Press Release

Sanofi's amlitelimab met all primary and key secondary endpoints in the COAST 1 phase 3 study in adults and adolescents with atopic dermatitis

- Amlitelimab, dosed every four weeks or every 12 weeks, demonstrated statistically significant and clinically meaningful efficacy in skin clearance and disease severity compared to placebo at Week 24, with efficacy progressively increasing throughout the treatment period
- Study results reinforce the potential of amlitelimab as the first and only atopic dermatitis treatment with possible dosing of only four times per year
- Additional phase 3 data will provide a comprehensive understanding of amlitelimab's efficacy and safety profile, including the role of long-term maintenance treatment and the potential for off-treatment efficacy across diverse treatment populations

Paris, September 4, 2025. Positive results from the global COAST 1 phase 3 study (clinical study identifier: NCT06130566) showed that amlitelimab, a fully human non-T cell depleting monoclonal antibody that targets OX40-ligand (OX40L), dosed either every four weeks (Q4W) or every 12 weeks (Q12W), met all primary and key secondary endpoints, demonstrating statistically significant and clinically meaningful skin clearance and disease severity compared to placebo at Week 24 in patients aged 12 years and older with moderate-to-severe atopic dermatitis (AD). Amlitelimab was well-tolerated, with no new safety concerns identified in this study.

> *"These positive first phase 3 results of amlitelimab reinforce the potential of targeting the OX40-ligand to normalize the overactive immune system, without depleting T cells,"* said **Houman Ashrafian**, Executive Vice President, Head of Research & Development at Sanofi. *"Amlitelimab may represent a significant advance in the treatment of atopic dermatitis with clinically meaningful and progressively increasing efficacy, with the potential of dosing only four times per year. These promising data seen in a study population that more closely resembles today's diverse patient landscape, including a substantial proportion previously treated with advanced therapies, support our ambition to deliver a differentiated medicine. We look forward to sharing additional phase 3 results from the OCEANA clinical development program."*

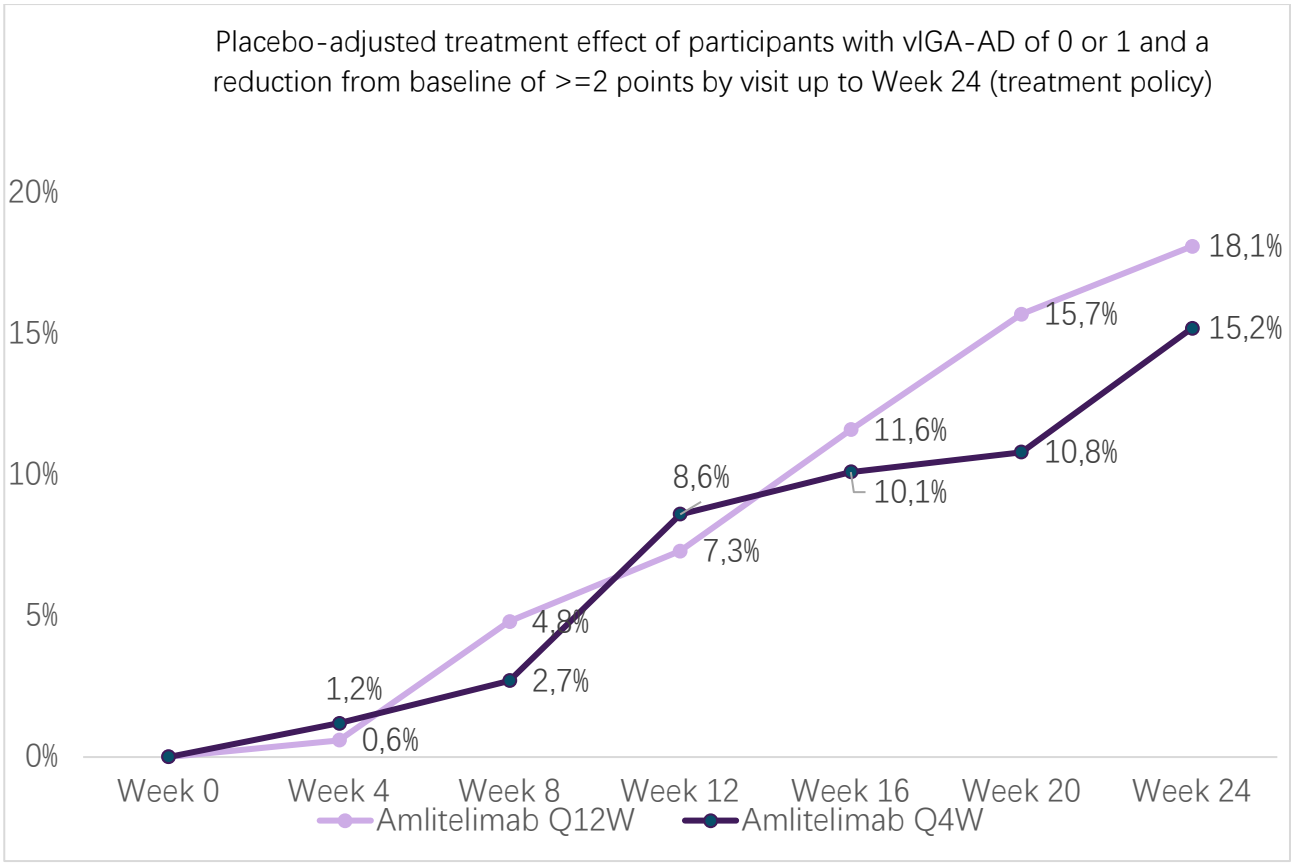
The key endpoints were measured at Week 24 in patients who received amlitelimab either Q4W or Q12W. For US and US reference countries, the primary endpoint was the proportion of patients with a validated investigator global assessment scale for AD (vIGA-AD) of 0 (clear) or 1 (almost clear) and a reduction from baseline score of ≥2 points. For the EU, EU reference countries and Japan, the co-primary endpoints comprised the proportion of patients with vIGA-AD 0/1 and a reduction from baseline score of ≥2 points along with the proportion of patients reaching a 75% or greater improvement in the eczema area and severity index total score (EASI-75).

