Media Update

ATS: Sanofi showcases leadership and breadth of scientific innovation in chronic inflammatory respiratory conditions

- 33 abstracts across Sanofi's immunology portfolio and pipeline to be featured, including one oral presentation and four late-breaking posters
- New COPD data for Dupixent from phase 3 studies assess the impact on multiple measures of lung function and health-related quality of life in broad populations of patients with type 2 inflammation

Paris, May 1, 2025. New data from 33 abstracts, including one oral presentation and four late-breaking posters will be presented at the American Thoracic Society (ATS) International Conference in San Francisco, CA, US from May 18 to 21, 2025, reinforcing Sanofi's leadership in advancing chronic respiratory disease research and addressing critical inflammatory pathways, including drivers of type 2 inflammation. Presentations related to Dupixent, which is developed in partnership with Regeneron, include notable new analyses from the BOREAS and NOTUS phase 3 studies evaluating Dupixent in patients with chronic obstructive pulmonary disease (COPD).

> ***Alyssa Johnsen, MD, PhD***
> Global Therapeutic Area Head, Immunology and Oncology Development
> *"The breadth of data featured at ATS reinforce our ongoing commitment to leveraging immunoscience expertise in pursuit of transformative advancements in the treatment of chronic respiratory conditions. Across the Dupixent clinical program and our immunology pipeline, these results hold promise to make a positive impact on key clinical endpoints, including lung function, across chronic obstructive pulmonary disease, asthma and other diseases."*

Notable presentations across approved and pipeline medicines include:

Dupixent in COPD

New COPD data will be featured assessing the impact of Dupixent on lung function and exacerbations in COPD, including patients with or without emphysema.

- Pooled results from the pivotal landmark Phase 3 BOREAS and NOTUS studies shows Dupixent reduced exacerbations and improved lung function regardless of whether patients had emphysema.
- Additional data being presented shows that Dupixent improved multiple spirometry measures of lung function that were sustained through 52 weeks, compared to placebo.
- A late-breaking poster of a win-ratio post-hoc analysis assessed the likelihood of avoiding a composite of events including death, hospitalization, worsening symptoms and lung function decline in the COPD pivotal studies comparing Dupixent to placebo.

Safety results from both BOREAS and NOTUS COPD studies were generally consistent with the known safety profile of Dupixent in its other approved indications. In pooled data from both studies, the most common adverse events (AEs; ≥2%) more frequently observed with Dupixent than placebo were viral infection, headache, nasopharyngitis, back pain, diarrhea, arthralgia, urinary tract infection, local administration reaction, rhinitis, eosinophilia, toothache and gastritis. In the pivotal COPD studies, the majority of patients had chronic bronchitis (≥95%) and ≥30% had emphysema.

Dupixent in asthma

New asthma data reinforces the impact of Dupixent on lung function and exacerbations.

- **VESTIGE phase 4 study:** late-breaking poster shows Dupixent reduced mucous burden, as measured by mucous plug scores and volume, and regardless of baseline fractional exhaled nitric oxide levels, as early as week 4.

- **VOYAGE phase 3 study:** an analysis shows that in children aged 6 to 11 years with evidence of type 2 inflammation, Dupixent reduced exacerbations and improved disease control, as measured by the proportion of patients scoring ≤0.75 on the Interviewer-Administered 7-item Asthma Control Questionnaire, regardless of how long they have had disease.

The safety results in the above asthma studies were generally consistent with the known safety profile of Dupixent in moderate-to-severe asthma, with the addition of helminth infections in the VOYAGE study. In VOYAGE, the most common AEs (≥5%) more frequently observed with Dupixent than placebo were nasopharyngitis, viral upper respiratory tract infections, eosinophilia and injection site reactions. In VESTIGE, the most common AEs (≥5%) more frequently observed with Dupixent than placebo included COVID-19 and injection site reactions.

- **LIBERTY ABPA AIRED phase 2 study:** an oral presentation shows results of Dupixent on lung function, exacerbations and health-related QoL, as measured by the St. George's Respiratory Questionnaire, in adults with allergic bronchopulmonary aspergillosis (ABPA) and asthma. ABPA is a progressive lung disease caused by hypersensitivity to a fungal microorganism that can live in the airways of patients with asthma and other breathing disorders.

Immunology pipeline

New data from Sanofi's immunology pipeline will be featured, including new analyses evaluating rilzabrutinib in moderate-to-severe asthma, and transcriptomic data in patients with COPD to understand how combined targeting of the IL-13 and TSLP pathways may be a potential treatment approach.

- Results from a phase 2 study showing rilzabrutinib reduced loss of asthma control events in uncontrolled adult patients with moderate-to-severe asthma, as highlighted by a decrease in rescue medication use over 12 weeks.
- New data demonstrating the rationale for combined IL-13 and TSLP targeting in certain patients with COPD.

Rilzabrutinib is an investigational medicine, and its safety and efficacy have not been evaluated by any regulatory authority.

