Media Update

ERS: new data across Sanofi's immunology pipeline reinforce leadership in respiratory diseases

- 31 abstracts to be presented across chronic inflammatory respiratory diseases, including four oral presentations and two late-breaking abstracts
- Late-breaking abstracts will include the TIDE-Asthma phase 2 study of amlitelimab and a new analysis evaluating the impact of Dupixent (dupilumab) on severe exacerbations in COPD

Paris, September 4, 2025. New data from 31 abstracts highlighting the potential of Sanofi's approved and pipeline medicines to address critical gaps in care across chronic inflammatory respiratory diseases will be presented at the European Respiratory Society (ERS) International Congress. Data from Sanofi's extensive immunology pipeline, including late-breaking data from the TIDE-Asthma phase 2 study (clinical study identifier: NCT05421598) evaluating amlitelimab, a fully human non-T cell depleting monoclonal antibody that blocks OX40-ligand (OX40L), in adult patients with moderate-to-severe asthma, will be featured.

Presentations related to Dupixent, which is developed in partnership with Regeneron, further solidify its role in improving outcomes across chronic respiratory conditions, including a late-breaking analysis from the BOREAS and NOTUS phase 3 studies (clinical study identifiers: NCT03930732 and NCT04456673) in chronic obstructive pulmonary disease (COPD). In addition, results from the EVEREST phase 4 head-to-head study (clinical study identifier: NCT04998604) in patients with chronic rhinosinusitis with nasal polyps (CRSwNP) and coexisting asthma will be shared in an oral presentation and simultaneously published in *The Lancet Respiratory* on Sunday, September 28 at 15:45 CEST.

> *"Chronic respiratory diseases can manifest through severe and aggressive symptoms and pose a significant burden on patients, which is why we are steadfast in our approach to research and treatment development," said* ***Alyssa Johnsen****, MD, PhD, Global Therapeutic Area Head, Immunology and Oncology Development at Sanofi. "Our presentations at ERS underscore our commitment to addressing unmet patient needs and our goal of helping patients breathe better. New data from our immunology pipeline reinforce our progress across novel mechanisms and modalities, including amlitelimab, for the treatment of asthma. We also look forward to sharing results from our robust clinical program for Dupixent, which offer new insights into the future of treating asthma and chronic obstructive pulmonary disease."*

The ERS International Congress will be held in Amsterdam, Netherlands from September 27 to October 1, 2025. Notable presentations across pipeline and approved medicines include:

Immunology pipeline

New data for medicines in the immunology pipeline to be presented include:

- **TIDE-Asthma phase 2 study**: results evaluating amlitelimab in adult patients with moderate-to-severe asthma, including data on exacerbations, lung function and asthma control in a select biomarker defined population.

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

Dupixent

New data evaluating Dupixent's impact on severe exacerbations, lung function and other key outcomes will be presented including:

COPD:

- **BOREAS and NOTUS phase 3 studies**: a late-breaking analysis assessing the impact of Dupixent on severe exacerbations.

Asthma:

- New data assessing the impact of Dupixent plus medium-dose inhaled corticosteroids compared to high-dose corticosteroids on clinical remission rates in adults and adolescents, as well as lung function and asthma control in children aged 6 to 11 years.

CRSwNP and Asthma:

- **EVEREST phase 4 study**: an oral presentation featuring results of the first-ever presented head-to-head trial in respiratory biologics evaluating Dupixent compared to omalizumab in patients with CRSwNP and coexisting asthma.

