Media Update

EADV: New data reinforce Sanofi's innovative approach and leadership across immune-mediated skin diseases

- 24 abstracts for Dupixent, including 4 oral presentations, highlight impact of targeting interleukin-4 (IL4) and interleukin-13 (IL13) across atopic dermatitis (AD), prurigo nodularis (PN) and chronic spontaneous urticaria (CSU)
- New data show impact of Dupixent on potential for clinical remission in children as young as six years of age with moderate-to-severe AD
- 15 abstracts for immunology pipeline molecules, including phase 2 presentations in AD for amlitelimab, an OX40-ligand monoclonal antibody

Paris, September 25, 2024. Sanofi will present 39 abstracts across approved and pipeline medicines at the 2024 European Academy of Dermatology and Venereology (EADV) medical meeting from September 25-28 in Amsterdam, the Netherlands. Presentations will include 21 abstracts for Dupixent (dupilumab) in partnership with Regeneron, highlighting the impact of targeting IL4 and IL13 across three chronic skin conditions, including disease remission data and long-term data in children with moderate-to-severe atopic dermatitis (AD), and rapid results in adults with prurigo nodularis (PN). In addition, data presentations from Sanofi's extensive immunology pipeline include oral and poster presentations for amlitelimab, an OX40-ligand monoclonal antibody, demonstrating safety and efficacy results in moderate-to-severe AD, as well as in poster presentations for rilzabrutinib, a novel oral BTK inhibitor, showing its impact on symptoms of AD and moderate-to-severe chronic spontaneous urticaria (CSU).

> ***Dietmar Berger, M.D., Ph.D.***
> Chief Medical Officer, Global Head of Development at Sanofi
> *"Our data at EADV highlight the breadth of our diverse and novel approach across inflammatory dermatologic conditions, including AD, PN and CSU. Dupixent data demonstrates the potential benefit of important treatment goals such as clinical remission and the speed and durability of efficacy. We continue to evaluate Dupixent's real-world safety profile and consistency of patient impact and satisfaction in children, adolescents, and adults with atopic dermatitis across the globe. Additionally, we are excited to share new data from our pipeline, including results for amlitelimab showing the potential to provide durable efficacy that may enable a quarterly dosing interval, with favorable safety profile."*

Notable presentations include:

Dupixent

New results and analyses for Dupixent in children and adults with moderate-to-severe AD and adults with prurigo nodularis.

<u>Atopic dermatitis</u>

- multiple poster presentations will show results in children with moderate-to-severe AD, including those from an open-label extension study on clinical remission in children aged six to 17 years of age, including after stopping treatment with Dupixent, as well as long-term efficacy and safety data for up to two years on children aged six months to five years. Additionally, real-world data in children six months to 11 years of age will show patient-reported disease severity and health-related quality of life outcomes throughout one year.
- an oral presentation will show real-world safety data from around the world for Dupixent in adults and adolescents with moderate-to-severe AD.

Prurigo nodularis

- **PRIME and PRIME2:** an oral presentation will show new analyses on disease activity, itch, and skin clearance as early as two weeks from two pivotal clinical studies.

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

Dermatology pipeline

Data include new results and analyses for amlitelimab, an OX40-ligand monoclonal antibody, in AD, and rilzabrutinib, a novel oral BTK inhibitor, in AD and CSU.

Atopic dermatitis

- **amlitelimab:** six presentations will share data for amlitelimab in moderate-to-severe AD, including an oral presentation of 68-week safety results. Additional presentations highlight a PK model that support the potential use of a quarterly dosing regimen, a post-hoc analysis showing the impact of amlitelimab on AD of the head and neck, and results from an in vitro analysis demonstrating that the anti-OX40L mechanism of amlitelimab does not deplete T cells.

- **rilzabrutinib:** a poster presentation will show the impact of rilzabrutinib on itch in adults with moderate-to-severe AD.

Chronic spontaneous urticaria

- **rilzabrutinib:** three poster presentations will show the impact of rilzabrutinib on itch, hives and urticaria in adults with moderate-to-severe CSU.

Hidradenitis suppurativa

- three poster presentations will show the impact of disease symptoms on patients with hidradenitis suppurativa and highlight the need for increased disease awareness and effective treatment options.

Alopecia areata

- a poster presentation will show conceptual model and clinical outcome measures in alopecia areata based on the patient experience.

