Media Update

New data presented at ATS demonstrate Sanofi's leadership in advancing potential new therapies for patients with immune-mediated respiratory diseases

- Late-breaking data from the landmark NOTUS and BOREAS phase 3 studies support Dupixent's role as a potential first-in-class biologic treatment for certain adult patients with uncontrolled COPD with type 2 inflammation
- New findings from BOREAS study evaluate the role of biomarkers in predicting improvement in exacerbations and other responses to treatment
- First presentation of phase 2b results for rilzabrutinib in asthma which forms the basis for a phase 3 program

Paris, April 26, 2024. Twenty-five abstracts across approved and investigational medicines will be presented at this year's American Thoracic Society (ATS) International Conference taking place from May 17-22 in San Diego. Oral presentations will be given on data for Dupixent® (dupilumab), in partnership with Regeneron, evaluating its potential as a treatment for patients with chronic obstructive pulmonary disease (COPD) from two landmark phase 3 studies. Notable data presentations for Sanofi's immunology pipeline include the first presentation of phase 2b asthma data for rilzabrutinib, a novel oral BTK inhibitor, and an oral presentation for lunsekimig, a novel IL-13/TSLP Nanobody® VHH, currently in phase 2b development for asthma.

> ***Naimish Patel, M.D.***
> **Global Head of Development, Immunology and Inflammation at Sanofi**
> *"Our robust presence at this year's ATS conference showcases our novel research across inflammatory respiratory conditions, including COPD and asthma. The results from the pivotal NOTUS and BOREAS phase 3 studies for Dupixent further deepen our understanding of the role that type 2 inflammation plays in COPD and underscore the potential for Dupixent to be the first biologic approved for the treatment of COPD. We're also excited to present new data for our two pipeline molecules, rilzabrutinib, an oral BTKi, and lunsekimig, our IL-13/TSLP Nanobody VHH, showing their first- and best-in-class potential in asthma. Our collective data at the meeting underscores our commitment and progress to improving the lives of patients suffering from devastating respiratory diseases."*

Dupixent

Notable presentations include new findings from the pivotal phase 3 Dupixent COPD program (NOTUS and BOREAS studies), which showed significant reduction in COPD exacerbations and improvements in lung function. Additionally, research from the VESTIGE phase 4 study, a novel imaging study evaluating the effects of Dupixent on lung function in adult patients with uncontrolled moderate-to-severe asthma, will be featured as a late-breaking oral

presentation. Lastly, multiple poster presentations demonstrate the impact of Dupixent on asthma.

Clinical data in COPD

- **NOTUS study:** detailed efficacy and safety results from the NOTUS phase 3 study evaluating Dupixent in patients with uncontrolled COPD and evidence of type 2 inflammation will be featured in a late-breaking oral presentation. Positive topline data from the study, which showed that Dupixent significantly reduced exacerbations, were previously announced in November 2023.

- **BOREAS study:** findings across six abstracts from the BOREAS phase 3 study will be shared, including an analysis evaluating the treatment-by-biomarker interaction effects in patients with COPD, which will be presented in an oral abstract session as well as data on lung function.

Clinical data in uncontrolled moderate-to-severe asthma

- **VESTIGE clinical study**: an oral abstract session will feature data on the effect of Dupixent on airway inflammation and mucus plugging in adults with uncontrolled moderate-to-severe asthma.

- **LIBERTY and VOYAGE studies:** additional post-hoc analyses will be shared, including evaluating the impact of asthma duration on the efficacy of Dupixent in patients with uncontrolled moderate-to-severe asthma, clinical outcomes in patients with uncontrolled moderate-to-severe asthma who received Dupixent as an add-on to medium-dose inhaled corticosteroid, and the efficacy of Dupixent amongst children aged 6-11 with uncontrolled moderate-to-severe asthma.

The safety results of these studies were generally consistent with the known safety profile of Dupixent in its approved respiratory conditions.

Respiratory pipeline

Presentations include data for investigational compounds rilzabrutinib, an oral BTK inhibitor, and lunsekimig, a new IL-13/TSLP Nanobody VHH, in asthma.

- **Phase 2b study of rilzabrutinib:** a poster presentation will show the impact of treatment with rilzabrutinib on loss of asthma control (LOAC) events, asthma symptoms and quality of life in patients with moderate-to-severe asthma.
- **Lunsekimig:** an oral presentation will show the impact of lunsekimig on multiple pathological immune cell populations and epithelial cell subpopulations.