Complete list of ERS presentations:

Presenting author	**Abstract title**	**Presentation**
Chronic obstructive pulmonary disease		
Bafadhel	Dupilumab Reduces the Risk of Severe Exacerbations in Patients with Chronic Obstructive Pulmonary Disease: Results from BOREAS and NOTUS	# PA4778 Poster Presentation Tuesday, Sept 30 08:00 - 09:30 CEST
Bafadhel	Association Between Dupilumab and Repeated Exacerbations of Chronic Obstructive Pulmonary Disease: BOREAS and NOTUS	# PA4573 Poster Presentation Tuesday, Sept 30 08:00 - 09:30 CEST
Bhatt	Relationship Between Improvement in Lung Function and Patient-Reported Outcomes in Chronic Obstructive Pulmonary Disease with Dupilumab Treatment: Casual Mediation Analyses	# PA4577 Poster Presentation Tuesday, Sept 30 08:00 – 09:30 CEST
Franssen	Relationship Between Early Lung Function Improvement with Dupilumab and Long-Term Clinical Improvement in Chronic Obstructive Pulmonary Disease	# PA2471 Poster Presentation Monday, Sept 29 08:00 – 09:30 CEST
Hanania	The Number Needed to Treat with Dupilumab to Prevent Moderate or Severe Chronic Obstructive Pulmonary Disease Exacerbations: BOREAS and NOTUS	# PA4574 Poster Presentation Tuesday, Sept 30 08:00 – 09:30 CEST
Hurst	Dupilumab Efficacy in Patients with Chronic Obstructive Pulmonary Disease and Cardiovascular or Metabolic Disease: BOREAS and NOTUS	# PA4575 Poster Presentation Tuesday, Sept 30 08:00 – 09:30 CEST

Mannino	Effect of Add-On Dupilumab in Elderly Patients with Chronic Obstructive Pulmonary Disease: BOREAS and NOTUS	# PA4576 Poster Presentation Tuesday, Sept 30 08:00 – 09:30 CEST
Mayen	Cardiovascular Events and Pharmacological Treatment Patterns in Patients with Severe COPD Exacerbations: A US Payer Perspective	# PA370 Poster Presentation Sunday, Sept 28 08:00 - 09:30 CEST
Mayen	Healthcare Resource Utilisation and Healthcare Costs in COPD Patients with Moderate-to-Severe Exacerbations	# PA2560 Poster Presentation Monday, Sept 29 08:00 – 09:30 CEST
Mayen	Psychometric Validation of E-RS:COPD in Patients with Chronic Obstructive Pulmonary Disease	# PA2510 Poster Presentation Monday, Sept 29 08:00 – 09:30 CEST
Molina	Dupilumab as a Treatment in Patients with Gold-E Eosinophilic COPD: Experience in a Second-Level Hospital	# PA4584 Poster Presentation Tuesday, Sept 30 08:00 - 09:30 CEST
Ramakrishnan	Win Ratio Analysis of Dupilumab Efficacy in Patients with Chronic Obstructive Pulmonary Disease and Type 2 Inflammation: BOREAS and NOTUS	# PA4572 Poster Presentation Tuesday, Sept 30 08:00 – 09:30 CEST
<u>Asthma</u>		
Akuthota	Amlitelimab Phase 2 Clinical Trial Results in Patients with Moderate-to-Severe Asthma	# OA1180 Oral Presentation Sunday, Sept 28 09:30 – 9:35 CEST
Al-Ahmad	Baseline Characteristics of Patients with Asthma Initiating Dupilumab in the Real-World REVEAL Registry	# PA478 Poster Presentation Sunday, Sept 28 08:00 – 09:30 CEST
Bacharier	Baseline Asthma Burden by Inhaled Corticosteroid Dose: Patients Initiating Dupilumab in RAPID	# PA5819 Poster Presentation Tuesday, Sept 30 12:30 – 14:00 CEST
Bourdin	Dupilumab Efficacy in Patients with Asthma and Allergic Bronchopulmonary Aspergillosis (ABPA)	# OA2337 Oral Presentation Sunday, Sept 28 16:05 – 16:10 CEST
Canonica	Impact of Dupilumab on Type 2 Inflammatory Biomarkers in Asthma by Baseline Inhaled Corticosteroid Dose and Clinical Remission Status After Treatment	# PA1500 Poster Presentation Sunday, Sept 28 12:30 – 14:00 CEST
Dell	Dupilumab Reduces Severe Exacerbation Rates and Total IgE Levels in Children with Type 2 Asthma, Irrespective of Transient Increase in Eosinophils	# PA5890 Poster Presentation Tuesday, Sept 30 12:30 – 14:00 CEST
Gomez	Burden and Healthcare Resource Utilization Across Asthma Severities	# OA2205 Oral Presentation Sunday, Sept 28

