**Media Update**

# *New late-breaking data at ATS 2023 demonstrate significant advancements across Dupixent® and broader respiratory pipeline*

* 17 abstracts showcase new data for Dupixent, itepekimab and anti-IL-13/ TSLP NANOBODY® molecule in COPD and asthma
* Presentations on investigational use of Dupixent in COPD include two late-breaking abstracts for the BOREAS trial
* Additional late-breaking presentation shows proof-of-mechanism in asthma for first novel biologic to target both TSLP and IL-13 pathways

**Paris, May 5, 2023.** Seventeen abstracts will be presented at this year's American Thoracic Society International Conference (ATS 2023) taking place from May 19-24. Presentations include: two late-breaking abstracts from the Phase 3 Dupixent® (dupilumab) BOREAS trial for investigational use in chronic obstructive pulmonary disease (COPD); two oral presentations featuring new preclinical data on itepekimab, an IL-33 inhibitor, in COPD; and a late-breaking presentation from a Phase 1b study of SAR443765, an investigational bispecific NANOBODY® molecule targeting both thymic stromal lymphopoietin (TSLP) and interleukin-13 (IL-13) pathways.

> ***Naimish Patel, M.D.***
> Head of Global Development, Immunology and Inflammation, Sanofi
> *"We are looking forward to sharing these first-of-their kind results for an investigational biologic from the pivotal trial of Dupixent in COPD, which we believe, if approved, have the potential to transform the treatment paradigm of this devastating and debilitating disease. The addition of our proof-of-mechanism data in asthma for SAR443765 further reinforces our commitment to advancing our understanding of the respiratory disease pathways with the goal of improving the lives of patients with serious respiratory diseases."*

An investor event with members of the Sanofi leadership team discussing these key presentations and updates on the company's Immunology strategy will also be held in conjunction with the congress. The investor event will take place on Monday, May 22 from 6 p.m. to 7:30 p.m. CEST / Noon to 1:30 p.m. EDT (webcast only).

Additional information will be available on Sanofi's Investor Relations website: https://www.sanofi.com/en/investors.

## *Data to be Presented at the 2023 ATS Annual Meeting*

**Chronic Obstructive Pulmonary Disease (COPD)**
New research in COPD will evaluate the potential of targeting different aspects of airway inflammation that are believed to drive disease.

Detailed efficacy and safety data from the BOREAS trial, the first of two Phase 3 trials for investigational use of Dupixent in COPD, show that it is the first biologic that significantly reduced exacerbations and improved lung function, disease symptoms and quality of life for trial participants. The safety results were generally consistent with the known safety profile of Dupixent in its approved indications. The findings will be featured in two late-breaking oral presentation sessions, including the Breaking News: 2023 Clinical Trial Results in Pulmonary Medicine session. Positive topline data from the study, which met the primary and all key secondary endpoints, were previously announced in March 2023.

In addition, data from three abstracts on itepekimab assessing the IL-33 pathway blockade and its role in airway inflammation and lung remodeling will be presented. Itepekimab is a fully human monoclonal antibody that binds to and inhibits IL-33, an initiator and amplifier of broad inflammation in COPD.

- *Oral Late-Breaker Presentation (May 22, 9:00-11:00am ET):* Efficacy and Safety of Dupilumab in Chronic Obstructive Pulmonary Disease with Type 2 Inflammation
- *Oral Presentation (May 23, 9:00-11:00am ET):* Itepekimab Binds to IL-33 with High Affinity, Prevents the Formation of IL-33/ST2/IL-1RAcP Signaling Complex and Blocks Mediators of Airway Inflammation
- *Oral Presentation (May 23, 9:00-11:00am ET):* Interleukin-33 Drives Type 1 and Type 2 Inflammation and Instructs Airway Remodeling
- *Poster Presentation (May 22, 9:00am-4:15pm ET):* Blocking Either the IL-33 or IL-4Ra Pathway Attenuates Inflammatory Mediators of Airway Disease

Dupilumab and itepekimab are being jointly developed by Sanofi and Regeneron under a global collaboration agreement. The safety and efficacy of Dupixent and itepekimab in COPD have not been evaluated by any regulatory authority.

**Moderate-to-Severe Asthma**
Data from Sanofi's Phase 1b study of SAR443765 in adults with asthma will be presented during the Breaking News: 2023 Clinical Trial Results in Pulmonary Medicine session. These results demonstrate proof-of-mechanism in asthma and are the first report of a novel biologic targeting both the TSLP and IL-13 pathways.

