Late-breaking amlitelimab Phase 2b data presented at EADV show potential best-in-class profile in atopic dermatitis

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Late-breaking amlitelimab Phase 2b data presented at EADV show potential best-in-class profile in atopic dermatitis

- Patients treated with amlitelimab experienced up to 61.5% improvement in average Eczema Area and Severity Index (EASI) score from baseline at week 16, the primary endpoint, with continued improvement seen through 24 weeks

- Clinically meaningful improvements were seen in all key secondary endpoints at week 16 with continued improvements through week 24, including for IGA 0/1 where patients on the highest dose experienced 22.1% improvement at week 16 which increased to 45.5% by week 24

- Amlitelimab was well-tolerated and no fever/chills, oral ulcers or imbalances with conjunctivitis were observed across doses

- Amlitelimab has a unique non-depleting mechanism of action targeting OX40-Ligand with the potential to durably restore immune balance, sustained effect and infrequent dosing

Paris, October 13, 2023. Positive results from a Phase 2b study (STREAM-AD) showed that amlitelimab significantly improved signs and symptoms of moderate-to-severe atopic dermatitis in adults whose disease cannot be adequately controlled with topical medications or for whom topical medications are not a recommended treatment approach. These detailed results were presented today as part of a late-breaking session at the European Academy of Dermatology and Venereology (EADV) 2023 Congress in Berlin. The Phase 3 program for amlitelimab in atopic dermatitis is on track to start in the first half of 2024. This program is part of Sanofi’s immunology strategy built around exploring disruptive mechanisms of

action designed to deliver first and best-in-class treatments for people living with chronic inflammatory diseases.

In this dose-ranging study, subcutaneous treatment with amlitelimab resulted in statistically significant improvements in the primary endpoint of percent change in Eczema Area and Severity Index (EASI) score from baseline at 16 weeks compared to placebo for all four doses that were studied. Among these, patients treated with amlitelimab 250 mg Q4W with 500 mg loading dose (LD) had the numerically highest response versus placebo, showing a 61.5% reduction in EASI from baseline at week 16 (P

Professor Stephan Weidinger, M.D, Ph.D

Director, Professor, Chair of Department of Dermatology and Allergy, University Hospital Schleswig-Holstein

> These results are exciting news for patients with moderate-to-severe atopic dermatitis who continue to suffer from symptoms including persistent itch and skin lesions, despite available treatment options. Across all four doses studied, we saw consistent improvements in important signs and symptoms of the disease with an unremarkable safety profile. These data also add to the growing body of evidence that targeting OX40-Ligand potentially stops the inflammatory cascade across multiple pathways resulting in significant benefit for patients.

Across amlitelimab doses, clinically meaningful and nominally significant improvements were seen in all key secondary endpoints at weeks 16 and 24, including Investigator Global Assessment response of 0 (clear) or 1 (almost clear skin) (IGA 0/1), 75% reduction from baseline in EASI (EASI-75) and weekly average reduction of Peak Pruritus Numerical Rating Scale ≥4 points from baseline (PP-NRS ≥4), with the exception of the 250 mg (no LD) in IGA 0/1 at Week 16 (p=0.0562).

22.1% and 45.5% of patients treated with amlitelimab 250 mg with LD achieved IGA 0/1 at weeks 16 and 24, respectively, compared to 5.1% and 11.4% of placebo patients (P=0.0022 and P

Across all doses at weeks 16 and 24, amlitelimab treatment substantially reduced levels of biomarkers elevated in atopic dermatitis, including Th2-related IL-13 and TARC, Th17/Th22-related

IL-17A and IL-22, and blood eosinophil counts, with significant reduction observed as early as week 4 in the 250 mg with LD arm.

Houman Ashrafian, M.D., Ph.D.

Global Head of Research & Development, Sanofi

> The data presented at EADV provide more detailed insight into amlitelimab's potential as a best-in-class therapy for people with atopic dermatitis. In addition, our ability to pursue a differentiated dosing regimen could be very meaningful to patients. We look forward to initiating a larger Phase 3 development program for amlitelimab in atopic dermatitis in the first half of 2024, which further underscores our commitment to delivering a diverse range of solutions for this chronic condition.

Amlitelimab was well-tolerated in the study across all dose arms and no new safety concerns were identified. The overall rates of treatment-emergent adverse events (TEAEs) were 67.4% for amlitelimab and 60.3% for placebo. TEAEs more commonly observed with amlitelimab compared to placebo included nasopharyngitis (11.0% amlitelimab, 9.0% placebo), COVID-19 (7.7% amlitelimab, 6.4% placebo) and headache (6.1% amlitelimab, 2.6% placebo). Worsening of atopic dermatitis was more commonly observed with placebo compared to amlitelimab (38.5% placebo, 17.1% amlitelimab). No adverse events such as fever or chills, oral ulcers or imbalances with conjunctivitis were observed across doses.

Amlitelimab is a fully human non-depleting monoclonal antibody that binds to OX40-Ligand, a key immune regulator, and has the potential to be a first-in-class treatment for a range of immune-mediated diseases and inflammatory disorders, including moderate-to-severe atopic dermatitis and asthma. By targeting OX40-Ligand, amlitelimab aims to restore balance between pro-inflammatory and regulatory T cells.

Amlitelimab is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority.

STREAM-AD, a Phase 2b study, is a randomized double-blind, placebo-controlled study, evaluating amlitelimab in adult patients with moderate-to-severe atopic dermatitis whose disease was inadequately

controlled with topical therapies or where such therapies were not advisable. This study is designed with two parts and is double-blind through both. The first part is a 24-week treatment period and the second part, which is still ongoing, is a 36-week maintenance/withdrawal period.

The primary endpoint is percentage change in EASI from baseline at 16 weeks. Key secondary endpoints include change in EASI from baseline at 24 weeks, percentage of patients with a response of IGA 0 (clear) or 1 (almost clear skin) and a reduction from baseline ≥ 2 points at 16 and 24 weeks, percentage of patients with at least a 75% reduction from baseline in EASI at 16 and 24 weeks, and proportion of patients with improvement (reduction) of weekly average of pruritus NRS ≥ 4 with a baseline pruritus of ≥ 4 from baseline at 16 and 24 weeks.

In the first part, participants were randomized 1:1:1:1:1 to receive subcutaneous amlitelimab every four weeks or placebo. The doses were: 250 mg with 500 mg loading dose [LD] (n=77), 250 mg without LD (n=78), 125 mg without LD (n=77), 62.5 mg without LD, (n=79) or placebo (n=79).

The study enrolled 390 people in Australia, Bulgaria, Canada, Czechia, Germany, Hungary, Japan, Poland, Spain, Taiwan, the United Kingdom and the United States.

About Sanofi’s Immunology Pipeline

Through world-class R&D and a laser focus on patients, Sanofi discovers, develops and delivers first and 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 action beyond Type 2 inflammation through using a variety of approaches including NANOBODY® molecules, synthetic cytokines and degraders. The immunology pipeline consists of 6 investigational agents in Phase 1 clinical development, 5 in Phase 2 clinical development, and 1 in Phase 3 clinical development. These programs include investigational agents across a wide range of inflammatory conditions.

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.

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