Amlitelimab and rilzabrutinib are investigational medicines for which safety and efficacy have not been evaluated by any regulatory authority.

Complete list of EADV 2024 presentations:

Presenting author	Abstract title	Presentation details
Atopic dermatitis		
Dodge	Characterization Of Atopic Dermatitis Medication Use Before and During Pregnancy in The United States (dupilumab)	P0710 and FC08 Oral and e-Poster Friday, September 27 4:40-4:50 CEST
Irvine	Growth Analysis in Children Aged 6 to 11 Years with Severe Atopic Dermatitis and Impact of 16 Weeks of Dupilumab Treatment on Height	Late Breaking News Number: 8073 Thursday, September 26 4:45-5:00 CEST
Tzellos	Comprehensive Safety Data in Adult and Adolescent Patients With Atopic Dermatitis Treated With Dupilumab: Real-World Insights 1 Year Into the GLOBOSTAD Multinational Prospective Observational Study (dupilumab)	P0452 and EPS05 Oral and e-Poster Thursday, September 26 2:25-2:35 CEST
Baselga	Dupilumab improves disease severity in children <12 years of age with severe atopic dermatitis: interim results from PEDISTAD Real-World Registry (dupilumab)	P0666 e-Poster
Beck	Impact of Dupilumab Treatment on Seasonal Disease Severity in Adults with Moderate-to-Severe Atopic Dermatitis (dupilumab)	P0672 e-Poster
Cork	Dupilumab Treatment Restores Skin Barrier in Children Aged 6 to 11 Years with Moderate-to-Severe Atopic Dermatitis (dupilumab)	P0710 e-Poster
Guyot	Dupilumab Demonstrates Higher Likelihood of Achieving Improvements in Signs, Symptoms and Quality of Life vs Lebrikizumab at Week 16: Results from a Placebo-adjusted Indirect Comparison Analysis	P0635 e-Poster
Guyot	Dupilumab Demonstrates Higher Likelihood of Maintaining Efficacy Outcomes Compared with Lebrikizumab in Monotherapy at Week 52: Results from a Placebo-adjusted Indirect Comparison Analysis	P0702 e-Poster
Irvine	Dupilumab Increases Levels of Bone Alkaline Phosphatase Irrespective of Prior	P0728 e-Poster

	Systemic Corticosteroids Use in Children with Moderate-To-Severe Atopic Dermatitis (dupilumab)	
Kim	Lower Total IgE After Dupilumab Treatment is Associated with a Reduction in Flares in Patients with Moderate-to-Severe Atopic Dermatitis (dupilumab)	P0667 e-Poster
Paller	The Effect of Atopic Dermatitis on The Height, Weight and BMI of Children Aged Up To 12 Years (dupilumab)	P0665 e-Poster
Paller	Dupilumab Efficacy and Safety Up To 2 Years in Children Aged 6 Months To 5 Years with Atopic Dermatitis (dupilumab)	P0725 e-Poster
Siegfried	To Define Remission On- And Off-Drug and To Show That Sustained Remission Can Be Achieved with Dupilumab Treatment in Pediatric Patients with Moderate-To-Severe AD (dupilumab)	P0655 e-Poster
Siegfried	Dupilumab Treatment Provides Long-Term Improvement in Sleep Loss and Disease Control Over 1 Year in Pediatric Patients with Moderate-to-Severe Atopic Dermatitis (dupilumab)	P0729 e-Poster
Simpson	Dupilumab Improved Quality of Life in Patients with Localized Atopic Hand Dermatitis (dupilumab)	P0699 e-Poster
Ständer	Maintenance of Itch Response in Adult Patients with Moderate-To-Severe Atopic Dermatitis Treated with Dupilumab: Post-Hoc Analysis from LIBERTY AD SOLO-CONTINUE (dupilumab)	P0708 e-Poster
Strober	Sustained Improvement in Atopic Dermatitis Disease Control and Treatment Satisfaction with Dupilumab in Clinical Practice: 5-Year Follow-up Results From the RELIEVE-AD Study (dupilumab)	P0704 e-Poster
Strober	Dupilumab Improves Patient-Reported Symptom Control Among Adults with Moderate-to-Severe Atopic Dermatitis in Clinical Practice: 5-Year Follow-Up Results From the RELIEVE-AD Study (dupilumab)	P0702 e-Poster
Bieber	Prediction of the efficacy of extended dosing of amlitelimab (an anti-OX40 Ligand antibody) in patients with moderate-to-severe atopic dermatitis using a modeling approach (amlitelimab)	P0687 e-Poster
Krueger	In vitro evidence demonstrating the nondepleting mechanism of action of amlitelimab, an OX40 Ligand monoclonal antibody (amlitelimab)	P0548 e-Poster

