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Press Release

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New Dupixent® (dupilumab) analyses reinforce long-term safety and efficacy profile in patients with atopic dermatitis as young as 6 years

- Nearly 30 data presentations at AAD and ESPD across clinical and real-world settings, including the impact of Dupixent on disease measures in uncontrolled moderate-to-severe atopic dermatitis
- Late-breaking Phase 2 data for rilzabrutinib, an investigational therapy for pemphigus vulgaris, a rare, debilitating autoimmune disease, to be presented at AAD

PARIS – April 23, 2021 - New analyses from Dupixent® (dupilumab) trials evaluated infection incidence reduction and reinforced the need for no laboratory monitoring in patients six years and older with moderate-to-severe atopic dermatitis. Additional analyses evaluated response rates across a broad population, and the impact of Dupixent on disease extent and severity, quality of life (QoL), and itch. These and other data from real-world settings and clinical trials, including the Dupixent open-label extension (OLE) trials, will be presented at the American Academy of Dermatology (AAD VMX 2021), April 23-25, and at the 20th European Society for Pediatric Dermatology Annual Meeting (ESPD 2021), May 12-14.

> *"The depth and breadth of data being presented at AAD and ESPD support the use of Dupixent in adults, adolescents and children six years and older, addressing multiple critical disease measures such as itch, disease extent and severity, and certain skin infections," said Naimish Patel, M.D. Head of Global Development in Immunology and Inflammation at Sanofi. "In addition, our expanded efforts in research and development in the immunology space, including rilzabrutinib, underscores our long-term commitment to addressing serious dermatological conditions with unmet patient needs."*

Results from a subgroup analysis of the Phase 2 study evaluating rilzabrutinib, an investigational oral Bruton's tyrosine kinase inhibitor (BTKi), for the treatment of pemphigus vulgaris (PV), include the rates of control of disease activity in patients with moderate-to-severe disease. These data will be presented as a late-breaking abstract oral presentation at AAD VMX 2021. PV is a rare, debilitating autoimmune disease that causes blistering of the skin and mucus membranes.

Abstracts to be presented at AAD VMX 2021

Pediatric efficacy and QoL data for Dupixent

- 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 27406: Dupilumab Treatment Improves Health-Related Quality of Life in Children Aged ≥6 to <12 Years With Severe Atopic Dermatitis, Alan Irvine

Adult efficacy data for Dupixent

- 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 from Dupixent OLE studies, up to three years in adults and up to one year in adolescents (aged 12-17 years) and children (aged 6-11 years) with moderate-to-severe atopic dermatitis.

- 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 for Dupixent

- 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 data on the burden and impact 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

A late-breaking abstract oral presentation for rilzabrutinib:

- Treatment with Rilzabrutinib Results in Rapid and Significant Decrease in Steroid Use and Improved Quality of Life in Patients with Chronic Relapsing Pemphigus: BELIEVE Phase 2 Study, Dedee F. Murrell

Abstracts to be presented at ESPD 2021

Abstracts related to data evaluating efficacy, safety and impact on health-related quality of life of Dupixent 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 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. 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.

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.

Dupilumab Development Program

To date, dupilumab has been studied in more than 10,000 patients across 50 clinical trials in 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 in part 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). The use of dupilumab in these settings is currently under clinical investigation and its safety and efficacy have not been fully evaluated by any regulatory authority. Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

About Rilzabrutinib

Rilzabrutinib is an oral, reversible covalent, Bruton's tyrosine kinase (BTK) inhibitor being investigated for the treatment of immune mediated diseases. BTK is involved in innate and adaptive immune responses and is a signaling molecule in immune mediated diseases. Rilzabrutinib pre-clinical data demonstrate an ability to help block inflammatory immune cells, eliminate autoantibody destructive signaling, and prevent new autoantibody production without depleting B cells. Rilzabrutinib has the potential to target the underlying disease pathogenesis and has not been shown to alter platelet aggregation. The clinical significance of this data is under investigation. Rilzabrutinib is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

Editor's Note: Rilzabrutinib has been granted orphan drug designation by the FDA for both pemphigus vulgaris (and from the European Commission for the treatment of pemphigus vulgaris and pemphigus foliaceus) and for its investigational use in immune thrombocytopenia (ITP). In November 2020, we announced that rilzabrutinib was granted FDA Fast Track Designation for ITP.

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 and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. 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, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, 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.