in Modified Total Lesion Sign Score (mTLSS; measured by a 0-36 scale), and disease severity was assessed by the change from baseline in Hand Eczema Severity Index (HECSI) score (measured by a 0-360 scale). Symptoms were assessed every one or two weeks during the trial.

Additional secondary endpoints included:

- Skin pain reduction as assessed by the change from baseline in weekly average of daily hand and foot peak pain NRS (measured by a 0-10 scale).
- Sleep improvement as assessed by change from baseline in weekly average of daily Sleep NRS (measured by a 0-10 scale).
- Health-related quality of life, assessed by change from baseline in the Quality of Life in Hand Eczema Questionnaire (QoLHEQ) (measured by a 0-117 scale).

### **About Dupixent**

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. 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 key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases. These diseases include approved indications for Dupixent, such as atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis (EoE) and prurigo nodularis.

Dupixent has received regulatory approvals in one or more countries around the world for use in certain patients with atopic dermatitis, asthma, CRSwNP, EoE or prurigo nodularis in different age populations. Dupixent is currently approved for one or more of these indications in more than 60 countries, including in the U.S., European Union and Japan. More than 600,000 patients are being treated with Dupixent 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 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, Sanofi and Regeneron are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes in Phase 3 trials, including pediatric EoE, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis and bullous pemphigoid. 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 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 for 35 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*<sup>®</sup> technologies, such as *VelocImmune*<sup>®</sup>, 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 more information, please visit [www.Regeneron.com](http://www.Regeneron.com) or follow @Regeneron on Twitter.

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### About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and NASDAQ: SNY.

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#### **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 or licensees (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 or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Dupixent; 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 atopic hand and foot dermatitis as discussed in this press release as well as for the treatment of pediatric eosinophilic esophagitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis, bullous pemphigoid, 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 (such as Dupixent) and Regeneron's Product Candidates; 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, 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 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; 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, Praluent® (alirocumab), and REGEN-COV® (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, 2022. 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.

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