ERS: New data highlight Sanofi's scientific innovation and leadership in immune-mediated respiratory diseases

- Dupixent presentations of new pooled analyses from the two landmark COPD phase 3 studies, and novel imaging technology insights on airway inflammation in asthma
- Itepekimab phase 2 study oral presentation evaluating the impact on exacerbations in former smokers with COPD
- Additional phase 2 presentations in asthma for rilzabrutinib, a novel oral BTK inhibitor, and lunsekimig, an IL-13/TSLP Nanobody compound.

Paris, August 26, 2024. Sanofi will present twenty-four abstracts across approved and pipeline medicines at the European Respiratory Society (ERS) International Congress from September 7th-11th in Vienna, Austria. Presentations will feature clinical and real-world data for Dupixent (dupilumab) and data for investigational therapy itepekimab (in collaboration with Regeneron) demonstrating the potential of targeting specific types of underlying inflammation across chronic obstructive pulmonary disease (COPD) and asthma to improve patient outcomes. Notable data presentations for Sanofi's extensive immunology pipeline include oral presentations for rilzabrutinib, a novel oral BTK inhibitor, evaluating safety and demonstrating efficacy on asthma symptom control, as well as poster presentations for lunsekimig, a novel IL13/TSLP Nanobody compound in asthma, evaluating its impact on type-2 inflammation.

> ***Dietmar Berger, MD, PhD***
> Chief Medical Officer, Global Head of Development at Sanofi
> *"Our strong presence at this year's ERS conference highlights our diverse, novel research across inflammatory respiratory conditions, including COPD and asthma. For the first time, we will share pooled analyses from the landmark BOREAS and NOTUS trials that reinforce pivotal data, which led to the first approval of a biologic for COPD in the EU. In addition, we look forward to sharing data for two pipeline molecules, rilzabrutinib, a novel oral BTK inhibitor, and lunsekimig, an IL13/TSLP Nanobody compound, showing their potential in asthma. These data underscore our commitment to progressing science to better serve patients suffering from devastating respiratory diseases."*

Notable presentations include:

Dupixent

Data from new analyses of the BOREAS and NOTUS phase 3 clinical studies in adults with uncontrolled COPD with evidence of type-2 inflammation, and new research from the phase 4 VESTIGE study, a novel imaging study evaluating the effects of Dupixent on airway remodeling measures in certain adults with asthma.

<u>COPD</u>

- **BOREAS and NOTUS studies:** poster presentation with a new pooled analysis of both pivotal studies, including data on exacerbations and lung function.
- **BOREAS study:** several poster presentations with detailed outcome assessments of Dupixent on daily symptom frequency and severity, the effect on exacerbations and lung function regardless of baseline body mass index, airflow obstruction, dyspnea (shortness of breath), and exercise capacity measures for adults with uncontrolled COPD with evidence of type-2 inflammation (i.e., raised blood eosinophils). Additional Dupixent data of its impact on quality of life, lung function and symptoms in patients who do not exacerbate.

Asthma

- **VESTIGE study:** two poster presentations with new data on the impact within four weeks of Dupixent treatment on airway inflammation, volume and flow, and mucus plugging, as well as outcomes for clinical remission at four and 24 weeks of treatment in adults with uncontrolled moderate-to-severe asthma. Additionally, an oral presentation on mucus plugging and volume.
- **Real-world data:** two poster presentations of real-world outcomes from the EU-ADVANTAGE study, including symptoms and oral corticosteroid use, for Dupixent compared to the IL5 antibodies benralizumab and mepolizumab, or omalizumab, an IgE antibody.

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

Respiratory pipeline
Data include new analyses for itepekimab, an IL33 antibody, in COPD, and rilzabrutinib, a novel oral BTK inhibitor, and lunsekimig, a IL13/TSLP Nanobody compound, in asthma.

COPD

- **itepekimab**: an oral presentation with new analyses from a COPD phase 2 study on the impact on exacerbations in former smokers regardless of exacerbation history.

Asthma

- **rilzabrutinib**: two oral presentations on the impact of treatment with rilzabrutinib in improving asthma control in adults with moderate-to-severe asthma, and on the role of BTK inhibition in eosinophilic inflammatory response.
- **lunsekimig**: two poster presentations on the broader benefits of lunsekimig, an IL-13/TSLP Nanobody compound on type-2 inflammation and the prevalence of elevated fractional exhaled nitric oxide in patients with mild-to-moderate asthma.

Itepekimab, rilzabrutinib and lunsekimig are investigational agents for which safety and efficacy have not been evaluated by any regulatory authority.

Complete list of ERS 2024 presentations:

Presenting author	**Abstract title**	**Presentation details**
COPD		
Rabe	Reduction in exacerbations with itepekimab in former smokers with chronic obstructive pulmonary disease (COPD) by prior exacerbation frequency (itepekimab)	OA3645 Oral Presentation Monday, September 9 2:15-3:30 PM CEST
Bhatt	Dupilumab Efficacy and Safety in Patients with Moderate-to-Severe COPD with Type 2	PA4787 Poster Presentation Tuesday, September 10

