Media Update

New Dupixent® (dupilumab) data at ERS adds to body of safety and efficacy data in chronic respiratory diseases

Paris, August 30, 2022. More than 10 scientific abstracts evaluating Dupixent® (dupilumab) in moderate-to-severe asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) will be presented at the European Respiratory Society (ERS) International Congress 2022 from September 4 to 6. The data add to a growing body of clinical and real-world evidence illustrating the benefit of Dupixent in targeting IL-4 and IL-13, key and central drivers of the type 2 inflammation that play a major role in asthma and CRSwNP.

Presentations include new analyses from a Phase 3 open-label extension trial (TRAVERSE), which showed that treatment with Dupixent reduced asthma exacerbations, improved lung function and reduced the need for oral corticosteroids in patients with moderate-to-severe asthma aged 12 years and older for up to three years. The safety results of this trial were generally consistent with the known safety profile of Dupixent in its respiratory indications.

Late-breaking, new long-term data from the longest global Phase 3 open-label extension trial of children aged 6-11 years with moderate-to-severe asthma (EXCURSION) will also be presented.

In addition, results of a Phase 3 trial in adults with CRSwNP will be presented, showing that the majority of patients treated with Dupixent maintained a clinically meaningful response over one year on multiple clinical endpoints, including nasal polyps score, loss of smell score and the Sino-nasal Outcome Test-22. The safety results were generally consistent with the known safety profile of Dupixent in its respiratory indications.

Data to be presented at ERS 2022

Clinical Efficacy and Safety of Dupixent in Children with Asthma

- Late-Breaking Oral Presentation (September 5, 4:30-4:35 CEST):
  - #OA2955: Assessment of the long-term safety and efficacy of dupilumab in children with asthma: LIBERTY ASTHMA EXCURSION, Leonard Bacharier
- Oral Presentation (September 5, 4:05-4:10 CEST) and Poster:
  - #OA2950: Dupilumab efficacy in children with uncontrolled type 2 asthma with baseline high/medium ICS dose, Jorge Maspero
- Oral Presentation (September 5, 4:15-4:20 CEST) and Poster:
  - #OA2952: Continuous Associations of Type 2 Biomarkers and Efficacy of Dupilumab in Children With Uncontrolled, Moderate-to-Severe Asthma, Leonard Bacharier

Impact of Dupixent on Key Efficacy and Safety Measures in Adolescents and Adults with Asthma

- Oral Presentation (September 6, 9:55-10:00 CEST) and Poster:
  - #OA3672: Dupilumab improved lung function and reduces exacerbations in patients with 1, 2, or 3 prior exacerbations: TRAVERSE, Jonathan Corren
- Oral Presentation (September 6, 10:10-10:15 CEST) and Poster:
  - #OA3675: Relation between reduction in fractional exhaled nitric oxide and efficacy in asthma patients treated with dupilumab, Ian Pavord
- Poster #PA3191: Randomised, double-blind, placebo-controlled study to assess long-term effect of dupilumab on prevention of lung function decline (LFD) in patients with uncontrolled moderate-to-severe asthma: ATLAS trial, Ian Pavord

- Poster #PA3209: Effect of Dupilumab on asthma control and asthma-related quality of life in patients with uncontrolled, moderate-to-severe type 2 asthma: TRAVERSE OLE study, Ian Pavord
- Poster #PA3212: Dupilumab reduces OCS use and improves lung function in patients with severe OCS-dependent asthma, Christian Domingo Ribas
- Poster #PA3210: Biomarkers associated with lung function decline and dupilumab response in patients with moderate-to-severe asthma, Ian Pavord

Real-World Effectiveness of Dupixent in People with Asthma

- Poster #PA2390: Real-World Effectiveness (RWE) of Dupilumab in Reducing Healthcare Resource Utilization among Moderate-to-Severe Asthma Patients, Ajinkya Pawar

Clinical Efficacy of Dupixent in People with CRSwNP

- Poster #PA3197: Onset, Maintenance, and Durability of Response with Dupilumab in Chronic Rhinosinusitis with Nasal Polyps, Claus Bachert

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 asthma, atopic dermatitis, CRSwNP and eosinophilic esophagitis (EoE), as well as investigational diseases such as prurigo nodularis.

In the EU, Dupixent is approved in children aged 6 to 11 years as an add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment. For adolescents and adults 12 years and older with severe asthma with type 2 inflammation, patients must be inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment.

Dupixent has received regulatory approvals around the world for use in in certain patients with atopic dermatitis, asthma, CRSwNP or EoE in different age populations. Dupixent is currently approved across these indications in the U.S. and for one or more of these indications in more than 60 countries, including in the European Union and Japan. More than 450,000 patients have been 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 prurigo nodularis, pediatric eosinophilic esophagitis, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritis 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 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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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, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.