Complete List of ATS 2024 presentations:

Presenting author	Abstract title	Presentation details
COPD		
Bafadhel	Dupilumab Does Not Impact Blood Eosinophil Levels in Patients with Moderate-to-Severe COPD and Type 2 Inflammation: From the Phase 3 Boreas Trial	7498 Poster Presentation Sunday, May 19 9:15 – 11:15 AM PDT
Bhatt	A 3-year Descriptive Assessment of Exacerbations and Double/Triple Inhaler Use	P584 Poster Presentation Monday, May 20

	among chronic obstructive pulmonary disease (COPD) patients in the United States (US)	11:30 AM – 1:15 PM PDT
Bhatt	Characterization of Chronic Obstructive Pulmonary Disease (COPD) in the United States	P585 Poster Presentation Monday, May 20 11:30 AM – 1:15 PM PDT
Bhatt	Efficacy and Safety of Dupilumab in Patients With Moderate-to-Severe COPD and Type 2 Inflammation: Phase 3 NOTUS Trial	15018 Oral Presentation Monday, May 20 9:15 – 11:15 AM PDT
Bhatt	In the Phase 3 BOREAS Trial, Dupilumab Reduced FeNO Levels Over Time in Patients with Moderate-To-Severe COPD with Type 2 Inflammation	7547 Poster Presentation Sunday, May 19 9:15 – 11:15 AM PDT
Buhl/Vogelmeier	Clinical and Economic Burden of COPD in Patients Poorly Controlled on LABA/LAMA or Inhaled Triple Therapy in Germany - A Retrospective Claims Data Analysis	P583 Poster Presentation Monday, May 20 11:30 AM – 1:15 PM PDT
Christenson	Dupilumab Increases the Proportion of Patients With Fractional Exhaled Nitric Oxide Levels <20 ppb Over Time in Patients With Moderate-to-Severe Chronic Obstructive Pulmonary Disease and Type 2 Inflammation: From Phase 3 BOREAS	7636 Poster Presentation Monday, May 20 11:30 AM – 1:15 PM PDT
Christenson	In the Phase 3 BOREAS Trial, Baseline Blood Eosinophils and Baseline Fractional Exhaled Nitric Oxide Levels Predict the Response to Dupilumab in Patients with Moderate-to-Severe Chronic Obstructive Pulmonary Disease and Type 2 Inflammation	7654 Oral Presentation Tuesday, May 21 2:15 – 4:15 PM PDT
Hanania	Dupilumab Improves Post-Bronchodilator Lung Function in Patients with Moderate-to-Severe Chronic Obstructive Pulmonary Disease (COPD) with Type 2 Inflammation: Data from The Phase 3 BOREAS Trial	7422 Poster Presentation Sunday, May 19 9:15 – 11:15 AM PDT
Heble	Treatment And Disease Burden Among Patients With Moderate Or Severe COPD: Real World Study	P604 Poster Presentation Monday, May 20 11:30 AM – 1:15 PM PDT
Mularski	Association Between Serial Spirometric Improver Phenotype (Improved FEV1 Over Time) Versus Decliner Phenotype in Healthcare Utilization in Chronic Obstructive Pulmonary Disease	P133 Poster Presentation Sunday, May 19 11:30 AM – 1:15 PM PDT
Papi	Dupilumab Improves Pre-Bronchodilator Lung Function Measures in Patients with Chronic Obstructive Pulmonary Disease (COPD) with Type 2 Inflammation: Data from The Phase 3 BOREAS Trial	7401 Poster Presentation Sunday, May 19 9:15 – 11:15 AM PDT
Qureshi	Healthcare Resource Utilization and Disease Burden in Chronic Obstructive Pulmonary Disease (COPD) Patients With Type 2	713 Poster Presentation Sunday, May 19

