Media Update

New data presented at AAAAI highlight Sanofi's scientific leadership across inflammatory diseases

- Late-breaking Dupixent® data leverages imaging technology to evaluate how Dupixent improves lung function in patients with uncontrolled moderate-to-severe asthma
- Multiple oral presentations reinforce potential of Dupixent to provide relief to people with eosinophilic esophagitis as young as 1 year old through adulthood
- First presentation of Phase 2 data for novel investigational oral BTK inhibitor rilzabrutinib in CSU; data forms the basis for Phase 3 program
- Holistic presence underscores continued commitment to advancing therapies for patients across multiple inflammatory diseases

Paris, February 9, 2024. Twenty-three abstracts across approved and investigational medicines will be presented at this year's American Academy of Allergy Asthma and Immunology (AAAAI) Annual Meeting from February 23 to 26. Abstracts include those evaluating Dupixent® (dupilumab) across six inflammatory diseases, including asthma, atopic dermatitis (AD), eosinophilic esophagitis (EoE), eosinophilic gastritis (EoG), chronic rhinosinusitis with nasal polyps (CRwNP), and chronic spontaneous urticaria (CSU); as well as rilzabrutinib in CSU.

> ***Naimish Patel, M.D.***
> Global Head of Development, Immunology and Inflammation at Sanofi
> *"We are proud of our broad scientific presence at this year's AAAAI, which underscores our commitment to working with our partner to continue to advance the science of Dupixent while also bringing forward novel and disruptive mechanisms of action that can address unmet needs. From novel imaging data that enables us to better understand the impact of Dupixent on lung function, to the latest EoE data in children as young as 1 year old, to the first presentation of our potentially best-in-class oral BTK inhibitor, we are committed to chasing the miracles of science for patients suffering from these chronic inflammatory conditions.*

Notable presentations include:

Dermatology pipeline

A late breaking poster shows pipeline advancements in the treatment of patients with chronic spontaneous urticaria.

Rilzabrutinib in chronic spontaneous urticaria

- **RILECSU Phase 2 Dose-Ranging Study:** Data showed that rilzabrutinib significantly improved itch, hives and urticaria in adults with moderate-to-severe chronic spontaneous urticaria (CSU).

Rilzabrutinib was well-tolerated with most frequent adverse events being diarrhea and nausea.

Dupixent

Late breaking poster provides new insights into the effect of Dupixent on lung function and is the first study to use novel functional respiratory imaging to assess the effect of a biologic on lung function and airway volume. Additional oral presentations underscore the potential of Dupixent to transform the treatment paradigm for pediatric, adolescent, and adult patients with eosinophilic esophagitis (EoE).

Uncontrolled moderate-to-severe asthma

- **VESTIGE Phase 4 trial:** Dupixent was associated with positive data on airway inflammation, mucus plugging, fractional exhaled nitric oxide (FeNO) and airway volume in patients with uncontrolled moderate-to-severe asthma.

Eosinophilic esophagitis

- **KIDS Phase 3 trial:** Positive Dupixent data on histologic and endoscopic outcomes in children with EoE aged 1 through 11 years old at week 16 and through 52 weeks. Additional analysis will also be presented on gene expression in these children.[i]
- **LIBERTY-EoE-TREET study:** Positive Dupixent data on histologic, symptomatic, and endoscopic aspects of EoE in adults and adolescents up to 52 weeks, regardless of prior elimination diet or food allergy.[i]

The safety results of these trials were generally consistent with the known safety profile of Dupixent.

