Press Release

AAD: new results from Sanofi's amlitelimab phase 3 studies in atopic dermatitis presented in late-breaking research session

- Across the COAST 1, COAST 2, and SHORE phase 3 studies, amlitelimab, dosed either Q4W or Q12W, showed progressively increasing efficacy, with no evidence of plateau at Week 24 across endpoints
- Data reinforce potential for Q12W dosing from the start

Paris, March 28, 2026. Positive results from three phase 3 studies of amlitelimab, a fully human non-T cell depleting monoclonal antibody that selectively targets OX40-ligand (OX40L), in moderate-to-severe atopic dermatitis (AD) as a monotherapy and in combination with topical therapies, showed improvements in skin clearance and disease severity with amlitelimab treatment compared to placebo in patients aged 12 years and older. The studies, COAST 1 (clinical study identifier: NCT06130566), COAST 2 (clinical study identifier: NCT06181435) and SHORE (clinical study identifier: NCT06224348) were presented during the late-breaking research session at the 2026 American Academy of Dermatology (AAD) Annual Meeting in Denver, Colorado, US. In these studies, amlitelimab was generally well-tolerated.

> *"The totality of data shared at AAD reinforce the progressive improvement in efficacy seen with amlitelimab over the course of treatment and the potential for Q12W dosing from the start,"* said **Houman Ashrafian**, Executive Vice President, Head of Research & Development at Sanofi. *"These data contribute to the body of evidence supporting amlitelimab's potential to be a meaningful option for patients with atopic dermatitis, a chronic, heterogenous disease where unmet needs still exist."*

Primary and key secondary endpoints in COAST 1, COAST 2, and SHORE were assessed at Week 24 in patients who received amlitelimab either every four weeks (Q4W) or every 12 weeks (Q12W) with or without topical medications. For US and US reference countries, the primary endpoint for all studies 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.

> *"Despite current medicines, a critical medical gap remains for moderate-to-severe atopic dermatitis patients and additional treatment options are needed,"* said **Eric Simpson**, MD, Professor of Dermatology and Director of Clinical Research at Oregon Health & Science University. *"These data, which show that amlitelimab delivers potentially progressive efficacy over time, further illustrate the potential of non-T cell depleting OX40L inhibition to help reduce disease severity and burdensome symptoms with less frequent dosing."*

In the COAST 1 and COAST 2 studies, amlitelimab met the primary endpoint. In COAST 1, key secondary endpoints, including vIGA-AD 0/1 with barely perceptible erythema (BPE), the proportion of patients reaching a 75% or greater improvement in the eczema area, severity

index total score (EASI-75), and a ≥4-point reduction in peak pruritus-numerical rating scale (PP-NRS) were statistically significant. In COAST 2, EASI-75 and PP-NRS≥4 reached nominal significance; vIGA-AD 0/1 with BPE did not reach statistical significance.

In the SHORE study, amlitelimab in combination with topical corticosteroids (TCS) with or without topical calcineurin inhibitors (TCI), dosed at both Q4W and Q12W, demonstrated significant improvements in AD clinical signs and symptoms versus placebo as measured across primary and key secondary endpoints at Week 24.

COAST 1 primary and key secondary endpoints			
Key endpoints *Proportion of patients*	NRI*+ *(US estimand)*		
	Q4W	Q12W	placebo
vIGA-AD 0/1	21.1% p≤0.01	22.5% p≤0.01	9.2%
vIGA-AD 0/1 with BPE	17.4% p<0.02	18.5% p<0.02	7.9%
EASI-75	35.9% p<0.001	39.1% p<0.001	19.1%
PP-NRS≥4	22.5% p≤0.02	24.5% p≤0.02	12.7%
COAST 2 primary and key secondary endpoints			
Key endpoints *Proportion of patients*	NRI*+ *(US estimand)*		
	Q4W	Q12W	placebo
vIGA-AD 0/1	25.3% p≤0.025	25.7% p≤0.025	14.8%
vIGA-AD 0/1 with BPE	21.6%	20.3%	13.4%
EASI-75	41.8% p<0.05***	40.5% p<0.05***	24.2%
PP-NRS≧4	26.8% p<0.05***	27.2% p<0.05***	17.1%
SHORE primary and key secondary endpoints			
Key endpoints *Proportion of patients*	NRI*++ *(US estimand)*		
	Q4W	Q12W	placebo
vIGA-AD 0/1	28.7% p≤0.01	32.3% p≤0.01	16.8%
vIGA-AD 0/1 with BPE	25.3% p≤0.01	29.1% p≤0.01	13.7%
EASI-75	48.1% p≤0.025	46.8% p≤0.025	32.3%
PP-NRS≥4	38.2% p≤0.025	33.3% p≤0.025	21.5%

** Non-responder imputation (NRI): patients with rescue or prohibited medication use before Week 24, early discontinuation due to lack of efficacy, or with missing efficacy assessments at Week 24 are classified as non-responders.*

+ For COAST 1 and COAST 2, statistical analyses followed a pre-specified hierarchical testing procedure to control for multiplicity. For the pre-specified endpoints across the two doses, the statistical significance level was adjusted to two-sided p<0.025. Nominal p-values<0.05 are also reported.

