Media Update

New Dupixent® (dupilumab) data at EADV 2022 adds to body of evidence across multiple inflammatory skin diseases

Paris, September 6, 2022. Twenty-five scientific abstracts evaluating Dupixent® (dupilumab) in moderate-to-severe atopic dermatitis from infancy to adulthood, prurigo nodularis and chronic spontaneous urticaria will be presented at the European Academy of Dermatology and Venereology (EADV) 2022 Congress from September 7 to 10. The data add to a growing body of clinical and real-world evidence illustrating the potential benefit of Dupixent in targeting IL-4 and IL-13, key and central drivers of the type 2 inflammation that plays a role in these inflammatory skin diseases.

New analyses from the pivotal trial in children aged 6 months to 5 years with moderate-to-severe atopic dermatitis will be shared across eight posters. Data presentations will show dupilumab plus low-potency topical corticosteroids significantly improved quality of life and sleep quality for both children and their caregivers. Presentations will also show that children aged 6 months to 5 years treated with dupilumab experienced improvement in skin pain and that dupilumab treatment was associated with lower overall infections and non-herpetic skin infections in this age group. The safety results of this pivotal trial were generally consistent with the known safety profile of dupilumab in atopic dermatitis.

Data in patients with moderate-to-severe atopic dermatitis aged 6 years and older will also be presented. Presentations of analyses from an open-label trial evaluating skin barrier function (BALISTAD) in patients 12 years and older will show Dupixent normalized skin barrier function for many patients and was associated with improvements in disease signs and symptoms and quality of life. In a separate Phase 4 randomized, placebo-controlled trial in adults assessing the effect of Dupixent on sleep (DUPISTAD), analyses will be presented showing that Dupixent treatment improved sleep quality, daytime sleepiness, symptoms of anxiety and depression, health-related quality of life measures and itch, including in patients who switched to Dupixent from placebo. The safety results of this pivotal trial were generally consistent with the known safety profile of Dupixent in atopic dermatitis.

Late-breaking results from a Phase 3 dupilumab trial showing improvement in signs and symptoms in adults with prurigo nodularis will also be presented.

The potential uses of dupilumab in prurigo nodularis, chronic spontaneous urticaria and bullous pemphigoid are currently under clinical development, and the safety and efficacy have not been fully evaluated by any regulatory authority.

Data to be presented at the EADV 2022 Congress

Investigation of Dupilumab in Prurigo Nodularis

- Late-breaking oral presentation (4:45-5:00 pm CEST):
  - #3583: Dupilumab Significantly Improves Itch and Skin Lesions in Patients with Prurigo Nodularis: Results from a 2nd Phase 3 Trial (LIBERTY-PN PRIME), Gil Yosipovitch

Investigation of Dupilumab in Chronic Spontaneous Urticaria

- Poster #P1754: Dupilumab Significantly Reduces Itch and Hives in Patients With Chronic Spontaneous Urticaria Irrespective of Baseline IgE Level: Results From a Phase 3 Trial (LIBERTY-CSU CUPID Study A), Marcus Maurer

Study Design for Dupilumab in Bullous Pemphigoid

- Poster #P0404: The Study Design of a Trial of Dupilumab in Adult Patients With Bullous Pemphigoid: LIBERTY-BP ADEPT, Dedee Murrell

Clinical Efficacy and Safety of Dupilumab in Infants and Young Children with Atopic Dermatitis

- Poster #P0322: Dupilumab Treatment Improves Health-Related Quality of Life in Children Aged 6 Months to 5 Years with Moderate-to-Severe Atopic Dermatitis and Their Caregivers, Amy Paller
- Poster #P0321: Dupilumab Treatment Improves Sleep Quality in Children Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis and Their Caregivers, Amy Paller
- Poster #P0297: Dupilumab Treatment Is Not Associated With an Increased Overall Risk of Infections in Patients Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis, Michael Cork
- Poster #P0320: Dupilumab Treatment Reduces Skin Pain in Infants and Young Children With Moderate-to-Severe Atopic Dermatitis Aged 6 Months to 5 Years, Amy Paller
- Poster #P0290: Dupilumab Treatment Shows Rapid and Consistent Improvement in Atopic Dermatitis in All Anatomical Regions in Patients Aged 6 Months to 5 Years, Andreas Wollenberg
- Poster #P0356: Laboratory Safety From a 16-Week Phase 3 Study of Dupilumab in Patients Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis, Amy Paller
- Poster #P0354: Clinically Meaningful Within-Patient Change Threshold for the Children's Dermatology Life Quality Index and Infants' Dermatitis Quality of Life Index Instruments in Patients Aged 6 Months to <6 Years With Atopic Dermatitis, Amy Paller
- Poster #P0199 Meaningful Change Threshold for the Dermatitis Family Impact (DFI) Questionnaire for Parents/Caregivers of Children Aged 6 Months to <6 Years With Atopic Dermatitis (AD), Amy Paller