Key endpoints *Proportion of patients*	Non-responder imputation*			Treatment policy**		
	Q4W	Q12W	Placebo	Q4W	Q12W	Placebo
vIGA-AD 0/1	21.1% p-value (p) <0.01	22.5% p <0.01	9.2%	26.5% p <0.001	29.1% p <0.001	10.5%
EASI-75	35.9% p <0.001	39.1% p <0.001	19.1%	46.0% p <0.001	50.3% p <0.001	27.6%

** Non-responder imputation: includes patients with rescue/prohibited medication use prior to Week 24 and missing data.*

*** Treatment policy: includes data for patients with rescue medication use prior to Week 24. Note: In both analyses non-responder imputation for patients with prohibited medication use and missing data.*

In both treatment arms, a progressive increase in efficacy without plateau was observed during the treatment period:



(Treatment effects at Week 24 are modeled and do not reconcile with the table).

The study's key secondary endpoints were also achieved across both dosing arms at Week 24, including the proportion of patients who achieved a vIGA-AD 0/1 with only barely perceptible erythema and a reduction from baseline of ≥2-points, and the proportion of patients who achieved a ≥4-point reduction in peak pruritus-numerical rating scale (PP-NRS) from baseline in patients with a baseline PP-NRS ≥4.

The most common treatment emergent adverse events (TEAEs) in COAST 1 (≥5% in any dose arm) were AD, nasopharyngitis and upper respiratory tract infection. All were more common in the placebo arm compared to amlitelimab-treated arms. Injection site reactions were numerically higher in amlitelimab arms (pooled amlitelimab 2.2%, placebo 0.7%). All were mild, patients recovered, and study medication was continued in all cases. Rates of pyrexia (1.1% in pooled amlitelimab arms vs. 0.7% in placebo arm) and chills (0.4% in pooled amlitelimab arms vs. 0% in placebo arm) were low. Overall, rates of treatment-emergent adverse events (TEAEs), serious adverse events, and TEAEs resulting in treatment discontinuation were similar in the placebo arm and pooled amlitelimab arms.

Full results will be submitted for presentation at a forthcoming medical meeting.

The OCEANA clinical development program of amlitelimab in AD, which includes COAST 1 and four other phase 3 studies (SHORE, COAST 2, AQUA, and ESTUARY) is anticipated to read out through 2026 and comprises the foundation for potential global regulatory submissions.

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

About the COAST 1 study

COAST 1 was a randomized, double-blind, placebo-controlled, parallel-group, 3-arm, global, multicenter phase 3 study to evaluate the efficacy and safety of amlitelimab monotherapy by subcutaneous injection in 601 adults and adolescents aged 12 years and older with moderate-to-severe AD. Key objectives included measuring the efficacy and safety of amlitelimab compared to placebo at Week 24. In the study, amlitelimab was administered at a dose of 250 mg (125 mg for those with body weight <40 kg) on either a Q4W or Q12W schedule following a loading dose of 500 mg (250 mg for those with body weight <40 kg). The study included sites in 15 countries across North America, Latin America, Europe, Asia-Pacific and the Middle East, reflecting a diverse study population.

About amlitelimab

Amlitelimab (SAR445229, KY1005) is a fully human, non-T cell depleting monoclonal antibody that blocks OX40L, a key immune regulator. With its novel mechanism of action, amlitelimab aims to normalize the overactive immune system, without depleting T cells. It has the potential to be a first- or best-in-class treatment for a range of immune-mediated diseases and inflammatory disorders, including the anchor indication of moderate-to-severe AD, and potentially in moderate-to-severe asthma, systemic sclerosis, celiac disease, and alopecia areata.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

Media Relations

Sandrine Guendoul | +33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com
Léo Le Bourhis | +33 6 75 06 43 81 | leo.lebourhis@sanofi.com
Victor Rouault | +33 6 70 93 71 40 | victor.rouault@sanofi.com
Timothy Gilbert | +1 516 521 2929 | timothy.gilbert@sanofi.com
Léa Ubaldi | +33 6 30 19 66 46 | lea.ubaldi@sanofi.com

Investor Relations

Thomas Kudsk Larsen | +44 7545 513 693 | thomas.larsen@sanofi.com
Alizé Kaisserian | +33 6 47 04 12 11 | alize.kaisserian@sanofi.com
Felix Lauscher | +1 908 612 7239 | felix.lauscher@sanofi.com
Keita Browne | +1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | +33 7 85 93 30 17 | nathalie.pham@sanofi.com
Tarik Elgoutni | +1 617 710 3587 | tarik.elgoutni@sanofi.com
Thibaud Châtelet | +33 6 80 80 89 90 | thibaud.chatelet@sanofi.com
Yun Li | +33 6 84 00 90 72 | yun.li3@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 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, 2024. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.