++ For SHORE, statistical analysis followed a pre-specified hierarchical testing procedure to control for multiplicity. For the pre-specified endpoints across the two doses, the statistical significance level was adjusted (alpha-split) to two-sided p<0.025.
**** P-values are nominal without multiplicity adjustment.*

In the COAST 1, COAST 2, and SHORE studies, the safety profile of amlitelimab was consistent with previously reported data. In COAST 1, the most common treatment-emergent adverse events (TEAEs, ≥5% in any dose arm; pooled amlitelimab vs placebo) were nasopharyngitis (7.3% vs 10.5%), dermatitis atopic (7.3% vs 22.4%), and upper respiratory tract infection (5.3% vs 8.6%). In COAST 2, the most common TEAEs were nasopharyngitis (5.9% vs 7.4%), dermatitis atopic (5.3% vs 2.7%), and upper respiratory tract infection (4.8% vs 4.0%). The most common TEAEs in the SHORE study included nasopharyngitis (9.5% vs 12.5%), upper respiratory tract infection (7.9% vs 4.4%) and dermatitis atopic (2.7% vs 5.6%). In addition, across the three studies, the incidence of pyrexia, chills and headaches were low, with the majority not injection-related. Malignancy rates were low (<1%) and generally similar between amlitelimab and placebo groups. There were no events of severe injection site reactions, serious gastrointestinal ulceration, or Kaposi's sarcoma (KS).

Cumulatively, a total of two KS cases, both in patients with known risk factors, were reported out of 3,778 patients confirmed to have been exposed to amlitelimab across all indications. One was previously presented at the Winter Clinical Miami conference from the open-label ATLANTIS phase 2 study (clinical study identifier: NCT05769777). At the AAD meeting, Sanofi presented the second case, identified in the still-blinded ESTUARY phase 3 study (clinical study identifier: NCT06407934). In each case, the patient stopped treatment with amlitelimab and is in the recovery phase. Sanofi has not identified any further cases of KS across an estimated 4,630 patients in the full amlitelimab development program, including still-blinded studies. Sanofi believes that amlitelimab continues to have the potential to be a meaningful and convenient option for patients with AD.

Results from ESTUARY, a phase 3 extension study evaluating Q12W maintenance dosing and longer-term safety, are anticipated in H2 2026.

Amlitelimab is currently in clinical development, and its safety and efficacy has 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 250mg (125mg for those with body weight <40kg) on either a Q4W or Q12W schedule following a loading dose of 500mg (250mg for those with body weight <40kg). The study included sites in 15 countries across North America, EU, Argentina, Brazil, Chile, China, India, Israel, South Korea, and Taiwan, reflecting a diverse study population.

About the COAST 2 study
COAST 2 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 589 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 (125mg for those with body weight <40kg) on either a Q4W or Q12W schedule

following a loading dose of 500mg (250mg for those with body weight <40kg). The study included sites in 16 countries across the US, EU, UK, Argentina, Chile, Mexico, South Africa, Turkey, China, and Japan.

About the SHORE study
SHORE was a randomized, double-blind, placebo-controlled, parallel-group, 3-arm, multinational, multicenter phase 3 study to evaluate the efficacy and safety of amlitelimab by subcutaneous injection in combination TCS with or without TCI in 643 participants aged 12 years and older with moderate-to-severe AD. Key objectives include measuring the efficacy and safety of amlitelimab compared to placebo at Week 24 when used in combination with TCS/TCI. In the study, amlitelimab was administered at a dose of 250mg (125 mg for those with body weight <40kg) on either a Q4W or Q12W schedule following a loading dose of 500mg (250mg for those with body weight <40kg). Patients were given medium-potency TCS (with or without TCI), applied up to twice daily to treat active lesions, and were instructed to reduce the dose to three times weekly or discontinue use based on lesion control or clearance. The study included sites in 14 countries across North America, EU, Argentina, Chile, Brazil, Turkey, Canada, China, and Japan.

About amlitelimab
Amlitelimab (SAR445229, KY1005) is a fully human, non-T cell depleting monoclonal antibody that blocks the OX40L, a key immune regulator. With its novel mechanism of action, amlitelimab selectively blocks OX40L signaling during the inflammatory prequel, the initiating phase of an overactive immune system, to potentially normalize T-cell-mediated inflammation without T-cell depletion.

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.

Sanofi 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
Ekaterina Pesheva | +1 410 926 6780 | ekaterina.pesheva@sanofi.com

Sanofi 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
Keita Browne | +1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | +33 7 85 93 30 17 | nathalie.pham@sanofi.com
Nina Goworek | +1 908 569 7086 | nina.goworek@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 within the meaning of applicable securities laws, including 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 events and economic performance. Words such as "expect," "anticipate," "believe," "intend," "estimate," "plan," "can," "contemplate," "could," "is designed to," "may," "might," "potential," "objective," "attempt," "target," "project," "strategy," "strive," "desire," "predict," "forecast," "ambition," "guideline," "seek," "should," "will," "goal," or the negative of these, and similar expressions are intended to identify forward-looking statements. 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 U.S Food and Drug Administration or the European Medicines Agency, 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; unexpected regulatory actions or delays, or government regulation generally; authorities' decisions regarding whether and when to approve a product candidate; political pressure in the United States to mandate lower drug prices including "most favored nation" pricing for State Medicaid programs; 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, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general; 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 French Markets Authority (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, 2025 or contained in our periodic reports on Form 6-K. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements. In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward-looking statements contained herein.

All trademarks mentioned in this press release are the property of the Sanofi group.