BALISTAD Skin Barrier Trial of Dupilumab in Atopic Dermatitis

- Poster #P0319: Dupilumab Treatment Normalizes Skin Barrier Structure and Function and Improves Quality of Life in Adult and Adolescent Patients With Moderate-to-Severe Atopic Dermatitis, Robert Bissonnette
- Poster #P0317: Dupilumab Treatment Normalizes Skin Barrier Function and Improves Clinical Outcomes in Patients With Atopic Dermatitis, Robert Bissonnette

DUPISTAD Sleep Trial of Dupilumab in Atopic Dermatitis

- Poster #P0328: Dupilumab ameliorates sleep disturbance and relieves itch in adults with moderate-to-severe atopic dermatitis over 24 weeks, Joseph Merola
- Poster #P0331: Improvement in sleep quality anxiety and depression in adults with moderate-to-severe atopic dermatitis with dupilumab treatment, Joseph Merola
- Poster #P0332: Improvement in symptoms of atopic dermatitis (AD) and AD-related quality of life with dupilumab treatment in adults: 24-week results of the DUPISTAD study, Joseph Merola

Clinical and Real-World Efficacy and Safety of Dupilumab in Atopic Dermatitis

- Oral Presentation (September 8, 10:45-10:55 am CEST):
  - #FC02.04: Real-world treatment outcomes for up to 2 years in patients aged less than 12 years with inadequately controlled moderate-to-severe atopic dermatitis, Amy Paller
- Poster #P0323: Dupilumab 16-Week Efficacy and Safety Is Robust and Consistent in Adults Over 60 Years of Age With Moderate-to-Severe Atopic Dermatitis, Johnathan Silverberg
- Poster #P0312: Dupilumab Treatment Leads to Rapid, Progressive, and Sustained Reduction in Lichenification in Children, Adolescents, and Adults With Atopic Dermatitis, Emma Guttman-Yassky
- Poster #P0313: Dupilumab Treatment Leads to Rapid, Progressive and Sustained Reduction in Lichenification in White, African American/Black and Asian Patients With Atopic Dermatitis, Emma Guttman-Yassky

Disease Burden of Atopic Dermatitis in Children 6 to 11 Years of Age

- Poster #P0358: High Burden of Disease and Comorbidities in Children Aged 6 to 11 Years With Moderate and Severe Atopic Dermatitis and Their Families: A Survey Study on Daily Experience (PEDI-BURDEN), Elena Galli

- Poster #P0359: Children Aged 6 to 11 Years With Moderate and Severe Atopic Dermatitis Frequently Experience Disease Flares (PEDI-BURDEN), Iria Neri
- Poster #P0355: Impaired Sleep Quality and Increased Daytime Drowsiness in Patients Aged 6 to 11 Years With Moderate and Severe Atopic Dermatitis and Their Caregivers: A Survey Study on Daily Experience (PEDI-BURDEN), Ilaria Baiardini

Regional Dupilumab Abstracts

- Poster #P0200: Dupilumab demonstrates rapid onset of action in signs, symptoms, and quality of life in patients with atopic dermatitis: real-world evidence from the large, nationwide PROLEAD trial, Mike Bastian
- Poster #P0204: Dupilumab treatment of atopic dermatitis in routine clinical care: baseline characteristics of patients in the PROLEAD prospective, observational study, Mike Bastian

About Dupixent

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) 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 trials, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases. These diseases include approved indications for Dupixent such as asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis (CRSwNP) and eosinophilic esophagitis (EoE), as well as investigational diseases such as prurigo nodularis.

In the European Union, Dupixent is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy and for the treatment of severe atopic dermatitis in children 6 to 11 years old who are candidates for systemic therapy. The efficacy and safety of Dupixent in children below the age of 6 years has not been fully evaluated by the European Medicines Agency.

Dupixent has received regulatory approvals around the world for use in in certain patients with atopic dermatitis, asthma, CRSwNP or EoE in different age populations. Dupixent is currently approved across these indications in the U.S. and for one or more of these indications in more than 60 countries, including in the European Union and Japan. More than 500,000 patients have been 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 trials 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 trials, including prurigo nodularis, pediatric eosinophilic esophagitis, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritis of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis 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.

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 some 100 countries, 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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