	Inflammation in the United States: Real-world Evidence	2:15 – 4:15 PM PDT
Asthma		
Washko	Effect of Dupilumab on Airway Oscillometry, Ventilation/Perfusion, and Mucus Plugging in Moderate-to-Severe Asthma: The Vestige Trial	14998 Oral Presentation Monday, May 20 9:51 – 10:03 AM PDT
Bacharier	Improved Lung Function Is Associated With Better Asthma Control in Children With Moderate-To-Severe Type 2 Asthma: VOYAGE Study	8324 Poster Presentation Tuesday, May 21 11:30 AM – 1:15 PM PDT
Bourdin	Dupilumab Asthma ADVANTAGE-EU: Real-World Evidence on the Association Between Dupilumab and Use of Corticosteroid and Asthma Exacerbations in Patients with Severe Asthma in Europe	10135 Poster Presentation Tuesday, May 21 2:15 – 4:15 PM PDT
Busse	Dupilumab Add-On to Medium-Dose Inhaled Corticosteroid (ICS) Increases Odds of Asthma Control and Reduces FeNO Compared With Placebo Add-On to High-Dose ICS	7437 Poster Presentation Tuesday, May 21 11:30 AM – 1:15 PM PDT
Busse	Dupilumab Reduces Severe Exacerbations and Improves Lung Function in Patients with Type 2 Asthma Irrespective of Asthma Duration	8322 Poster Presentation Tuesday, May 21 11:30 AM – 1:15 PM PDT
Do	Characterization of Patients with Severe Asthma Who Initiated Biologic Treatment Within ≤90 and >90 days After Biologic Eligibility	8484 Poster Presentation Wednesday, May 22 8:15 – 10:15 AM PDT
Jackson	Dupilumab Efficacy by Baseline Disease Severity Among Children with Uncontrolled Moderate-to-severe Asthma: Post-hoc Results from the Randomized, Placebo-controlled VOYAGE Trial	8302 Poster Presentation Tuesday, May 21 2:15 – 4:15 PM PDT
Lipworth	Improved Lung Function Is Associated With Better Asthma Control in Adolescents and Adults Aged 12 Years and Older With Moderate-to-Severe Type 2 Asthma: A Post hoc Analysis of QUEST	7469 Poster Presentation Tuesday, May 21 11:30 AM – 1:15 PM PDT
Pavord	Impact of Early Transient Increase in Eosinophil Count on the Long-Term Efficacy of Dupilumab in Patients With Moderate-to-Severe Asthma: LIBERTY ASTHMA TRAVERSE	7451 Poster Presentation Tuesday, May 21 11:30 AM – 1:15 PM PDT
Porsbjerg	Effect of Dupilumab Treatment on Mucus Plugging and Mucus Volume in Type 2 Asthma: The Phase 4 VESTIGE Trial	15171 Poster Presentation Sunday, May 19 11:30 AM – 1:15 PM PDT
Laidlaw	Efficacy and Safety of Rilzabrutinib - A Novel Oral Treatment in Asthma: Results From a Double Blind Placebo Controlled Phase 2b Study	15074 Poster Presentation Wednesday, May 22 8:15 – 10:15 AM PDT

Brahmachary	Single-Cell RNA Sequencing Analysis of Blood and Nasal Brushing From Asthma Patients Receiving a Single Dose of SAR443765, a novel, bispecific anti-TSLP/anti-IL-13 NANOBODY® Molecule Reveals Significant Impact on Multiple Pathological Immune Cell Populations and Downregulation of CCL26 Expression in Epithelial Cell Subpopulations	Oral Presentation Monday, May 20 10:15 – 10:27 AM PDT

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 two of the key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including in certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis (EoE), prurigo nodularis, and chronic spontaneous urticaria (CSU) in different age populations. More than 850,000 patients are being treated with Dupixent globally. Dupixent is currently under Priority Review by the U.S. Food and Drug Administration as an add-on maintenance treatment in certain adult patients with uncontrolled COPD.

About rilzabrutinib
Rilzabrutinib is an investigational oral, reversible, covalent BTK inhibitor that has the potential to be a first- or best-in-class treatment of a number of immune-mediated diseases, including CSU, prurigo nodularis, asthma, immune thrombocytopenia (ITP), IgG4-related disease and warm autoimmune hemolytic anemia (wAIHA). BTK is expressed in B cells, mast cells, eosinophils, basophils and macrophages which play a critical role in multiple immune-mediated disease processes. With the application of Sanofi's TAILORED COVALENCY® technology, rilzabrutinib can selectively inhibit the BTK target while potentially reducing the risk of off-target side effects.

About lunsekimig
Lunsekimig is an investigational novel nanobody VHH that combines targeting of IL-13, a downstream cytokine causing tissue organ damage in respiratory diseases and TSLP, an upstream initiator of inflammation. Pre-clinical research suggests that the combination of these targets can create more potent effect on type-2 inflammation, making lunsekimig a potentially best-in-class treatment for asthma and a range of other respiratory diseases.

Rilzabrutinib and Lunsekimig are under clinical investigation and their safety and efficacy have not been evaluated by any regulatory authority.

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 chronic pruritus of unknown origin, chronic obstructive pulmonary disease (COPD) 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 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 the world, 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 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 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, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.