Media Update

EADV: Sanofi builds on legacy in immunology with new data highlighting advances in treatment of chronic inflammatory skin diseases

- New positive analyses for Dupixent across atopic dermatitis, prurigo nodularis and chronic spontaneous urticaria
- New phase 2a results for brivekimig evaluating efficacy and safety in moderate-to-severe hidradenitis suppurativa

Paris, September 3, 2025. Sanofi will present data from 45 abstracts, including 4 oral presentations, across approved and investigational medicines at the European Academy of Dermatology and Venereology (EADV) Congress in Paris, France from September 17 to 20, 2025. Presentations in partnership with Regeneron include studies assessing the impact of Dupixent across various inflammatory skin diseases, including atopic dermatitis (AD), prurigo nodularis (PN) and chronic spontaneous urticaria (CSU). From Sanofi's extensive immunology pipeline, new analyses will be shared, including an oral presentation featuring for the first time, results from the HS-OBTAIN phase 2a study evaluating brivekimig, a dual-target nanobody VHH inhibiting tumor necrosis factor (TNF) and OX40 ligand (OX40L), in adult patients with moderate-to-severe hidradenitis suppurativa (HS).

> *"Our wide range of data being presented at EADV is a testament to our relentless focus on advancing transformative therapies to treat patients living with a variety of chronic inflammatory skin diseases, many of whom are in urgent need of novel therapeutic options," said **Alyssa Johnsen**, MD, PhD, Global Therapeutic Area Head, Immunology and Oncology Development at Sanofi. "Our Dupixent data builds on the growing body of evidence in atopic dermatitis, including clinical and real-world data evaluating longer-term outcomes in children as well as adult patients with skin of color. In addition, the first results for brivekimig in hidradenitis suppurativa support that targeting the OX40L pathway and TNF blockade together may be a promising strategy to reduce inflammation and improve HS."*

Notable presentations across approved and pipeline medicines include:

Dupixent

Presentations highlighting data from the Dupixent clinical program will be featured, including studies across AD, PN, and CSU. Key posters include:

Atopic dermatitis

- **LIBERTY PEDS AD study** (clinical study identifier: NCT03345914): an analysis examining the impact of Dupixent on growth in children with AD.
- **DISCOVER study** (clinical study identifier: NCT05590585): an analysis evaluating the impact of Dupixent on skin structure in individuals with skin of color, including lesions and epidermal thickness, as measured by a 3D-imaging technique in adults.
- Three abstracts from open-label extension and real-world studies examining the effect of Dupixent on long-term outcomes up to four years in children with skin of color.

Prurigo nodularis

- **PRIME and PRIME2 studies** (clinical study identifiers: NCT04183335 and NCT04202679): analyses evaluating the impact of Dupixent on the multi-dimensional burden of the disease, including the physical lesions and feelings of itch, skin pain, and stinging as well as the emotional burden of embarrassment and self-consciousness.

Chronic spontaneous urticaria

- **CUPID study A and study C** (clinical study identifier: NCT04180488): assessing early and sustained effects of Dupixent on itch and hives.

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

Immunology pipeline

New data from Sanofi's immunology pipeline will be featured, with studies evaluating brivekimig in moderate-to-severe HS, amlitelimab in moderate-to-severe AD and a proof of mechanism study for SAR445399, a novel IL1R3 monoclonal antibody (mAb) in reducing skin inflammation. Key oral presentations include:

- **HS-OBTAIN phase 2a study** (clinical study identifier: NCT05849922): 16-week results assessing the efficacy and safety of brivekimig in adults with moderate-to-severe HS.
- **STREAM-AD phase 2b study** (clinical study identifier: NCT05131477): 52-week results evaluating the maintenance of treatment response with amlitelimab in moderate-to-severe AD.
- **RILECSU phase 2 study** (clinical study identifier: NCT05107115): 12-week results evaluating the effects of rilzabrutinib on angioedema in participants with moderate-to-severe CSU.
- Proof-of-mechanism study evaluating SAR445399, a novel IL1R3 mAb in reducing skin inflammation via the IL1 and IL36 pathways.

Brivekimig, amlitelimab and rilzabrutinib are investigational and no conclusions regarding efficacy and safety should be drawn.