Complete list of ATS presentations:

Presenting author	**Abstract title**	**Presentation details**
Chronic obstructive pulmonary disease		
Bafadhel	Stability of Blood Eosinophil Counts in Patients With Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation in the BOREAS and NOTUS Trials	Poster #P660 Late-Breaking Poster Presentation May 20, 2025 11:30 a.m. – 1:15 p.m. PST
Bafadhel	Use of Systemic Corticosteroids and Antibiotics in Patients With Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation Receiving Dupilumab	Poster #P659 Late-Breaking Poster Presentation May 20, 2025 11:30 a.m. – 1:15 p.m. PST
Ramakrishnan	Win Ratio Analysis of BOREAS and NOTUS: Faster Trials, Clearer Wins for Patients With Chronic Obstructive Pulmonary Disease With Type 2 Inflammation	Poster #P1017 Late-Breaking Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST

Bafadhel	Impact Of Dupilumab Treatment on Lung Function in Patients With Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation	Poster #P946 Poster Presentation May 19, 2025 11:30 a.m. – 1:15 p.m. PST
Bhatt	Assessing the Risks of Exacerbations and Mortality Among COPD Patients in the Global Initiative for Chronic Obstructive Lung Disease Category E Based on Blood Eosinophils Level and Smoking Status	Poster #617 Poster Presentation May 19, 2025 9:15 a.m. – 11:15 a.m. PST
Bhatt	Dupilumab Efficacy in Patients With Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation With and Without Emphysema	Poster #P1420 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Christenson	Dupilumab Efficacy in Patients With Chronic Obstructive Pulmonary Disease (COPD) With Type 2 Inflammation Across Baseline Eosinophil Counts	Poster #P1419 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Couillard	Reduction of Exacerbations According to Type 2 Inflammatory Biomarkers With Dupilumab Treatment in Patients With Chronic Obstructive Pulmonary Disease (COPD)	Poster #P1418 Poster Session May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Han	Dupilumab Improves Lung Function in Patients With Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation: A Pooled Analysis from the Phase 3 NOTUS and BOREAS Trials	Poster #P1411 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Hanania	Dupilumab Efficacy on Chronic Obstructive Pulmonary Disease (COPD) Exacerbations and Lung Function by Cough and Sputum Score: Pooled Results from Phase 3 BOREAS and NOTUS	Poster #1018 Poster Presentation May 19, 2025 2:15 p.m. – 4:15 p.m. PST
Herrera	Assessment of Symptom Burden and Related Quality of Life in GOLD E COPD Patients in the United States via a Real-World Cross-Sectional Survey	Poster #P955 Poster Presentation May 19, 2025 11:30 a.m. – 1:15 p.m. PST
Herrera	Symptom Burden and COPD Quality of Life by Smoking Status and Eosinophil Level: a United States Cross-Sectional Survey	Poster #P956 Poster Presentation May 19, 2025 11:30 a.m. – 1:15 p.m. PST
Mularski	Variability of Eosinophil Levels Over Time in Chronic Obstructive Pulmonary Disease Patients Within an Integrated Healthcare Delivery System	Poster #P261 Poster Presentation May 19, 2025 11:30 a.m. – 1:15 p.m. PST
Ramakrishnan	Type 2 Inflammatory Biomarkers and Lung Function Improvement in Patients With Chronic Obstructive Pulmonary Disease (COPD) Receiving Placebo Therapy	Poster #P1533 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Singh	Dupilumab Efficacy in Patients With Chronic Obstructive Pulmonary Disease (COPD) and Type 2 Inflammation by Evaluating Respiratory Symptoms in COPD (E-	Poster #P949 Poster Presentation May 19, 2025

