Press Release

Sanofi's respiratory pipeline advances with new data in asthma and plans for new clinical studies in COPD

- New phase 2 data for amlitelimab show efficacy in heterogeneous inflammatory asthma
- Lunsekimig now targeting chronic rhinosinusitis and COPD in addition to asthma
- Itepekimab expanding into chronic rhinosinusitis along with COPD and bronchiectasis; phase 3 readouts in COPD in H2 2025 and phase 2 readout in bronchiectasis in 2026

Paris, April 15, 2025. Sanofi today shared new progress from its mid- to late-stage respiratory pipeline, including preliminary phase 2 results for amlitelimab in adults with moderate-to-severe asthma.

Amlitelimab: clinically meaningful efficacy in asthma
Preliminary results from the TIDE-Asthma phase 2 study (clinical study identifier: NCT05421598) show that the primary endpoint of annualized exacerbation rate at week 48 was not met at the highest dose level, leading to nominal significance at the medium dose. However, the study demonstrates amlitelimab's compelling efficacy in heterogeneous inflammatory asthma, potentially representing a breakthrough for this underserved patient population if observed in later studies. Treatment with amlitelimab led to nominally significant and clinically meaningful reductions in asthma exacerbations at the medium dose tested and a numerically greater reduction in exacerbations at the high dose at week 60. The study also demonstrated nominally significant and clinically meaningful improvement in secondary endpoints of lung function and asthma control. Notably, in a patient sub-group defined by biomarkers (eosinophils ≥300 cells/ml and elevated neutrophils), amlitelimab showed nominally significant and clinically meaningful improvements in exacerbations (with a reduction of more than 70%), lung function and asthma control at week 60. These results demonstrate that amlitelimab has potential to improve key disease outcomes in asthma patients with continued unmet need. The phase 3 program is currently being planned.

> ***Houman Ashrafian***
> Executive Vice President, Head of Research & Development
> *"We are pleased by the significant progress we have made with our pipeline across respiratory indications. In asthma, amlitelimab shows potential as an effective, long-acting medicine, including in patients with moderate-to-severe heterogenous inflammation. If the preliminary effect we have seen is confirmed in phase 3 studies, amlitelimab could become a differentiated treatment option in asthma. These data validate our strategy to advance innovative science and provide new solutions for patients with challenging-to-treat respiratory diseases."*

Amlitelimab has a unique non-depleting mechanism of action targeting OX40-Ligand with the potential to durably restore immune balance, with a sustained effect and infrequent dosing. In the TIDE-Asthma study, patients were treated every four weeks for the first 24 weeks and every 12 weeks for the remaining 36 weeks. The durable efficacy shown by amlitelimab through 60 weeks of treatment supports a quarterly maintenance dosing schedule. The safety profile was consistent with previous studies across indications, with no new safety signals identified throughout the 60-week treatment period. The incidence of treatment emergent adverse effects (TEAEs) or treatment discontinuation was similar between the amlitelimab and the placebo groups. The most frequent TEAEs (≥ 5% in any

arm) more common (≥ 1%) than placebo were COVID-19, bronchitis, acute sinusitis and headache. All were mild-to-moderate in severity and all non-serious.

Full and final results will be presented at a forthcoming medical meeting.

Lunsekimig: potential for broader use in chronic obstructive pulmonary disease (COPD)
Lunsekimig is being explored in a broad population of asthma patients, regardless of their inflammation and severity status.

The readout of the AIRCULES phase 2 study (clinical study identifier: NCT06102005) in moderate to severe asthma is anticipated in 2026 while the AIRLYMPUS phase 2 study (clinical study identifier: NCT06676319) in high-risk asthma was initiated in Q4 2024.

The readout of the phase 2 study in patients with chronic rhinosinusitis with nasal polyps (clinical study identifier: NCT06454240) is anticipated in 2026.

A phase 2/3 study in COPD is anticipated to begin in 2025.

Itepekimab: expanding clinical studies beyond COPD into chronic rhinosinusitis
In partnership with Regeneron, two phase 3 studies in patients with chronic rhinosinusitis with nasal polyps (CRSwNP), CEREN 1 (clinical study identifier: NCT06834347) and CEREN 2 (clinical study identifier: NCT06834360) and one phase 2 study in patients with chronic rhinosinusitis without nasal polyps (CRSsNP) (clinical study identifier: NCT06691113) were initiated in Q1 2025.

Itepekimab is currently being explored in patients with COPD in two phase 3 studies AERIFY-1 (clinical study identifier: NCT04701983) and AERIFY-2 (clinical study identifier: NCT04751487) with the readout anticipated in H2 2025, and in one phase 2 study, AERIFY-3 (clinical study identifier: NCT05326412), with the readout anticipated in H2 2025.

Finally, itepekimab is being explored in a phase 2 study (clinical study identifier: NCT06280391) in bronchiectasis, with the readout anticipated in 2026.

About amlitelimab
Amlitelimab is a fully human non-T cell depleting monoclonal antibody that blocks OX40-Ligand, a key immune regulator, and has the potential to be a first- or best-in-class treatment for a range of immune-mediated diseases and inflammatory disorders, including moderate-to-severe atopic dermatitis (phase 3), asthma (phase 2), hidradenitis suppurativa (phase 2), systemic sclerosis (phase 2), celiac disease (phase 2), and alopecia (phase 2). By targeting OX40-Ligand, amlitelimab aims to preserve the balance between pro-inflammatory and regulatory T cells. Amlitelimab is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority.

About TIDE-Asthma
The phase 2 TIDE-Asthma study is a randomized, double-blind, placebo-controlled, dose-ranging study, evaluating amlitelimab as an add-on therapy in 437 adults with moderate-to-severe asthma. Participants were on standard-of-care medicines with medium-to-high doses of inhaled corticosteroids and up to two other controllers. The study included three dose levels of amlitelimab, each with a loading dose administered every four weeks for the first 24 weeks, followed by once every 12 weeks until week 60, with participants randomized 2:1:2:2 to receive one of the three active doses or placebo. The primary endpoint was the annualized rate of severe asthma exacerbations. Key secondary endpoints include lung function (pre-BD FEV1) and asthma control (ACQ-5).

About lunsekimig

Lunsekimig is a novel Nanobody VHH® that combines targeting of IL13, a downstream cytokine causing tissue organ damage in respiratory diseases and TSLP, an upstream initiator of inflammation. 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. Lunsekimig is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority.

About itepekimab

In partnership with Regeneron, Sanofi is exploring itepekimab, a fully human monoclonal antibody that binds to and inhibits IL33, an initiator and amplifier of broad inflammation in respiratory diseases. Itepekimab is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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