Complete list of EADV presentations:

Presenting author	**Abstract title**	**Presentation details**
Atopic dermatitis		
Alexis	Dupilumab Monotherapy in Patients with Skin of Color and Moderate-to-Severe Atopic Dermatitis: Results from a Phase 4, Open-Label Study	e-Poster P3377
Barbarot	Dupilumab Monotherapy for 1 Year Provides Rapid and Sustained Improvement in SCORAD Across Dose Regimens in Adults with Moderate-to-Severe Atopic Dermatitis	e-Poster P2883
Beck	Patients Who Do Not Flare During Maintenance Treatment with Dupilumab Monotherapy for 1 Year Have Lower Baseline CCL17/TARC Regardless of Dose Regime	e-Poster P3845
Blauvelt	Durable Maintenance of EASI-90 with Amlitelimab in Adults with Moderate-to-Severe Atopic Dermatitis: 52-Week Results From the STREAM-AD Phase 2b Trial	Oral Presentation Friday, Sept 19 16:00 CEST
Chovatiya	Design and Rationale of ARMADA-AD Disease Registry: An International, Prospective, Observational Registry to Characterize Unmet Needs and Evaluate Real-World Effectiveness and Safety of Systemic Therapies in Adults and Adolescents with Atopic Dermatitis	e-Poster P0329
Cork	Dupilumab Treatment Restores Stratum Corneum Lipid Structure and Skin Barrier Function in Patients Aged 6 to 11 Years with Moderate-to-Severe Atopic Dermatitis	e-Poster P2967
Cork	Long-Term Dupilumab Treatment Resulted in Consistent Anatomic Regions	e-Poster P3290

	Improvements in Pediatric Patients with Severe Atopic Dermatitis	
Gray	Unveiling the Burden and Impact of Flare in Patients with Moderate-to-Severe Atopic Dermatitis: Results from the Adelphi Real World Disease Specific Program in Europe	e-Poster P0328
Gray	Understanding the Burden of Flares in Patients with Moderate-to-Severe Atopic Dermatitis: A Targeted Literature Review	e-Poster P0363
Irvine	Growth Improvement in Children 6-11 Years with Severe Atopic Dermatitis Treated with Dupilumab Irrespective of TCS Use	e-Poster P3297
Irvine	Real-World EASI Component Outcomes in Children Receiving Systemic Therapies for up to 4 Years (PEDISTAD Study)	e-Poster P3283
Kimball	Impact of Dupilumab on Mental and Emotional Well-Being in Patients with Moderate-to-Severe Atopic Dermatitis	e-Poster P3831
Kimball	Patient Perception of Life Course Impairment with Moderate-to-Severe Atopic Dermatitis	e-Poster P3937
Kimball	Impact of Dupilumab on the Lives of Patients with Moderate-to-Severe Atopic Dermatitis	e-Poster P3408
Kircik	Interim Safety Results of Amlitelimab (Anti-OX40 Ligand Antibody) in Participants with Moderate-to-Severe Atopic Dermatitis From the RIVER-AD Phase 2/3 Ongoing Open-Label Study	e-Poster P3229
Markowitz	Dupilumab Monotherapy Improves Multiple Skin Measures in Skin of Color Patients with Atopic Dermatitis as Measured by Line-Field Optical Coherence Tomography	e-Poster P3950
Mikol	Unravelling the Mechanism of Action of Rilzabrutinib in Atopic Dermatitis: An Attractive Therapeutic Agent for the Treatment of Itch Related Conditions	e-Poster P3239
Paller	Safety and Efficacy of up to 3 Years of Dupilumab Treatment in Infants and Children with Severe Atopic Dermatitis	e-Poster P2964
Paller	Systemic Treatment Outcomes for Pediatric Atopic Dermatitis in Minority Groups: PEDISTAD 4-Year Results	e-Poster P3289
Paller	Patient Perception of Life Course Impairment with Moderate-to-Severe Atopic Dermatitis	e-Poster P3124
Siegfried	Dupilumab Safety and Efficacy Up to 3 Years Across Racial Subgroups in Pediatric Patients Aged 6 Months to 11 Years with Atopic Dermatitis	e-Poster P3349
Siegfried	Dupilumab Treatment Up to 3 Years Improves Symptoms and Quality of Life Across Racial Subgroups in Infants and Children Aged 6 Months to 11 Years with Atopic Dermatitis	e-Poster P2869
Tavi	Number Needed to Treat and Associated Costs per Additional Responder of Biologic Therapies in Adult Patients with Moderate to Severe Atopic Dermatitis	e-Poster P3822
Wang	Sustained Improvement in Atopic Dermatitis Disease Control and Treatment Satisfaction	e-Poster P2796