Kwatra	Amlitelimab (an anti-OX40 Ligand antibody) normalises the atopic dermatitis gene signature in the skin of patients with moderate-to-severe atopic dermatitis (amlitelimab)	P0542 e-Poster
Reich	Impact of amlitelimab (an anti-OX40 Ligand antibody) on atopic dermatitis of the head and neck: post hoc results from the STREAM-AD phase 2b study of moderate-to-severe atopic dermatitis (amlitelimab)	P0685 e-Poster
Stein Gold	Amlitelimab (an anti-OX40 Ligand antibody) vs placebo in patients with moderate-to-severe atopic dermatitis: Study design of phase 3 OCEANA clinical trials COAST 1/2, SHORE, AQUA, and ESTUARY [Encore] (amlitelimab)	P0549 e-Poster
Weidinger	68-week safety results of amlitelimab (an anti-OX40 Ligand antibody) in participants with moderate-to-severe atopic dermatitis from STREAM-AD Phase 2b dose-ranging and withdrawal study (amlitelimab)	3310 and FC08 Oral Presentation Friday, September 27 4:00-4:10 PM CEST
Magdalena	Attributes of treatment and factors influencing patient preference and satisfaction in Atopic Dermatitis: Literature review (led by HVT) (disease awareness)	P0531 e-Poster
Guttman-Yassky	Rilzabrutinib improves itch in atopic dermatitis (rilzabrutinib)	P0709 e-Poster
<u>Prurigo nodularis</u>		
Ständer	Dupilumab Provides Rapid and Continuous Improvement in Prurigo Nodularis Signs and Symptoms Over Time: Results From PRIME/PRIME2 (dupilumab)	P2434 and EPS05 Oral and e-Poster Thursday, September 26 2:15-2:25 CEST
Jachie	Dupilumab in Adult Patients with Moderate-to-severe Prurigo Nodularis: 6-months Real-world Follow-up Results from the French Early Access Program (dupilumab)	P3056 e-Poster
Kim	Sequence of Improvement of Signs, Symptoms, and Quality of Life in Patients with Prurigo Nodularis Receiving Dupilumab (dupilumab)	P2598 e-Poster
Kim	Dupilumab Is Efficacious in Patients with Prurigo Nodularis Regardless of History of Atopic Comorbidities: Pooled Results from Two Phase 3 Trials (LIBERTY-PN PRIME and PRIME2) (dupilumab)	P3076 e-Poster
<u>Chronic spontaneous urticaria</u>		

Maurer	Results From Two Phase 3 Studies of Dupilumab in CSU (dupilumab)	P3585 e-Poster
Maurer	Dupilumab Reduces Disease Activity in Patients with Chronic Spontaneous Urticaria: LIBERTY-CSU CUPID Study A (dupilumab)	P3593 e-Poster
Ben-Shoshan	A 12-Week Safety Assessment of Rilzabrutinib in Patients With Chronic Spontaneous Urticaria From the RILECSU Phase 2 Dose-Ranging Study [Encore] (rilzabrutinib)	P3614 e-Poster
Giménez-Arnau	Leveraging machine learning to develop a prognostic model for chronic spontaneous urticaria (rilzabrutinib)	P3602 e-Poster
Maurer	Rilzabrutinib reduces biomarkers related to itch and disease severity in chronic spontaneous urticaria and atopic dermatitis (rilzabrutinib)	P3069 e-Poster
Hidradenitis suppurativa		
Agnes	Patient experience of hidradenitis suppurativa: Ranking the burden of symptoms and impacts (led by HVT) (disease awareness)	P0114 e-Poster
Agnes	Patient experience of pain in hidradenitis suppurativa: qualitative research on location, burden, impacts and management (led by HVT) (disease awareness)	P0115 e-Poster
Lucy	Hidradenitis suppurativa community online across 7 countries converges on the need for disease awareness and effective treatment (led by HVT) (disease awareness)	P0116 e-Poster
Alopecia areata		
Favaro Marcelo	Patient experience in Alopecia Areata: Conceptual model and review of clinical outcome measures (led by HVT) (disease awareness)	P2071 e-Poster

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
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