		14:55 – 15:00 CEST
Martincova	Psychometric Validation of the Asthma Daytime/Nighttime Symptom Diary (ADSD/ANSD) in a Phase 2 Trial with Adults with Uncontrolled Asthma	# PA474 Poster Presentation Sunday, Sept 28 08:00 – 09:30 CEST
Maspero	Evaluation of ACQ-5 Components from the Rilzabrutinib Phase 2 Asthma Study	# PA2476 Poster Presentation Monday, Sept 29 08:00 – 09:30 CEST
Maspero	Efficacy Outcomes in Children with Asthma Receiving Dupilumab Plus Medium-Dose Inhaled Corticosteroids vs Children who Receive Placebo and Continue High-Dose Inhaled Corticosteroids	# PA5892 Poster Presentation Tuesday, Sept 30 12:30 – 14:00 CEST
Meng	Correlating FeNO Persistence and Lung Function Trajectories Among Patients with Uncontrolled Asthma	# PA1491 Poster Presentation Sunday, Sept 28 12:30 – 14:00 CEST
Mosnaim	Dupilumab Impact on Clinical Asthma Remission by Baseline Inhaled Corticosteroid Dose	# PA5710 Poster Presentation Tuesday, Sept 30 12:30 – 14:00 CEST
Shade	Impact of Rilzabrutinib on Inflammatory Responses in Human Mast Cells and Eosinophils	# PA380 Poster Presentation Sunday, Sept 28 08:00 – 09:30 CEST
Soliman	Efficacy and Safety of Add-On Dupilumab vs Inhaled Corticosteroid (ICS) Dose Escalation in Patients with Asthma Uncontrolled on Medium-Dose ICS/Long-Acting β2-Agonist (LABA) – AIM4: Next Step Study	# PA479 Poster Presentation Sunday, Sept 28 08:00 – 09:30 CEST
Wang	Identification of Suitable Sputum Processing Methods for Robust Downstream Biomarker Analysis in Bronchiectasis	# PA5269 Poster Presentation Tuesday, Sept 30 08:00 – 09:30 CEST
Watz	Real-World Outcomes After 2 Years of Dupilumab Therapy for Severe Asthma: The ProVENT Study	# PA477 Poster Presentation Sunday, Sept 28 08:00 – 09:30 CEST
<u>Chronic rhinosinusitis with nasal polyps</u>		
Gomez	Characterizing the Burden of CRSwNP in the Biologic Era	# PA1409 Poster Presentation Sunday, Sept 28 12:30 –14:00 CEST
Heffler	Efficacy and Safety of Dupilumab vs Omalizumab in Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) With Asthma (EVEREST Study)	# RCT1114 Oral Presentation Sunday, Sept 28 09:15 – 9:22 CEST
Radwan	Dupilumab Real-World Effectiveness through 18 Months in Patients with CRSwNP and Coexisting Asthma in the AROMA Registry	# PA5821 Poster Presentation Tuesday, Sept 30 12:30 – 14:00 CEST

About Dupixent
Dupixent (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the interleukin 4 (IL4) and interleukin 13 (IL13) 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 IL4 and IL13 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, 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 amlitelimab
Amlitelimab is a fully human, non-T cell depleting monoclonal antibody that blocks OX40L, a key immune regulator. With its novel mechanism of action, amlitelimab aims to normalize the overactive immune system and restore immune balance, without depleting T cells, with the goal of enabling a quarterly dosing interval for patients. It has the potential to be a first- or best-in-class treatment for a range of immune-mediated diseases and inflammatory disorders, including moderate-to-severe atopic dermatitis, moderate-to-severe asthma, systemic sclerosis, celiac disease, and alopecia.

About Sanofi
Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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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.