	with Dupilumab in Clinical Practice: 6-Year Follow-up Results From the RELIEVE-AD Study	
Chronic pruritus of unknown origin		
Kim	Dupilumab Improves Itch in Patients with Chronic Pruritus of Unknown Origin: Results from a Phase 3 Trial (LIBERTY-CPUO-CHIC-A)	e-Poster P3453
Chronic spontaneous urticaria		
Bernstein	Dupilumab Provides Early and Sustained Improvement in Urticaria Activity in Patients with Chronic Spontaneous Urticaria: Pooled Results From LIBERTY-CSU CUPID Study A and Study C	e-Poster 2376
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	e-Poster P3770
Casale	Dupilumab improves signs and symptoms of chronic spontaneous urticaria regardless of baseline body mass index	e-Poster P1690
Casale	Dupilumab Provides Early and Sustained Improvement in Itch in Patients with Chronic Spontaneous Urticaria: Pooled Results from LIBERTY-CSU CUPID Study A and Study C	e-Poster P2374
Saini	Dupilumab Efficacy Regardless of Baseline Total Serum IgE Levels: Results from the Pooled LIBERTY-CSU CUPID Study A and Study C	e-Poster P2375
Talia	Rilzabrutinib Improves Chronic Spontaneous Urticaria in Patients with and without Allergic Comorbidities: A Subgroup Analysis from the RILECSU Study	e-Poster P3768
Hidradenitis suppurativa		
Brookes	Content Validation of Clinician Reported Outcome Instruments Utilized in Hidradenitis Suppurativa Clinical Trials	e-Poster P3339
Kimball	Efficacy and Safety of Brivekimig (a Dual-Target, Anti-Tumour Necrosis Factor and Anti-OX40 Ligand NANOBODY-Based Biologic) in Participants with Moderate-to-Severe Hidradenitis Suppurativa	Oral Presentation Friday, Sept. 19 11:15 – 11:25 CEST
Lucats	Development and Content Validation of a Novel Patient-Reported Outcome Instrument for Use with Patients with Moderate-to-Severe Hidradenitis Suppurativa	e-Poster P3341
Zhang	Skin Transcriptomic-Based Classification of Hidradenitis Suppurativa Identifies a Hyper-Inflamed Phenotype Associated with Poor Treatment Response	e-Poster P3269
Prurigo nodularis		
Kwatra	Dupilumab Is Efficacious in Patients Above and Below 65 Years Old with Prurigo Nodularis: Pooled Results from Two Phase 3 Trials (LIBERTY-PN PRIME and PRIME2)]	e-Poster P3285
Ständer	The Physical and Emotional Burden of Prurigo Nodularis in Adult Patients: Impact	e-Poster P2941

	of Dupilumab on Itch, Pain, and Skin-Related Distress in PRIME 1/2	
Ständer	Dupilumab Treatment Provides Multidimensional Benefits in Patients with Prurigo Nodularis	e-Poster P2915
Ständer	Sleep Disturbance and Quality of Life Impact in Patients with Prurigo Nodularis in Europe: Results from the PN – paTient Reported burdEn of sicKness (PN-TREK) Study	e-Poster P2531
Ständer	Mental Health Burden in Prurigo Nodularis: Results from the PN- paTient Reported burdEn of sicKness (PN-TREK) EU Real-World Study	e-Poster P2438
Ständer	Skin Pain in Patients with Prurigo Nodularis: Results from the Real-World Patient Survey: PN-TREK EU Study	e-Poster P2440
Yosipovitch	Dupilumab Monotherapy vs Topical Corticosteroids in Prurigo Nodularis: Impact on Signs and Symptoms in the PRIME/PRIME2 studies	e-Poster P2938
Zeidler	Dupilumab Improves Prurigo Activity and Severity in Patients with Prurigo Nodularis: Pooled Results from the PRIME and PRIME2 Trials	e-Poster P3358
<u>Psoriasis</u>		
Valenzuela	Balinatunfib, the first oral selective inhibitor of TNFR1 signalling, in plaque psoriasis: A double-blind, randomized, placebo-controlled Phase 2b study	Oral Presentation Wednesday, Sept. 17 16:00 – 17:30 CEST
<u>Other</u>		
Meijs	The Novel, First-in-Class IL-1R3 Antagonist SAR445399 Reduces Skin Inflammation in an Innovative Proof-of-Mechanism Study with Dual Immune Challenge Models and Comparator Drugs	Oral Presentation Friday, Sept. 19 14:15 – 14:25 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 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 certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, chronic obstructive pulmonary disease, and bullous pemphigoid in different age populations. More than one million patients are 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 brivekimig

Brivekimig is a dual-target nanobody inhibiting TNF and OX40L, key immune regulators. It is being investigated for potential uses across a range of immune-mediated diseases and inflammatory disorders, including atopic dermatitis, inflammatory bowel disease, type 1 diabetes mellitus, primary focal segmental glomerulosclerosis and minimal change disease.

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 rilzabrutinib

Rilzabrutinib is an 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. BTK, expressed in B cells and mast cells, plays 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 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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