Complete List of AAAAI 2024 Presentations:

Presenting author	Abstract title	Presentation details
Asthma		
Bacharier	Improved Lung Function is Associated With Better Asthma Control in Children Aged 6 to 11 Years With Moderate-To-Severe Type 2 Asthma: A Post Hoc Analysis of VOYAGE	Poster #300 Poster session Saturday, February 24 9.45-10.45 AM
Busse	Asthma Treatment With Add-On Dupilumab Plus Medium-Dose Inhaled Corticosteroid (ICS) Improved Lung Function and Asthma Control Compared With Placebo Plus High-Dose ICS	Poster #L23 Poster session (LB) Saturday, February 24 9.45-10.45 AM
Castro	Evaluating the Effect of Dupilumab on Type 2 Airway Inflammation and Mucus Plugging in Patients with Uncontrolled Moderate-To-Severe Asthma: the VESTIGE Trial	Poster #L24 Poster session (LB) Saturday, February 24 9.45-10.45 AM
Domingo	Association Of Baseline Lung Function and Likelihood of Oral Corticosteroid Reduction in Patients With OCS-Dependent Severe Asthma	Poster #308 Poster session Saturday, February 24 9.45-10.45 AM
Peters	Coexisting Allergic Rhinitis in Patients With Moderate-To-Severe Asthma Initiating Dupilumab in Real-World Clinical Practice: The RAPID Registry Study	Poster #290 Poster session Saturday, February 24 9.45-10.45 AM
Wechsler	Long-term Efficacy of Dupilumab in Patients with Moderate-to-severe Type 2 Asthma Stratified by Baseline Characteristics during the 96-week TRAVERSE Study	Poster #292 Poster session Saturday, February 24 9.45-10.45 AM
Eosinophilic Esophagitis		
Chehade	Dupilumab Improves Histologic and Endoscopic Outcomes in Children Aged 1 to <12 Years With Eosinophilic Esophagitis (EoE): 52-Week Results from the Phase 3 EoE KIDS Trial	Oral presentation #821 Oral abstract session Monday, February 26 12.50-1.00 PM
Chehade	Baseline Demographics and Disease Characteristics of Pediatric Patients With Eosinophilic Esophagitis (EoE) from the Randomised, Placebo-Controlled, Phase 3 EoE KIDS Study	Poster #620 Poster session Sunday, February 25 9.45-10.45 AM
Rothenberg	Dupilumab Normalized the Expression of Genes Dysregulated in Eosinophilic Esophagitis (EoE) in Esophageal Biopsies from a Clinical Trial of Children Aged 1–11 Years	Oral presentation #458 Oral abstract session Saturday, February 24 2.45-2.55 PM
Spergel	Dupilumab Is Efficacious Up To 52 Weeks in Patients with Eosinophilic Esophagitis Irrespective of Prior Food Elimination Diet or History of Food Allergy	Oral presentation #457 Oral abstract session Saturday, February 24 2.35-2.45 PM