Additional presentations include new long-term safety findings from the LIBERTY ASTHMA TRAVERSE continuation study evaluating Dupixent up to five years in adolescents and adults with asthma, as well as results from a Phase 3 study assessing Dupixent efficacy and safety in adult and adolescent patients aged 12 and older with persistent asthma in the Asia-Pacific region.

- *Oral Late-Breaker Presentation (May 22, 9:00-11:00am ET):* Targeting of TSLP and IL-13 by the novel NANOBODY® molecule SAR443765 reduces FeNO in asthma following single dose exposure
- *Poster Presentation (May 23, 2:15-4:15pm ET)*: Dupilumab Improved Long-Term Lung Function in Children Aged 6 to 11 Years with Moderate-to-Severe Asthma: LIBERTY ASTHMA EXCURSION
- *Poster Presentation (May 23, 9:00am-4:15pm ET)*: Dupilumab Reduced Severe Exacerbation Rates and Improved Pre-Bronchodilator FEV1 in Patients with Moderate-to-Severe Asthma Regardless of Exacerbation History of ≥1, ≥2, or ≥3 Prior Exacerbations: LIBERTY ASTHMA TRAVERSE
- *Poster Presentation (May 23, 2:15-4:15pm ET):* Dupilumab Improves Lung Function in Children with Moderate-to-Severe Type 2 Asthma at Week 12

- *Poster Presentation (May 23, 9:00am-4:15pm ET):* Long-Term Safety of Dupilumab in Patients with Moderate-to-Severe Asthma: The LIBERTY ASTHMA TRAVERSE Continuation Study
- *Poster Presentation (May 23, 2:15-4:15pm ET):* Dupilumab Induces Clinical Remission in Patients with Uncontrolled, Moderate-to-Severe, Type 2 Inflammatory Asthma
- *Poster Presentation (May 23, 9:00am-4:15pm ET):* Efficacy of Dupilumab in Patients with and without a Minimally Important Reduction in Fractional Exhaled Nitric Oxide After 2 Weeks of Treatment
- *Poster Presentation (May 22, 9:00am-4:15pm ET):* Dupilumab Real-World Effectiveness (RWE) in Reducing Healthcare Resource Utilization Among Moderate-to-Severe Asthma Patients
- *Poster Presentation (May 23, 2:15-4:15pm ET):* Real-World Effectiveness of Dupilumab on Oral Corticosteroid Use and Asthma Exacerbations in Patients with Moderate-to-Severe Asthma
- *Poster Presentation (May 23, 9:00am-4:14pm ET):* Efficacy and Safety of Dupilumab in Patients with Persistent Asthma from the Asia-Pacific Region: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study
- *Poster Presentation (May 23, 9:00am-4:15pm ET):* Efficacy and Safety of Dupilumab in Patients from China with Persistent Asthma: A Subgroup Analysis of a Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study
- *Poster Presentation (May 23, 2:15-4:15pm ET):* Comparative Effectiveness of Dupilumab Versus Omalizumab in Asthma Among Biologic-Naïve Patients: Findings from the Real-World US ADVANTAGE Study
- *Poster Presentation (May 23, 9:00am-4:15pm ET):* Real-World Effectiveness of Dupilumab in Biologic Naïve Patients with Asthma: Analysis from the US ADVANTAGE Study

The safety and efficacy of SAR443765 in asthma has not been evaluated by any regulatory authority.

**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), prurigo nodularis and eosinophilic esophagitis (EoE).

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 Europe, the U.S. and Japan. More than 600,000 patients are being treated with Dupixent globally.

**About Sanofi's Immunology Pipeline**
Through world-class R&D and a laser focus on patients, Sanofi discovers, develops and delivers best-in-class treatments that improve the lives of people living with chronic inflammatory diseases. Our scientific strategy for the future of immunology is built around the intentional choice of exploring disruptive mechanisms of actions beyond type 2 including NANOBODY molecules, synthetic cytokines and degraders. The immunology pipeline consists of 6

investigational agents in Phase 1 clinical development, 5 in Phase 2 clinical development, and 1 in Phase 3 clinical development. These programs include investigational agents across a wide range of inflammatory conditions.

### *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 pandemics or other global crises may 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. 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*