# SANOFI 🧳

# Media Update

# New Dupixent® (dupilumab) data showcasing improvements across four type 2 inflammatory diseases to be presented at 2021 AAAAI Annual Meeting

- Improvements were noted across key disease measures in certain patients with asthma, atopic dermatitis, eosinophilic esophagitis and chronic rhinosinusitis with nasal polyposis
- New analyses build on a robust body of evidence reinforcing the role of Dupixent in certain diseases driven by type 2 inflammation

# **February 1, 2021**

New data further examining Dupixent<sup>®</sup> (dupilumab) in diseases driven by type 2 inflammation including atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP) and eosinophilic esophagitis will be presented at the American Academy of Allergy, Asthma and Immunology (AAAAI) Virtual Annual Meeting, taking place from February 26 to March 1.

Abstracts have been published in an online supplement to *The Journal of Allergy and Clinical Immunology (JACI)*, and include:

# **Atopic Dermatitis**

New analyses evaluate the efficacy of Dupixent in children with severe atopic dermatitis with atopic comorbidities.

- Oral Abstract 461A (February 27, 5:10 pm 6:25 pm ET): Dupilumab Improves Signs and Symptoms of Severe Atopic Dermatitis in Children Aged 6–11 Years with and without Comorbid Allergic Rhinitis, Lisa Beck
- Poster 99: Dupilumab Improves Signs and Symptoms of Severe Atopic Dermatitis in Children Aged 6–11 Years with and without Comorbid Asthma, Mark Boguniewicz

# **Asthma**

New analyses evaluate the efficacy of Dupixent in moderate-to-severe asthma patients with an allergic phenotype over the long-term, as well as difficult-to-treat patients. Analyses also explore the potential of clinical remission in patients with moderate-to-severe disease with type 2 inflammation.

- Featured Poster 010 (February 26, 4:35 pm 5:50 pm ET): Dupilumab Treatment Leads to Clinical Asthma Remission in Patients With Uncontrolled Moderate-to-Severe Asthma With Type 2 Inflammation, Ian Pavord
- Poster 183: Dupilumab Efficacy in GINA-Defined Difficult-to-Treat Type 2 Asthma Patients in the LIBERTY ASTHMA QUEST Study, Klaus Rabe

 Poster 184: Long-Term Efficacy of Dupilumab in Patients With Asthma With an Allergic Phenotype Rolled Over From LIBERTY ASTHMA QUEST: LIBERTY ASTHMA TRAVERSE Study, Lawrence Sher

# **Eosinophilic Esophagitis**

New analysis further explores the impact of Dupixent on health-related quality of life (HRQoL) in patients with eosinophilic esophagitis. The use of Dupixent in eosinophilic esophagitis is currently under clinical investigation and its safety and efficacy have not been fully evaluated by any regulatory authority.

 Poster 290: Dupilumab Improves Health-Related Quality of Life (HRQoL) and Reduces Symptom Burden in Patients with Eosinophilic Esophagitis (EoE): Results From Part A of a Randomized, Placebo-Controlled Three-Part Phase 3 Study, Evan Dellon

# **Chronic Rhinosinusitis with Nasal Polyposis**

New analyses examine the burden on HRQoL in patients with severe CRSwNP, and the impact on objective and subjective disease measures with Dupixent treatment.

- Poster 423: A Responder Analysis to Demonstrate Dupilumab Treatment Effect Across Objective and Patient-Reported Subjective Endpoints For Patients With Severe Chronic Rhinosinusitis With Nasal Polyps (CRSwNP), Claus Bachert
- Poster 425: Health-Related Quality of Life Impairment Among Patients With Severe Chronic Rhinosinusitis With Nasal Polyps in the SINUS-24 Trial, Jorge Maspero

# **Cross-Indication Blood Eosinophils**

New analysis assesses the effect of Dupixent on blood eosinophils over time across approved and investigational indications.

 Poster 447: Effect of Dupilumab Treatment on Blood Eosinophil Levels in Patients With Asthma, Chronic Rhinosinusitis With Nasal Polyps (CRSwNP), Eosinophilic Esophagitis (EoE), or Atopic Dermatitis (AD), Michael Wechsler

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins. Data from Dupixent clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma, CRSwNP, and eosinophilic esophagitis.

# **About Dupixent**

In the United States and Europe, Dupixent is approved for patients 6 years and older with moderate-to-severe atopic dermatitis, patients 12 years and older with moderate-to-severe asthma, and in adults with uncontrolled CRSwNP. Dupixent is also approved in one or more of these indications in more than 60 countries around the world and more than 200,000 patients have been treated globally.

Dupixent is intended for use under the guidance of a healthcare professional and can be given in a clinic or at home by self-administration after training by a healthcare professional. In children younger than 12 years of age, Dupixent should be administered by a caregiver.

# **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, 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), and food and environmental allergies (Phase 2). These potential uses are investigational, 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 Sanofi and Regeneron under a global collaboration agreement.

# **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 eight FDA-approved treatments and numerous product candidates in development, 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.

## **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.

Sanofi, Empowering Life

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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, 2019. 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 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 dupilumab for the treatment of pediatric asthma, chronic obstructive pulmonary disease, pediatric atopic dermatitis, eosinophilic esophagitis, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, food and environmental allergies, and other potential indications; uncertainty of market acceptance and commercial success of Regeneron's Products and 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 and product candidates; safety issues resulting from the administration of Regeneron's Products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and 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 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 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 product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or quidance and changes to the assumptions underlying those projections or quidance; 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, and Praluent® (alirocumab)), 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, 2019 and its Form 10-Q for the quarterly period ended September 30, 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 (<a href="http://newsroom.regeneron.com">http://newsroom.regeneron.com</a>) and its Twitter feed (<a href="http://twitter.com/regeneron">http://twitter.com/regeneron</a>).