Media Update

AAAAI: new data reinforce Sanofi's leadership in immunology and scientific innovation for patients

- New data evaluating Dupixent across multiple disease areas, including four oral presentations and late-breaking poster presentation in its investigational use in CSU
- New phase 2 data evaluating the use of rilzabrutinib in patients with moderate-to-severe CSU

Paris. February 6, 2025. Sanofi will present 24 abstracts, including four oral presentations and a late-breaking poster, across approved and investigational medicines at the American Academy of Allergy, Asthma and Immunology (AAAAI) Annual Meeting in San Diego, CA from February 28 – March 3, 2025. Presentations in partnership with Regeneron include new pooled results from the investigational use of Dupixent in chronic spontaneous urticaria (CSU) from the LIBERTY-CSU CUPID phase 3 study program (Study A and Study C), as well as data from disease areas, including asthma, chronic obstructive pulmonary disease (COPD), chronic rhinosinusitis with nasal polyps (CRSwNP), and eosinophilic esophagitis (EoE), which demonstrate the use of Dupixent in addressing type 2 inflammation across several inflammatory conditions. New analyses from Sanofi's extensive immunology pipeline, including the RILECSU phase 2 study evaluating rilzabrutinib, a novel oral BTK inhibitor, in adult patients with moderate-to-severe CSU, will also be presented.

> ***Alyssa Johnsen, MD, PhD***
> Global Therapeutic Area Head, Immunology and Oncology Development
> *"Our robust presence at AAAAI emphasizes the progress of our clinical development in immunology and underscores our commitment to transforming treatment paradigms in immunoscience. We look forward to sharing these data across multiple disease areas, building upon the body of clinical evidence supporting the breadth of Dupixent in conditions driven by type 2 inflammation and exemplifying the potential of our pipeline medicines."*

Notable presentations include:

Dupixent

Key presentations highlighting pivotal data from the Dupixent clinical program will be featured.

- **LIBERTY-CSU CUPID phase 3 study:** pooled results from Study A and Study C evaluating Dupixent in patients with moderate-to-severe CSU patients uncontrolled with H1-antihistamines.
- **VESTIGE phase 4 study:** new results evaluating improvements in small airway dysfunction in patients with uncontrolled moderate-to-severe asthma.
- **NOTUS and BOREAS phase 3 studies:** pooled results in adults with COPD and evidence of type 2 inflammation.
- **LIBERTY EoE TREET phase 3 study:** post-hoc analysis in adults and adolescents with EoE, with and without concurrent elimination diet.

In addition to clinical data, Sanofi will also feature five presentations across three disease states demonstrating Dupixent's impact on outcomes in the real-world setting.

Immunology pipeline

New data analyses will be presented from the RILECSU phase 2 study evaluating rilzabrutinib in adult patients with moderate-to-severe CSU, including:

- New results analyzing the effects of rilzabrutinib on angioedema over 12 weeks.
- Subgroup analysis assessing the effect of rilzabrutinib in patients with and without a history of allergic comorbidities.

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

Complete list of AAAAI presentations:

Presenting author	**Abstract title**	**Presentation details**
Asthma		
Bacharier	Baseline Asthma Burden of Patients Who Initiated Dupilumab In The RAPID Registry, Stratified By Dose Of Inhaled Corticosteroid	Poster #709 Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Canonica	Baseline Characteristics Associated With Multicomponent Clinical Remission Following Dupilumab Treatment In Patients With Moderate-To-Severe Asthma	Poster #63 Poster Session February 28, 2025 2:45 p.m. – 3:45 p.m. PST
Castro	Patients With Moderate-to-Severe Asthma Receiving Dupilumab Are More Likely to Meet 4 Key Clinical Remission Criteria: Results From the VESTIGE Trial	Poster #705 Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Fiocchi	Long-Term Effects Of Dupilumab On Children With Type 2 Asthma With Or Without Evidence Of Allergy	Poster #101 Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Lipworth	Dupilumab Produces Clinically Relevant Improvement in Small Airway Dysfunction in Patients With Moderate-to-Severe Asthma: Results From the Phase 4 VESTIGE Study	Oral Abstract Session March 3, 2025 1:20 p.m. – 1:30 p.m. PST
Peters	The Safety and Efficacy of Dupilumab in a Real-World Clinical Setting: The RAPID Asthma Prospective Registry	Poster #230 Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Bourdin	Real-World Effectiveness of Dupilumab vs Omalizumab, Benralizumab, and Mepolizumab on Lung Function Improvement in Severe Asthma Patients: Findings from the EU-ADVANTAGE Study	Poster #715 Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Chronic obstructive pulmonary disease		
Bhatt	Efficacy and Safety of Dupilumab in Patients with Chronic Obstructive Pulmonary Disease and Type 2 Inflammation: Pooled Analysis of BOREAS and NOTUS Trials	Oral Abstract Session March 3, 2025 12:50 p.m. – 1:00 p.m. PST
Chronic rhinosinusitis with nasal polyps		
Buchheit	Real-World Dupilumab Effectiveness Through 18 months In Patients With CRSwNP And Coexisting Asthma: Results From The Global AROMA Registry	Poster #232 Poster Session February 28, 2025 2:45 p.m. – 3:45 p.m. PST
Han	Predictive Characteristics of Sino-Nasal Surgery in CRSwNP Patients in the US from a Large Physician Network Database	Poster #231 Poster Session February 28, 2025 2:45 p.m. – 3:45 p.m. PST
Lee	A Study of dupilumab in adults with CRSsNP: results from the Liberty ORION study	Poster #237 Poster Session February 28, 2025 2:45 p.m. – 3:45 p.m. PST
Peters	Dupilumab Effectiveness Through Two Years In Patients With CRSwNP Treated In Real-World Practice: Results From The Global AROMA Registry	Oral Presentation #579 Oral Abstract Session March 3, 2025 2:00 p.m. – 3:15 p.m. PST

