Press Release

Sanofi announces decision not to submit amlitelimab in atopic dermatitis for global regulatory reviews

Paris, July 24, 2026. Sanofi today announced the discontinuation of clinical development of amlitelimab, an OX40-ligand monoclonal antibody, in moderate-to-severe atopic dermatitis (AD). This decision not to submit for global regulatory reviews was made as part of an ongoing strategic assessment of the pipeline.

Sanofi has determined that the totality of efficacy and safety evidence generated to date does not support further development of amlitelimab in AD. While the ESTUARY phase 3 long-term extension study (clinical study identifier: NCT06407934) showed long-term maintenance of clinical response without relapse in patients aged 12 years and older with moderate-to-severe AD and an emerging safety profile that builds on previous data, amlitelimab would not represent a meaningful improvement to the standard of care for patients with AD. Additional results from the amlitelimab development program in AD, including from the ESTUARY study, will be presented at a forthcoming medical meeting.

Patients and their physicians need additional effective treatments due to the heterogeneity of underlying immune mechanisms that contribute to AD, and Sanofi remains committed to pursuing advances in inflammatory skin conditions.

Sanofi is deeply grateful to the patients, caregivers, and investigators who supported the development of amlitelimab in AD, including in the ESTUARY study. Sanofi will work closely with investigators, site teams, and regulatory authorities to ensure a wind-down of ongoing amlitelimab AD studies, with appropriate transition of care for all enrolled patients.

Financial considerations
Sanofi is not amending its full-year 2026 guidance as a result of this announcement.

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.

The phase 2 study of amlitelimab in celiac disease is ongoing and expected to readout in the second half of 2026.

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.

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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.