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Press Release

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New, late-breaking data at EADV highlights emerging clinical profile of amlitelimab (formerly KY1005) in adults with inadequately controlled moderate-to-severe atopic dermatitis

- Low dose arm of the study met the co-primary endpoints of percent change in Eczema Area and Severity Index (EASI) score from baseline, and incidence of treatment-emergent adverse events, through week 16
- First trial to assess the effects of blocking OX40-Ligand, a key immune system regulator, in patients with moderate-to-severe atopic dermatitis
- Data support amlitelimab as a potential first-in-class anti-OX40-Ligand monoclonal antibody for adults with moderate-to-severe atopic dermatitis

PARIS – September 30, 2021 – Positive results from a Phase 2a study evaluating the safety and efficacy of amlitelimab, a human monoclonal antibody targeting key immune system regulator OX40-Ligand, were presented as a late-breaker today at the European Academy of Dermatology and Venerology (EADV) 2021 Virtual Congress. In the study, amlitelimab showed significant improvements in signs and symptoms of moderate-to-severe atopic dermatitis with a well-tolerated safety profile in adults whose disease cannot be adequately controlled with topical medications or for whom topical medications are not a recommended treatment approach.

> *"While new options are increasingly available for the treatment of atopic dermatitis, individual patients have different responses to therapies and therefore require different solutions,"* said Professor Stephan Weidinger, M.D., Ph.D., Vice Director, Professor, Department of Dermatology and Allergy, University Hospital Schleswig-Holstein. *"In the Phase 2a study presented at EADV, amlitelimab was shown to meaningfully improve the signs and symptoms of atopic dermatitis patients with moderate to severe disease with an unremarkable safety profile. These early results are exciting, and we look forward to seeking confirmatory data in future amlitelimab clinical trials."*

In this Phase 2a double-blind, placebo-controlled study, participants were randomized to either intravenous amlitelimab-low dose (LD) (n=29), intravenous amlitelimab-high dose (HD) (n=30) or placebo (n=29) and were treated every four weeks over a 12-week period. Eligible patients included adults with moderate-to-severe atopic dermatitis whose disease is inadequately controlled with topical therapies such as corticosteroids, or where such therapies were not advisable.

Co-primary endpoints included percent change in EASI from baseline, and incidence of treatment-emergent adverse events (TEAEs), at week 16.

At week 16, the data demonstrated that when dosed every four weeks:

- Patients treated with amlitelimab-LD showed 80% improvement in average EASI from baseline, and patients treated with amlitelimab-HD showed 70% improvement in average EASI from baseline, compared to 49% for the placebo group (p=0.009 and p=0.072, respectively). The difference between amlitelimab-LD and placebo was nominally statistically significant.

- The onset of response versus placebo was seen as early as Week 2 for both amlitelimab groups. No meaningful difference in responses was seen for the amlitelimab-LD and amlitelimab-HD groups.

- The overall rate of TEAEs was 35% for amlitelimab-LD, 17% for amlitelimab-HD and 31% for placebo. One serious adverse event was reported in the amlitelimab-LD group (infected atheroma) deemed related by the investigator at week 16; the event was resolved, and the patient was able to complete the study. No hypersensitivity reactions were reported.

Also, at 16 weeks, key secondary endpoint data included:

- 44% of patients treated with amlitelimab-LD and 37% of patients treated with amlitelimab-HD achieved a score of 0 (clear) or 1 (almost clear) on the validated Investigator's Global Assessment (vIGA) scale compared with 8% with placebo (p<0.001 both LD and HD). The vIGA is a 5-point scale ranging from 0 (clear) to 4 (severe) that measures the overall severity of skin lesions.

- 59% of amlitelimab-LD and 52% of amlitelimab-HD patients achieved 75% or greater skin improvement (EASI-75) compared to 25% with placebo.

- 33% of amlitelimab-LD and 30% of amlitelimab-HD patients achieved 90% or greater skin improvement (EASI-790 compared to 13% with placebo.

- A 60% improvement in the amlitelimab-LD group and a 59% improvement in the amlitelimab-HD group compared with 37% improvement in the placebo group in mean percent change from baseline in SCORing Atopic Dermatitis (SCORAD), a combined measure of area and severity of atopic dermatitis on the skin as well as patient-reported symptoms of itch and sleeplessness, (p=0.011 and p=0.016, respectively).

- At Week 36, 68% of patients who achieved a vIGA score of 0 or 1 at Week 16 maintained their response — 24 weeks after their last dose.

“The amlitelimab data presented at EADV support our belief that OX40-Ligand has the potential to provide a novel approach to treating a range of immune-mediated diseases," said Naimish Patel, M.D. Head of Global Development in Immunology

and Inflammation at Sanofi. *"This Phase 2a trial is the foundation of our clinical trial program with amlitelimab in atopic dermatitis. The forthcoming global Phase 2b trial will further evaluate the impact of amlitelimab when given subcutaneously in patients with moderate-to-severe atopic dermatitis. The results from these two trials will help form the basis for designing a phase 3 clinical trial program to further evaluate the safety and efficacy of amlitelimab."*

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. By targeting OX40-Ligand, amlitelimab aims to restore immune homeostasis between pro-inflammatory and anti-inflammatory T cells.

Amlitelimab is being studied in patients with moderate-to-severe atopic dermatitis with suboptimal response to topical therapies. The potential for long-lasting treatment responses in atopic dermatitis patients may help reduce the burden of frequent dosing, and further investigation will be conducted in a future Phase 2b study. Amlitelimab is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority.

In April 2021, Sanofi finalized the acquisition of Kymab, a clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immuno-oncology therapeutics, adding amlitelimab to the company's dynamic pipeline.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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