	RS:COPD) Breathlessness and St. George's Respiratory Questionnaire (SGRQ) Activity Scores	11:30 a.m. – 1:15 p.m. PST
Singh	Impact of Dupilumab on Type 2 Inflammatory Biomarkers in Patients With Chronic Obstructive Pulmonary Disease (COPD)	Poster #P1532 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Han/Mattoo	Leveraging Transcriptomic Data to Investigate the Biology of IL13 and TSLP in COPD	Poster #802 Poster Presentation May 19, 2025 9:15 a.m. – 11:15 a.m. PST
Waghray/Habiel	Modeling Effects of Smoking and Smoking Cessation in COPD Airways Using Human Airway Organoids	Poster #P5 Poster Presentation May 19, 2025 11:30 a.m. – 1:15 p.m. PST
ABPA and Asthma		
Bourdin	Dupilumab Improves Lung Function, Asthma Control and Exacerbation Frequency in Allergic Bronchopulmonary Aspergillosis - Results from the Phase 2 LIBERTY ABPA AIRED Study	Oral Presentation May 20, 2025 9:15 a.m. – 9:27 a.m. PST
Asthma		
Bourdin	Association Between Baseline Fractional Exhaled Nitric Oxide and Mucus Response in Patients With Uncontrolled Moderate-to-Severe Asthma Treated With Dupilumab in the VESTIGE Study	Poster #P665 Late-Breaking Poster Presentation May 20, 2025 11:30 a.m. – 1:15 p.m. PST
Al-Ahmad	Characteristics of Patients With Severe Asthma Initiating Dupilumab in a Real-World Setting: The REVEAL Registry	Poster #P1436 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Brusselle	Impact of Dupilumab on Type 2 Inflammatory Biomarkers in Asthma by Clinical Remission Status	Poster #1024 Poster Presentation May 19, 2025 2:15 p.m. – 4:15 p.m. PST
Busse	Reduction in the Use of Rescue Medication for Asthma Symptom Relief With Rilzabrutinib: Results from a Phase 2 Study	Poster #P1371 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Castro	Association Between Improvements in Mucus Score and Volume and Changes in Type 2 Biomarkers in Patients with Moderate-To-Severe Asthma Receiving Dupilumab in the VESTIGE Study	Poster #P1428 May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Côté	Dupilumab Improves Health-Related Quality of Life and Asthma Control in Patients With and Without Coexisting Type 2 Conditions: Results from the RAPID Study	Poster #P1441 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Cox	Comparison of Systemic Corticosteroid Use (SCS) for Asthma in Family Medicine Versus	Poster #P78 Poster Presentation May 19, 2025

	Internal Medicine Specialty Care: A Real-World Study	11:30 a.m. – 1:15 p.m.
Hossain	FeNO as a Prognostic Biomarker for Clinical Response in Asthma: An Evaluation of Response Thresholds	Poster #P1519 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Lugogo	Safety and Efficacy of Dupilumab in Adults and Adolescents With Asthma in the RAPID Registry	Poster #P1412 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Phipatanakul	Dupilumab Reduces Exacerbations and Improves Asthma Control in Children Regardless of Asthma Duration	Poster #P1416 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Walker	Disease Burden of Asthma in African Americans in the US: Real World Data Analysis	Poster #P1455 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Watz	Severe Asthma After 2 Years of Dupilumab Therapy: Real-World Data from the ProVENT Study	Poster #P1414 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST
Wechsler	RNA Sequencing Analysis of Nasal Brushings from Participants Administered Rilzabrutinib 1200 mg Demonstrated an Impact on Multiple Pathways Relevant for Asthma	Poster #1005 Poster Presentation May 21, 2025 11:00 a.m. – 1:00 p.m. PST
Aldhouse/Wells	Towards Patient-Centric Asthma Endpoints: A Targeted Review of Exacerbation, Control, and Remission Concepts	Poster #P1450 Poster Presentation May 18, 2025 11:30 a.m. – 1:15 p.m. PST

About Dupixent

Dupixent (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the interleukin (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 studies, establishing that IL-4 and IL-13 are two of the key and central drivers of 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 certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, and chronic obstructive pulmonary disease in different age populations. More than 1,000,000 patients are currently 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 studies 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 studies, including chronic pruritus of unknown origin, bullous pemphigoid and lichen simplex chronicus. 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 rilzabrutinib

Rilzabrutinib is an oral, reversible, covalent BTK inhibitor that has the potential to be a first- and best-in-class treatment of several immune-mediated diseases, including asthma, chronic spontaneous urticaria, IgG4-related disease, immune thrombocytopenia and warm autoimmune hemolytic anemia. BTK, expressed in B cells, macrophages, and other immune cells, plays a critical role in inflammatory pathways and 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. Rilzabrutinib is currently under regulatory review in the US, EU and China for potential use in immune thrombocytopenia. In April 2025, the US Food and Drug Administration granted rilzabrutinib Orphan Drug Designation for warm autoimmune hemolytic anemia and IgG4-related disease.

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

Media Relations

Sandrine Guendoul | +33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com
Nicolas Obrist | +33 6 77 21 27 55 | nicolas.obrist@sanofi.com
Léo Le Bourhis | +33 6 75 06 43 81 | leo.lebourhis@sanofi.com
Victor Rouault | +33 6 70 93 71 40 | victor.rouault@sanofi.com
Timothy Gilbert | +1 516 521 2929 | timothy.gilbert@sanofi.com

Investor Relations

Thomas Kudsk Larsen |+44 7545 513 693 | thomas.larsen@sanofi.com
Alizé Kaisserian | +33 6 47 04 12 11 | alize.kaisserian@sanofi.com
Felix Lauscher | +1 908 612 7239 | felix.lauscher@sanofi.com
Keita Browne | +1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | +33 7 85 93 30 17 | nathalie.pham@sanofi.com
Tarik Elgoutni | +1 617 710 3587 | tarik.elgoutni@sanofi.com
Thibaud Châtelet | +33 6 80 80 89 90 | thibaud.chatelet@sanofi.com
Yun Li | +33 6 84 00 90 72 | yun.li3@sanofi.com

Sanofi forward-looking statements

This media update 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 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, 2024. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.