Media Update

AAD: new data advance Sanofi's scientific leadership across innovative treatments for inflammatory skin diseases

- New amlitelimab phase 2 data show impact on symptoms for patients with moderate-to-severe AD
- Positive Dupixent data include a late-breaking oral presentation featuring phase 2/3 data evaluating the efficacy and safety of Dupixent in patients with BP

Paris, February 28, 2025. Sanofi will present 26 abstracts, including one late-breaking and five additional oral presentations, across approved and investigational medicines at the American Academy of Dermatology (AAD) Annual Meeting in Orlando, FL, US from March 7 – 11, 2025. Presentations in partnership with Regeneron include studies evaluating Dupixent in patients with bullous pemphigoid (BP), atopic dermatitis (AD), chronic spontaneous urticaria and prurigo nodularis (PN). New analyses evaluating Sanofi's pipeline medicine amlitelimab, an anti-OX40-ligand monoclonal antibody, will also be presented, including long-term (52-week) results from the STREAM-AD phase 2b study in adult patients with moderate-to-severe AD, and the first interim results from the RIVER-AD phase 2 study in adult patients who did not initially achieve clinical response in Part 1 of the STREAM-AD study at 24 weeks.

> ***Alyssa Johnsen, MD, PhD***
> Global Therapeutic Area Head, Immunology and Oncology Development
> *"Our breadth of data at AAD demonstrates our commitment to patients and advancing treatments for an unmatched number of type 2 inflammatory skin conditions driven by intense itch. The Dupixent data being shared reinforce its clinical evidence across skin diseases, including results from a phase 2/3 study in patients with bullous pemphigoid. Additionally, we are excited to share new data highlighting the potential of our novel anti-OX40-ligand, amlitelimab, in atopic dermatitis, which offers a unique mechanism of action that could help normalize the overactive immune system and restore immune balance without T-cell depletion."*

Notable presentations include:

Dupixent

Key presentations highlighting data from the Dupixent clinical program will be featured, including a late-breaking oral presentation:

- **LIBERTY-BP ADEPT phase 2/3 study:** results evaluating the efficacy and safety of Dupixent in patients with moderate-to-severe BP.

Immunology pipeline

New data evaluating amlitelimab in patients with moderate-to-severe AD will also be presented, including:

- **STREAM-AD phase 2b study:** 52-week results evaluating the impact of amlitelimab on maintenance of itch response in AD.
- **RIVER-AD phase 2 study:** first interim results assessing the safety and efficacy of amlitelimab in patients with AD at 28 weeks that did not achieve clinical response in the STREAM-AD study at 24 weeks.

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

Complete list of AAD presentations:

Presenting author	Abstract title	Presentation details
Atopic dermatitis		
Beck	Dupilumab Treatment Significantly Reduces Age-Dependent Total IgE Levels in Young Children With Atopic Dermatitis	Poster #64623 e-Poster
Bissonnette	Dupilumab Treatment Improves Skin Barrier Function in Adolescent and Adult Patients With Atopic Dermatitis: Results from the BALISTAD and BALISTAD-CN Studies	Poster #63413 e-Poster
Goleva	Dupilumab Normalizes Filaggrin Processing and Improves Clinical Outcomes in Children With Moderate-to-Severe Atopic Dermatitis	Poster #61982 e-Poster
Irvine	Growth Analysis in Children Aged 6 to 11 Years with Severe Atopic Dermatitis and Impact of up to 52 Weeks of Dupilumab Treatment on Height	Oral Presentation #62057 March 7, 2025 4:40 p.m. – 4:45 p.m. ET
Paller	Dupilumab Safety and Efficacy Up To 3 Years in Children Aged 6 Months to 11 Years With Atopic Dermatitis	Poster #62960 e-Poster
Paller	Baseline Growth Analysis of Children and Adolescents With Moderate-to-Severe Atopic Dermatitis Enrolled in Phase 3 Dupilumab Trials	Oral Presentation #62286 March 7, 2025 10:00 a.m. – 10:05 a.m. ET
Ramien	Dupilumab Improves Patient-Reported Outcomes in Patients of Color Aged Less Than 12 Years With Atopic Dermatitis: 4-Year Results from the PEDISTAD Registry	Poster #64507 e-Poster
Simpson	Real-World Effectiveness of Dupilumab in African American Patients With Atopic Dermatitis: 3-Year Data from the PROSE Registry	Poster # 64411 e-Poster
Ständer	Dupilumab Treatment Corrects Upregulation of Type 2 Cytokines Cascades and Improves Pruritus Symptoms in Patients With Moderate-to-Severe Atopic Dermatitis	Poster #63364 e-Poster
Tada	Effectiveness and Safety Data of Dupilumab in Asian Adult Patients With Atopic Dermatitis are Consistent With the Overall Global Population: Real-World Insights 2 Years into the GLOBOSTAD Multinational Prospective Observational Study	Poster #63294 e-Poster
Wang	Dupilumab Improves Health-Related Quality of Life and Work Productivity Among Adults With Moderate-to-Severe Atopic Dermatitis in Clinical Practice: 5-Year Follow-up Results From the RELIEVE-AD Study	Poster # 63592 e-Poster
Wang	Sustained Disease Control Among Adults With Moderate-to-Severe Atopic Dermatitis in Clinical Practice: 5-Year Follow-up Results From the RELIEVE-AD Study	Oral Presentation #63519 March 8, 2025 10:00 a.m. – 10:05 a.m. ET
Wine Lee	Real-World Treatment Outcomes of Systemic Treatments for Moderate-to-Severe Atopic Dermatitis in Children Aged Less Than 12 Years from Racial Minority Groups: 4-Year Results from the PEDISTAD Registry	Poster #64468 e-Poster
Chovatiya	Design and Rationale of ARMADA-AD Disease Registry: An International, Prospective,	Poster #60502 e-Poster

