Press Release

Sanofi's lunsekimig met primary and key secondary endpoints in phase 2 respiratory studies in asthma and CRSwNP

- The AIRCULES phase 2b study achieved its primary and key secondary endpoints in moderate-to-severe asthma regardless of biomarker status
- The DUET phase 2a study met its primary and key secondary endpoints in chronic rhinosinusitis with nasal polyps, reinforcing lunsekimig's potential as a respiratory treatment
- The exploratory VELVET phase 2b study did not meet its primary endpoint in moderate-to-severe atopic dermatitis
- In all studies, lunsekimig was well tolerated

Paris, April 7, 2026. Phase 2 studies of lunsekimig in two chronic respiratory diseases met their primary and key secondary endpoints compared to placebo. Lunsekimig, a novel bispecific Nanobody® VHH, is made of five linked antibody fragments designed to simultaneously block TSLP and IL-13, two separate drivers of inflammation that contribute to tissue damage in asthma and related diseases. In both studies, lunsekimig was well tolerated, with an acceptable safety profile.

> *"These data are promising and support our belief that the dual-targeting mechanism of lunsekimig may offer a novel treatment option for patients living with respiratory diseases, including asthma,"* said **Houman Ashrafian**, Executive Vice President, Head of Research & Development at Sanofi. *"Importantly, these findings underscore lunsekimig's potential to address multiple critical aspects of respiratory disease management through its unique mechanism."*

In the AIRCULES phase 2b study (clinical study identifier: NCT06102005), lunsekimig met its primary and key secondary endpoints demonstrating a statistically significant and clinically meaningful reduction in exacerbations and improvement in lung function, as measured by pre-bronchodilator forced expiratory volume in one second (pre-BD FEV_1). The study enrolled adult patients with moderate-to-severe asthma, a form of the disease marked by recurrent symptoms and frequent flareups despite standard-of-care treatment.

The DUET phase 2a proof-of-concept study (clinical study identifier: NCT06454240), of lunsekimig in chronic rhinosinusitis with nasal polyps (CRSwNP), met its primary endpoint of change in nasal polyp score from baseline and met its key secondary endpoints of change in patient reported nasal congestion/obstruction score and change in Lund-Mackay Computed Tomography (LMK-CT) score, all compared to placebo at Week 24.

The separate exploratory VELVET phase 2b study (clinical study identifier: NCT06790121) evaluating lunsekimig in moderate-to-severe atopic dermatitis did not meet its primary endpoint of percent change from baseline in eczema area severity index (EASI) score. However, improvements were seen in the key secondary endpoints measuring skin clearance including EASI-75 (proportion of patients reaching a 75% or greater improvement in the EASI total score), and vIGA-AD 0/1 (proportion of patients reaching validated investigator global assessment scale for atopic dermatitis score of 0 or 1).

Across these studies, lunsekimig was generally well tolerated. In the AIRCULES study, among those who received at least one dose of lunsekimig, the most common (≥5%) treatment-emergent adverse events (TEAEs) were nasopharyngitis, upper respiratory tract infection, headache, and dose scheduling errors. In the DUET study, among those who received at least

one dose of lunsekimig, the most common (≥5%) TEAEs were injection site reaction or erythema, viral upper respiratory tract infection, nasopharyngitis, epistaxis, ear pain, and increased creatine phosphokinase. Overall, rates of serious adverse events and TEAEs leading to treatment discontinuation in both studies were similar in the lunsekimig group and the placebo group. In the VELVET study, lunsekimig was generally well tolerated and had a safety profile consistent with the other studies.

Detailed results from the AIRCULES, DUET, and VELVET studies will be presented at upcoming medical congresses.

Lunsekimig is currently in clinical development in the AIRLYMPUS phase 2 study in high-risk asthma (clinical study identifier: NCT06676319) and in the PERSEPHONE and the THESEUS phase 3 studies (clinical study identifiers PERSEPHONE: NCT07190209, THESEUS: NCT07190222), and its safety and efficacy have not been evaluated by any regulatory authority.

About asthma

Asthma is one of the most common chronic diseases worldwide, with an estimated 262 million patients diagnosed globally as of 2019. However, despite several available therapies, more than 50% of patients have asthma that is not well controlled. A significant unmet need persists for treatments that prevent and reduce asthma exacerbations, which profoundly diminish patients' quality of life, disrupt daily activities, and contribute substantially to healthcare resource utilization.

About CRSwNP

CRSwNP is a persistent inflammatory disease of the nose and sinuses characterized by the presence of soft, noncancerous growths, called nasal polyps, in the nasal passages. Individuals with CRSwNP often experience symptoms such as nasal congestion, facial pressure, and a reduced sense of smell, which can significantly impact their quality of life. The majority of patients with CRSwNP have comorbid asthma, which increases in frequency with severity of the disease.

About the AIRCULES study

AIRCULES was a randomized, double-blind, placebo-controlled, parallel-group, dose-ranging phase 2b study to evaluate the efficacy, safety, and tolerability of subcutaneous lunsekimig added to standard of care in adult patients with moderate-to-severe asthma across the range of FeNO (fractional exhaled nitric oxide) and eosinophil values. Lunsekimig was administered in multiple dosing regimens, and the primary endpoint was the annualized rate of asthma exacerbation events over 48 weeks. The key secondary endpoint evaluated lung function improvement, as measured by pre-BD FEV_1 at Week 48. Lung function was assessed indirectly by measuring the volume of air a patient can exhale forcefully in one second. The study included sites across the US, Canada, Argentina, Brazil, Chile, China, India, Israel, Japan, Mexico, South Africa, South Korea, Turkey, and the UK.

About the DUET study

DUET was a randomized, double-blind, placebo-controlled, parallel-group phase 2a study designed to evaluate the efficacy, safety, and tolerability of subcutaneous lunsekimig in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP). Key objectives include measuring the efficacy and safety of lunsekimig compared to placebo over 24 weeks. The primary endpoint was change in nasal polyps score from baseline at Week 24 through bilateral endoscopy and the key secondary endpoints were change from baseline in patient-reported nasal congestion/obstruction score and change from baseline in LMK-CT score, both at Week 24. The study included sites across the US, Argentina, Belgium, Bulgaria, Poland, and the UK.

About the VELVET study

VELVET was a randomized, double-blind, placebo-controlled, multicenter exploratory study to assess the efficacy and safety of three subcutaneous dose regimens of lunsekimig in adult patients with moderate-to-severe atopic dermatitis. Key objectives include measuring the efficacy and safety of subcutaneous lunsekimig compared to placebo over 24 weeks. Lunsekimig was administered in three dosing regimens, and the primary endpoint was the percent change

in EASI score from baseline at week 24. The study included sites across the United States, Czechia, Japan, and Poland.

About lunsekimig

Lunsekimig is a novel, pentavalent Nanobody® VHH that combines bispecific targeting of TSLP, an upstream initiator of inflammation and IL-13, a downstream cytokine causing tissue organ damage in respiratory diseases. As a pentavalent Nanobody® VHH (variable heavy-chain domains of a heavy-chain antibody), lunsekimig is made of five linked antibody fragments designed to simultaneously block TSLP and IL-13, which drive airway inflammation and can contribute to tissue damage in certain diseases and bind albumin for longer half-life. Pre-clinical research suggests that the combination of these targets simultaneously can potentially lead to additive and synergistic benefits in immune-mediated diseases such as asthma.

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

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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

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