Dupixent® (dupilumab) efficacy and quality of life data in asthma patients across multiple age groups to be presented at 2021 ERS international congress

* Breadth of Dupixent analyses across a broad population of patients with moderate-to-severe asthma further underscores the importance of addressing type 2 inflammation

September 3, 2021

New Dupixent® (dupilumab) data showing clinical outcomes in adults, adolescents and children who have moderate-to-severe asthma with underlying type 2 inflammation, including patients with oral-corticosteroid (OCS)-dependent asthma, will be presented at the 2021 European Respiratory Society International Congress, September 5 – 8.

The analyses evaluated key disease measures including severe asthma attacks, lung function, OCS reduction, and health-related quality of life.

This will be the first presentation of health-related quality of life results for Dupixent in children aged 6 to 11 years with uncontrolled moderate-to-severe asthma, which can impact their whole families, as well as analyses on the impact of Dupixent on physical activity limitation and sleep in adults and adolescents 12 years and older with OCS-dependent asthma. Additional post-hoc analyses presented will show the impact of Dupixent on severe asthma attacks and lung function in children, adolescents, and adults with a broad range of asthma phenotypes. Also, post hoc analysis of Dupixent in patients with chronic rhinosinusitis with nasal polyposis will be presented.

Clinical Data in Asthma with Type 2 Inflammation

- Oral Presentation OA2837(September 7, 9:30 am – 11:00 am CET): Dupilumab Efficacy in Patients With GINA-Defined Type 2 Asthma: TRAVERSE, Eric Bateman
- Oral Presentation OA2568(September 6, 2:45 pm – 4:15 pm CET): Dupilumab Efficacy in Children With Uncontrolled, Moderate-to-Severe Asthma With and Without an Allergic Phenotype, Nikolaos Papadopoulos
- Oral Presentation OA2836 (September 7, 9:30 – 11:00 am CET): Impact of Severe Exacerbations on Lung Function in Dupilumab-Treated Patients: LIBERTY ASTHMA QUEST, Alberto Papi
- E-Poster PA2521: Efficacy of Dupilumab in Patients With oral corticosteroid (OCS)-dependent, Severe Asthma With and Without an Allergic Phenotype: Phase 3 LIBERTY ASTHMA VENTURE, Guy Brusselle
• E-Poster PA2519: Dupilumab Sustains Long-Term OCS Reduction in OCS-Dependent Asthma Patients, Lawrence Sher
• E-Poster PA564: Late Breaking Abstract: Real-World Characteristics of Patients Receiving Dupilumab in Routine Clinical Practice in a Multinational, Non-Interventional Study (ProVENT), Marek Lommatzsch

Quality of Life Data in Asthma

• E-Poster PA3920: Dupilumab Improves Asthma Control and Quality of Life in Children With Uncontrolled Persistent Asthma, Alessandro Fiocchi
• E-Poster PA880: Effect of Dupilumab on Improving Physical Activity in Patients with Severe Asthma, Lawrence Sher
• E-Poster PA3733: Effect of Dupilumab on Patient-Reported Sleep Outcomes in Patients with Severe Asthma, Lawrence Sher

Chronic Rhinosinusitis with Nasal Polyposis

• E-Poster PA2520: SNOT-22 Items and Association With Objective Measures in Dupilumab-Treated Patients With Severe Chronic Rhinosinusitis With Nasal Polyps From SINUS-24 and SINUS-52 Trials, Joaquim Mullol

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 asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), and atopic dermatitis.

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
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. Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

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.

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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.