	Observational Registry to Characterize Unmet Needs and Evaluate Real-World Effectiveness and Safety of Systemic Therapies in Adults and Adolescents With Atopic Dermatitis	
Geng	Amlitelimab Reduces Th2-, Th1-, and Th17/22-Related Cytokines and Chemokines in Adults With Moderate-to-Severe Atopic Dermatitis): Results From an Exploratory Analysis of the Phase 2b STREAM-AD Study	Poster #62188 e-Poster
Kim	Impact of amlitelimab (an anti-OX40 Ligand antibody) on Maintenance of Itch Response in Atopic Dermatitis: Results from the 52-Week STREAM-AD Phase 2b Study	Poster #62198 e-Poster
Thaci	Interim Results of RIVER-AD: 28-Week Open-Label Safety and Efficacy of amlitelimab in Patients With Atopic Dermatitis Not Initially Achieving Clinical Response at Week 24 of the STREAM-AD Phase 2b Trial	Poster #63598 e-Poster
Bullous pemphigoid		
TBC	Efficacy and Safety of Dupilumab in Patients With Bullous Pemphigoid: Results from LIBERTY-BP ADEPT Phase 2/3 Study	Late Breaking Oral Presentation #66987 March 8, 2025 Time TBC
Chronic spontaneous urticaria		
Friedman	Persistence and Adherence Among Patients With Chronic Spontaneous Urticaria Initiating Advanced Therapies: A Real-World, Claims Database Study	Poster #64349 e-Poster
Prurigo nodularis		
Elmariah	Real-World Prevalence of Psychiatric and Sleep Disorders Among Adult Patients With Prurigo Nodularis and Prurigo Nodularis Patients Initiating Dupilumab in the US	Poster #63307 e-Poster
Kim	Real-World Prevalence of Comorbidities Among Adult Patients With Prurigo Nodularis With and Without Type 2 Inflammatory Diseases in the US	Poster #63337 e-Poster
Kwatra	Real-World Comorbidities of Adult Patients With Prurigo Nodularis Initiating Dupilumab in the US by Race/Ethnicity	Poster #63345 e-Poster
Mollanazar	Real World Comorbidities of Adult Patients With Prurigo Nodularis Initiating Dupilumab in the US	Oral Presentation #63281 March 7, 2025 11:40 a.m. - 11:45 a.m. ET
Mollanazar	Real-World Medication Use Prior to Dupilumab Initiation Among Adult Patients With Prurigo Nodularis in the US	Poster #63298 e-Poster
Thomas	Dupilumab Improves Disease Control as Early as 1 Month among Adults With Prurigo Nodularis in Clinical Practice: Initial Results from the RELIEVE-PN Study	Poster #64375 e-Poster
Yosipovitch	Real-World Comorbidities, Treatment Use, and Healthcare Resource Utilization Among Elderly Patients With Prurigo Nodularis Initiating Dupilumab in the US	Oral Presentation #63341 March 8, 2025 1:05 p.m. - 1:10 p.m. ET

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, 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.

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 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 amlitelimab

Amlitelimab is a fully human, nondepleting, OX40-ligand (OX40L) monoclonal antibody that specifically blocks upstream OX40L signaling to potentially normalize T-cell mediated inflammation without T-cell depletion. It is being studied in a range of immune-mediated diseases and inflammatory disorders, including atopic dermatitis, hidradenitis suppurativa, alopecia areata, scleroderma, celiac disease and asthma. The potential uses of amlitelimab are currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

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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