	Inflammation: Pooled Analysis of BOREAS and NOTUS Trials (dupilumab)	12:30-2:00 PM CEST
Papi	Dupilumab improves respiratory symptoms in patients with moderate-to-severe COPD with type 2 inflammation in phase 3 BOREAS trial (dupilumab)	PA4786 Poster Presentation Tuesday, September 10 12:30-2:00 PM CEST
Rabe	Dupilumab improves quality of life in non-exacerbators with moderate-to-severe COPD and type 2 inflammation: phase 3 BOREAS trial (dupilumab)	PA4784 Poster Presentation Tuesday, September 10 12:30-2:00 PM CEST
Rabe	Dupilumab improves lung function in non-exacerbators with moderate-to-severe COPD with type 2 inflammation in phase 3 BOREAS trial (dupilumab)	PA4785 Poster Presentation Tuesday, September 10 12:30-2:00 PM CEST
Vogelmeier	Dupilumab efficacy in patients with COPD and type 2 inflammation irrespective of mortality risk score (dupilumab)	PA4782 Poster Presentation Tuesday, September 10 12:30-2:00 CEST
<u>Asthma</u>		
Bacharier	Clinical remission with dupilumab in children with uncontrolled, moderate-to-severe, type 2 asthma (dupilumab)	RCT3719 Late-Breaking Oral Presentation Monday, September 9 3:30-5:00 PM CEST
Pavord	Impact of early transient increase in eosinophils in patients with moderate-to-severe asthma on the long-term efficacy of dupilumab in TRAVERSE (dupilumab)	OA2779 Oral Presentation Monday, September 9 9:30-10:45 AM CEST
Porsberg	Dupilumab reduces mucus plugging and volume: phase 4 VESTIGE trial (dupilumab)	OA3649 Oral Presentation Monday, September 9 2:35-3:30 PM CEST
Canonica	Effectiveness of dupilumab vs omalizumab in patients with severe asthma – The EU-ADVANTAGE study (dupilumab)	PA2171 Poster Presentation Monday, September 9 8:00-9:30 AM CEST
Chan	Characteristics of long-term oral corticosteroid users stratified by blood eosinophil count in the International Severe Asthma Registry (dupilumab)	PA439 Poster Presentation Sunday, September 8 8:00-9:30 AM CEST
Chan	Phenotype and biomarkers in patients who initiated biologic therapy stratified by oral corticosteroids use in the International Severe Asthma Registry (dupilumab)	PA438 Poster Presentation Sunday, September 8 8:00-9:30 AM CEST
Lugogo	Dupilumab-treated patients with moderate-to-severe asthma are more likely to meet clinical remission criteria: results from the VESTIGE trial (dupilumab)	PA1202 Poster Presentation Sunday, September 8 12:30-2:00 PM CEST
Lugogo	Baseline Characteristics of Patients with Asthma Initiating Dupilumab in a Real-World Setting: the RAPID Registry (dupilumab)	PA4484 Poster Presentation Tuesday, September 10 8:00-9:30 AM CEST

Papi	Early treatment response to dupilumab on airway inflammation, airway dynamics, and mucus plugging in VESTIGE (dupilumab)	PA3933 Poster Presentation Tuesday, September 10 8:00-9:30 AM CEST
Virchow	Real-world effectiveness of dupilumab vs benralizumab and vs mepolizumab in severe asthma: The EU-ADVANTAGE study (dupilumab)	PA2170 Poster Presentation Monday, September 9 8:00-9:30 AM CEST
Wechsler	Dupilumab Reduces Exacerbations and FeNO Levels and Improves Asthma Control with Inhaled Corticosteroid Withdrawal: a Phase 2 Study (dupilumab)	PA5371 Poster Presentation Tuesday, September 10 12:30-2:00 PM CEST
Wechsler	Dupilumab improves lung function and reduces exacerbations despite withdrawal of inhaled corticosteroids/long-acting beta agonists (dupilumab)	PA1172 Poster Presentation Sunday, September 8 12:30-2:00 PM CEST
Shade	Rilzabrutinib, a potent and selective Bruton's tyrosine kinase inhibitor, suppresses reactive oxygen species production and CD11b activation in human eosinophils (rilzabrutinib)	OA1077 Oral Presentation Sunday, September 8 11:40-11:45 AM ET
Pavord	Efficacy of High- and Low-Dose Rilzabrutinib On Asthma Control From a Phase 2 Study (rilzabrutinib)	OA2774 Oral presentation Monday, September 9 9:30-10:45 AM CEST
Deiteren	Elevated fractional exhaled nitric oxide is prevalent in those with mild-to-moderate asthma with self-reported asthma control (lunsekimig)	PA1222 Poster Presentation Sunday, September 8 12:30-2:00 PM CEST
Wang	TSLP AND IL-13 Dual Blockade By Lunsekimig Provides Broader Benefits On Type-2 Inflammation (lunsekimig)	PA4861 Poster Presentation Tuesday, September 10 12:30-2:00 PM CEST
<u>Chronic rhinosinusitis with nasal polyps (CRSwNP)</u>		
Heffler	Baseline Characteristics of Patients with Chronic Rhinosinusitis with Nasal Polyps and Coexisting Asthma Initiating Dupilumab in the AROMA Global Registry (dupilumab)	PA425 Poster Presentation Sunday, September 8 8:00-9:30 AM CEST
Lee	Initiation of dupilumab led to reduced use of oral corticosteroids (OCS) and other medications over 12 months in patients with chronic rhinosinusitis with nasal polyps (CRSwNP): A US real-world practice study (dupilumab)	PA2177 Poster Presentation Monday, September 9 8:00-9:30 AM CEST

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

Sanofi Media Relations
Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | + 1 215 432 0234 | evan.berland@sanofi.com
Victor Rouault | + 33 6 70 93 71 40 | victor.rouault@sanofi.com
Timothy Gilbert | + 1 516 521 2929 | timothy.gilbert@sanofi.com

Sanofi 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
Arnaud Delépine | + 33 6 73 69 36 93 |arnaud.delepine@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

---

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 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, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.