Media Update

New data at ERS showcases Sanofi's scientific leadership in addressing unmet needs across a variety of respiratory conditions

- *Data presentations include landmark results from pivotal trial evaluating Dupixent in COPD with evidence of type 2 inflammation*
- *Scientific presence highlights strong progress within Sanofi's current and future portfolio*

Paris, SEPTEMBER 5, 2023. 15 abstracts evaluating several Sanofi and collaboration products and investigational treatments will be presented at the 2023 European Respiratory Society (ERS) International Congress from September 9-13 in Milan, Italy. Presentations include data from the Dupixent (dupilumab) COPD and asthma pivotal trial programs, and data evaluating the role of Xenpozyme (olipudase alfa) in treating interstitial lung disease.

Results from the Dupixent Phase 3 trial (BOREAS), showing significant improvements in annualized rate of exacerbations, lung function, quality of life, as well as symptoms of chronic obstructive pulmonary disease (COPD) and a new analysis showing reduced systemic corticosteroid use in adults with uncontrolled COPD with evidence of type 2 inflammation, will be presented as an oral presentation during the New England Journal of Medicine NEJM/ERS journal session and as a late breaking abstract. Additionally, new data from a Phase 3 trial in children aged 6 to 11 years with moderate-to-severe asthma (VOYAGE) show Dupixent reduced systemic corticosteroid use related to exacerbations compared to placebo regardless of prior exacerbation history. The safety results of the COPD and asthma trials were generally consistent with the known safety profile of Dupixent in its approved respiratory indications.

Data from Sanofi's Phase 1b study of SAR443765 in adults with asthma also demonstrate proof-of-mechanism, the first report of a novel biologic targeting both the thymic stromal lymphopoietin (TSLP) and interleukin-13 (IL-13) pathways.

Late-breaking results from the Severe Asthma Index, a first-of-its-kind, free-to-access, evidence-based tool that provides a holistic view of how 29 different countries approach severe asthma care, will also be presented illustrating the inadequate prioritization of the condition around the world and the need for a comprehensive approach to disease management. The Severe Asthma Index was developed by the Copenhagen Institute for Futures Studies and funded by Sanofi and Regeneron.

New Phase 2/3 data demonstrated that Xenpozyme significantly improved pulmonary function in adults with acid sphingomyelinase deficiency (ASMD), providing positive disease modification across four critical domains of interstitial lung disease. The safety profile for Xenpozyme was comparable across studies.

Data to be presented at the 2023 ERS International Congress

Dupixent in adults with COPD

* Late Breaking Abstract (September 10, 12:30pm-14:00pm CEST):
    - #PA1308: Efficacy and Safety of Dupilumab for COPD with Type 2 Inflammation Indicated by Elevated Eosinophils
* Oral *NEJM*/ERS Joint Journal Session (September 11, 13:45pm-14:00pm CEST):
    - #3108: Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts

Dupixent in children and adults with asthma

* Poster #PA2101: Dupilumab reduces systemic corticosteroid exposure in children with uncontrolled moderate-to-severe asthma regardless of prior exacerbations
* Poster #PA2090: Dupilumab improves lung function responder rates in children with type 2 asthma in the VOYAGE study
* Poster #PA2091: Long-term dupilumab effect on lung function in paediatric patients with uncontrolled asthma
* Oral presentation (September 10, 2:15pm – 3:30pm CEST):
    - #OA1416: Long-Term Dupilumab Efficacy in Patients with Type 2 Asthma by Age of Onset: LIBERTY ASTHMA TRAVERSE
* Poster #PA3618: Long-term efficacy and tolerability of dupilumab in patients with moderate-to-severe type 2 asthma stratified by baseline characteristics
* Poster #PA5286: Dupilumab in Asia-Pacific patients with persistent asthma
* Poster #PA3607: Fractional exhaled nitric oxide as a biomarker in patients with uncontrolled asthma
* Poster #PA5290: Baseline characteristics of patients with asthma and prior systemic corticosteroid use in the RAPID (dupilumab) registry

Disease burden and diagnosis

* Late-Breaking Poster #PA4746: Novel Index assesses severe asthma care across 29 OECD countries
* Poster #PA4605: Oral corticosteroid (OCS) burden and healthcare resource utilization (HCRU) in patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who did or did not undergo functional endoscopic sinonasal surgery (FESS) in US real-world practice
* Poster #PA3948: Machine learned decision tree for diagnosis of ASMD among patients with unexplained ILD

Sanofi respiratory pipeline

* Late breaking abstract #OA4296: Early improvement in asthma small airway dysfunction after one dose of SAR443765, a novel bispecific anti-thymic stromal lymphopoietin/anti-IL-13 nanobody molecule

Xenpozyme in adults with ASMD

* Oral presentation (September 11, 3:45 - 5:00pm CEST)
    - #OA3281: Reversal of interstitial lung disease after olipudase alfa enzyme replacement therapy in adults with acid sphingomyelinase deficiency

About Dupixent

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the IL-4 and 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, CRSwNP, eosinophilic esophagitis (EoE) and prurigo nodularis.

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.

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 pediatric EoE, chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation 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 Xenpozyme
Xenpozyme® (olipudase alfa) is an enzyme replacement therapy designed to replace deficient or defective acid sphingomyelinase. Xenpozyme has been evaluated in pediatric and adult patients to treat non-central nervous system (non-CNS) manifestations of ASMD type A/B and ASMD type B. Xenpozyme has not been studied in patients with ASMD type A.

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.