White	Real-World Effectiveness Of Dupilumab Through 18 months In Patients With CRSwNP And Coexisting AERD: Results From The Global AROMA Registry	Poster #924 Poster Session March 2, 2025 3:30 p.m. – 5:00 p.m. PST
Eosinophilic esophagitis		
Aceves	Dupilumab Is Efficacious in Children With Eosinophilic Esophagitis (EoE) Weighing ≥15kg Independent of Individual Atopic Comorbidity History: 16-Week Results From the Phase 3 EoE KIDS Study	Poster #454 Poster Session March 1, 2025 9:45 a.m. – 10:45 a.m. PST
Cianferoni	Dupilumab Efficacy In Adolescents And Adults With Eosinophilic Esophagitis With And Without Concurrent Elimination Diet: Post Hoc Analysis Of LIBERTY EoE TREET At 52 Weeks	Poster #453 Poster Session March 1, 2025 9:45 a.m. – 10:45 a.m. PST
Spergel	Dupilumab Leads To Rapid And Sustained Improvements In Symptoms Of Dysphagia And Dysphagia-Related Pain In Patients With Eosinophilic Esophagitis (EoE): Post Hoc Analysis Of Part C Of The LIBERTY EoE TREET Study	Oral Abstract Session March 3, 2025 1:10 p.m. – 1:20 p.m. PST
Atopic dermatitis		
Berdyshev	Pediatric Atopic Dermatitis Is Associated With More Rapid Recovery of Protein Bound Ceramides After Treatment With Dupilumab	Poster #625 Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Goleva	The Abnormal Metabolomic Activity in Atopic Dermatitis Skin Is Restored With Dupilumab	Poster #611 Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Irvine	Growth Analysis in Children Aged 6 to 11 Years and Adolescents Aged 12 to 17 Years With Moderate-To-Severe Atopic Dermatitis and Impact of 16 Weeks of Dupilumab Treatment on Height	Poster #639 Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Chronic spontaneous urticaria		
Casale	Dupilumab Improves Signs And Symptoms Of Chronic Spontaneous Urticaria Regardless Of Baseline Body Mass Index	Poster #TBD Poster Session March 2, 2025 9:45 a.m. – 10:45 a.m. PST
Gimenez-Arnau	Dupilumab Improves Itch And Urticaria Activity in Patients With Chronic Spontaneous Urticaria: Pooled Results From Two Phase 3 Trials (LIBERTY-CSU CUPID Study A and Study C)	Late-Breaking Poster Poster #TBD Poster Session March 3, 2025 9:45 a.m. – 10:45 a.m. PST
Bernstein	Real-world Treatment Patterns Amongst Patients with Chronic Spontaneous Urticaria Initiating Advanced Therapies	Poster #597 Poster Session March 2, 2025 3:30 p.m. – 5:00 p.m. PST
Bernstein	Effects of Rilzabrutinib on Angioedema over 12 Weeks: Results from the Phase 2 RILECSU Trial in Participants With Moderate-to-Severe Chronic Spontaneous Urticaria	Poster #694 Poster Session March 2, 2025 9:45 a.m. -10:45 a.m.
Talia	Rilzabrutinib Improves Chronic Spontaneous Urticaria in Patients With and Without Allergic Comorbidities: A Subgroup Analysis From the RILECSU Study	Poster #694 Poster Session March 2, 2025 9:45 a.m. -10:45 a.m.

About Dupixent

Dupixent (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the IL4 and 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 play 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, CSU, and chronic obstructive pulmonary disease in different age populations. More than 1,000,000 patients are currently being treated with Dupixent globally.

Dupixent 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 in part by type-2 inflammation or other allergic processes in phase 3 studies, including chronic pruritus of unknown origin 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.

Dupixent has been approved for CSU in Japan and the United Arab Emirates (UAE) and is also under regulatory review in the US and EU based on earlier study readouts. Outside of Japan and the UAE, the safety and efficacy of Dupixent for CSU has 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 and inflammatory diseases. 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.

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 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 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.