

Itepekimab met the primary endpoint in one of two COPD phase 3 studies

- AERIFY-1 study met its primary endpoint of a statistically significant reduction in moderate or severe exacerbations in former smokers regardless of eosinophilic phenotype and provided a clinically meaningful benefit
- AERIFY-2 study, a second Phase 3 study, did not meet the primary endpoint despite a benefit seen earlier in the study
- Itepekimab was generally well tolerated in both AERIFY-1 and AERIFY-2
- Sanofi and Regeneron are assessing the data and will discuss with regulatory authorities to evaluate next steps

Paris and Tarrytown, NY, May 30, 2025. The AERIFY-1 phase 3 study evaluating itepekimab in former smokers with inadequately controlled chronic obstructive pulmonary disease (COPD) met the primary endpoint of a statistically significant reduction in moderate or severe acute exacerbations compared to placebo of 27% at week 52, a clinically meaningful benefit. The AERIFY-2 phase 3 study did not meet the same primary endpoint, although a benefit was seen earlier in the trial.

In the studies, patients were randomized to receive itepekimab every two weeks (AERIFY-1: n=375; AERIFY-2: n=326), every four weeks (AERIFY-1: n=377; AERIFY-2: n=303), or placebo (AERIFY-1: n=375; AERIFY-2: n=324), which was added to inhaled triple or double standard-of-care therapy. The primary endpoint analysis for AERIFY-1 and AERIFY-2 was the reduction in the annualized rate of acute moderate or severe COPD exacerbations with itepekimab treatment.

The table below summarizes the reductions in moderate or severe exacerbations (itepekimab compared to placebo) through weeks 24 and 52:

	AERIFY-1		AERIFY-2	
	Week 24	Week 52	Week 24	Week 52
Itepekimab every two weeks	30%	27% ^a	18%	2%
Itepekimab every four weeks	34%	21% ^a	21%	12%

^a Formal significance testing was only performed at 52 weeks in the Phase 3 trials, with significance achieved for both the every two-week arm and every four-week arm in AERIFY-1

The total number of exacerbations were lower than prospectively anticipated, decreasing the power of both trials. Enrollment largely occurred during the time of the global COVID pandemic, which could have contributed to the overall lower exacerbation rates.

Houman Ashrafian, MD, PhD

Executive Vice President, Head of Research and Development at Sanofi

“While we are encouraged by the results of AERIFY-1, the results of both studies merit further exploration to have a full understanding of the data and the role that IL33 plays in this complex disease. Certain people with COPD are in desperate need of new treatment options, especially those who continue to experience exacerbations despite being on maximal therapy, and we remain committed to discussing these data with regulatory agencies to evaluate our path forward.”

The safety profile of itepekimab was consistent across dosing regimens, and adverse events (AEs) were generally comparable between treatment and placebo groups. In AERIFY-1, the overall rates of AEs were 67% and 68% for itepekimab every two weeks and every four weeks, respectively, compared to 68% for placebo. In AERIFY-2, the overall rates of AEs were 64% and 71% for itepekimab every two weeks and every four weeks, respectively, compared to 64% for placebo. In AERIFY-1, the rate of serious infections was 7% for each itepekimab arm, compared to 10% for placebo. In AERIFY-2, the rate of serious infections was 10% and 7% for itepekimab every two weeks and every four weeks, respectively, compared to 7% for placebo. AEs leading to death were 1% for each itepekimab arm compared to 2% for placebo in AERIFY-1, and 3% for each itepekimab arm compared to 2% for placebo in AERIFY-2. Anti-drug antibodies were rare and had no apparent impact on itepekimab drug levels.

Sanofi and Regeneron are reviewing the data and will discuss with regulatory authorities to evaluate next steps.

Detailed results from these studies will be presented at a future medical meeting. Itepekimab is currently being evaluated in other studies, including chronic rhinosinusitis with nasal polyps (CRSwNP), chronic rhinosinusitis without nasal polyps (CRSsNP), and bronchiectasis.

George D. Yancopoulos, M.D., Ph.D.

Board co-Chair, President and Chief Scientific Officer at Regeneron

“COPD is a particularly complex disease, and novel approaches are needed to address the multiple underlying biological disease driver. We are proud of our work in this challenging treatment landscape, bringing Dupixent – the first-ever biologic medicine for COPD – to certain patients who previously had very limited options remaining. We are encouraged by the initial results from AERIFY-1 and are carefully reviewing the results from both itepekimab trials to inform next steps. We remain committed to our broader itepekimab development program. The learnings will be invaluable as we continue to advance itepekimab in respiratory diseases with unmet need.”

The safety and efficacy of itepekimab are currently under clinical investigation and have not been fully evaluated by any regulatory authority.

About itepekimab

Itepekimab is a fully human monoclonal antibody that binds to and inhibits interleukin-33 (IL33), an initiator and amplifier of broad inflammation in COPD. IL33 is thought to be involved in different types of inflammation and is particularly elevated in the lungs of former smokers.

Itepekimab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement and is currently in clinical development programs for CRSwNP (phase 3), non-cystic fibrosis bronchiectasis (phase 2), and CRSsNP (phase 2).

About the AERIFY clinical study program

AERIFY-1 and AERIFY-2 phase 3 studies were randomized, Phase 3, double-blind, placebo-controlled studies that evaluated the efficacy and safety of itepekimab in 1,127 (AERIFY-1) and 953 (AERIFY-2) adults aged 40-85 years

who were former smokers with moderate-to-severe COPD. Former smokers were defined as those who have not smoked for at least six months. Treatments were administered subcutaneously and added to double therapy (inhaled corticosteroid [ICS] plus long-acting beta2-agonist [LABA] or long-acting muscarinic antagonist [LAMA] plus LABA) or a maximal standard-of-care inhaled triple therapy (ICS, LABA and LAMA).

The primary endpoint for AERIFY-1 and AERIFY-2 was the annualized rate of acute moderate or severe COPD exacerbations. Moderate exacerbations were defined as those requiring systemic steroids and/or antibiotics. Severe exacerbations, also assessed separately as a pre-specified endpoint, were defined as those: requiring hospitalization; more than 24 hours of observation in an emergency department or urgent care facility; or resulting in death.

The AERIFY program includes two additional ongoing trials: AERIFY-3, a Phase 2 mechanistic study assessing the impact of itepekimab on airway inflammation in patients with COPD, and AERIFY-4, a Phase 3 study assessing the long-term safety of itepekimab in patients with COPD.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and creating 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.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite*[®], which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center[®] and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on [LinkedIn](#), [Instagram](#), [Facebook](#) or [X](#).

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These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, “Regeneron’s Products”) and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, “Regeneron’s Product Candidates”) and research and clinical programs now underway or planned, including without limitation itepekimab in adults who were former smokers with inadequately controlled chronic obstructive pulmonary disease (“COPD”) and other potential indications; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron’s Product Candidates and new indications for Regeneron’s Products, such as itepekimab for the treatment of COPD as discussed in this press release as well as itepekimab for the treatment of chronic rhinosinusitis with nasal polyps, non-cystic fibrosis bronchiectasis, and chronic rhinosinusitis without nasal polyps; 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