Eosinophilic Gastritis		
Dellon	A Phase 2/3 Study to Assess the Efficacy and Safety of Dupilumab Versus Placebo in Adults and Adolescents with Eosinophilic Gastritis With or Without Eosinophilic Duodenitis	Poster #621 Poster session Sunday, February 25 9.45-10.45 AM
Atopic Dermatitis		
Beck	Long-Term Efficacy of Dupilumab in Adults With Moderate-to-Severe Atopic Dermatitis: Results From A 5-Year Open-Label Extension Trial	Poster #015 Poster session Friday, February 23 3.15-4.15 PM
Beck	Dupilumab Consistently Reduces CCL-17 (TARC) in Patients with Atopic Dermatitis Across All Age Groups	Poster #038 Poster session Friday, February 23 3.15-4.15 PM
Bronova	Dupilumab Improves Skin Lipid Barrier in Pediatric Patients With Moderate-To-Severe Atopic Dermatitis	Poster #013 Poster session Friday, February 23 3.15-4.15 PM
Kim	Dupilumab Reduction of IgE Levels and Probability of Atopic Dermatitis Flares – Analysis of A Randomized Placebo-Controlled 52-Week Study	Poster #044 Poster session Friday, February 23 3.15-4.15 PM
Chronic Rhinosinusitis with Nasal Polyps		
Desrosiers	Prevalence NSAID-ERD Among Patients with Chronic Rhinosinusitis with Nasal Polyps in the Global AROMA registry	Poster #657 Featured poster session Sunday, February 25 9.45-10.45 AM
Han	Baseline Use of Orals Corticosteroids Among Patients With Chronic Rhinosinusitis With Nasal Polyps Enrolled in the Global AROMA Registry	Poster #777 Featured poster session Sunday, February 25 4.45-6.15 PM
Isaman	The Impact of Functional Endoscopic Sinonasal Surgery on Oral Corticosteroid Use and Costs Over 3 Years in Patients With Chronic Rhinosinusitis With Nasal Polyps in US Real-World Practice	Poster #777 Featured poster session Sunday, February 25 9.45-10.45 AM
Peters	Baseline Disease Characteristics Among Patients with Chronic Rhinosinusitis with Nasal Polyps and Coexisting Asthma in the Global AROMA registry	Poster #652 Featured poster session Sunday, February 25 9.45-10.45 AM
Chronic Spontaneous Urticaria		
Maurer	Efficacy and Safety of Rilzabrutinib in Patients With Chronic Spontaneous Urticaria: 12-Week Results From the RILECSU Phase 2 Dose-Ranging Study	Poster# L38 Poster Session (LB) Saturday, February 24 9:45 am - 10:45 AM
Maurer	Dupilumab Reduces Disease Activity in Patients with Chronic Spontaneous Urticaria: LIBERTY-CSU CUPID Study A	Poster #029 Poster session Friday, February 23 3.15-4.15 PM
Maurer	Dupilumab Improves Dermatology-Specific Quality of Life in Patients with Chronic Spontaneous Urticaria Inadequately Controlled with H1 Antihistamines	Poster #007 Poster session Friday, February 23 3.15-4.15 PM
Maurer	Dupilumab Improves Urticaria-Specific Quality of Life in Patients with Chronic Spontaneous Urticaria Uncontrolled by H1 Antihistamines	Poster #006 Poster session Friday, February 23rd 3.15-4.15 PM

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 atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis (EoE) and prurigo nodularis.

Dupixent has received regulatory approvals in one or more countries around the world for use in certain patients with atopic dermatitis, asthma, CRSwNP, EoE or prurigo nodularis in different age populations. Dupixent is currently approved for one or more of these indications in more than 60 countries, including in Europe, the U.S. and Japan. More than 800,000 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 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 chronic spontaneous urticaria, chronic pruritus of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation 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 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, including CSU, prurigo nodularis, asthma, immune thrombocytopenia (ITP), IgG4-related disease and warm autoimmune hemolytic anemia (wAIHA). 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's Immunology Pipeline
Through world-class R&D and a laser focus on patients, Sanofi discovers, develops and delivers best-in-class treatments that improve the lives of people living with chronic inflammatory diseases. Our scientific strategy for the future of immunology is built around the intentional choice of exploring disruptive mechanisms of actions beyond type 2 including NANOBODY molecules, synthetic cytokines and degraders. The immunology pipeline consists of 5 investigational agents in Phase 1 clinical development, 6 in Phase 2 clinical development, and 1 in Phase 3 clinical development. These programs include investigational agents across a wide range of inflammatory conditions.

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.

Media Relations
Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com

Investor Relations
Eva Schaefer-Jansen | + 33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com

Arnaud Delépine | + 33 06 73 69 36 93 | arnaud.delepine@sanofi.com
Corentine Driancourt | + 33 06 40 56 92 21 | corentine.driancourt@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Tarik Elgoutni | + 1 617 710 3587 | tarik.elgoutni@sanofi.com
Nathalie Pham | + 33 07 85 93 30 17 | natalie.pham@sanofi.com

---

Sanofi Forward-Looking Statements

This press release 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

---

[i] Thresholds for clinically meaningful changes in EREFS and HSS scores have not been established.