Press Release

ECCO 2025: new duvakitug data reinforce best-in-class potential in ulcerative colitis and Crohn's disease

- New detailed data from the RELIEVE UCCD study support overall efficacy and safety of duvakitug in all pre-specified subgroups across the different doses
- New endpoints presented include findings on clinical and endoscopic outcomes and histological-endoscopic mucosal improvement
- Findings to form the basis for a phase 3 program, anticipated to start in H2 2025

Paris and Parsippany, NJ, February 22, 2025. Sanofi and Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd., today presented new, detailed results from the RELIEVE UCCD phase 2b study of duvakitug, a human IgG1-λ2 monoclonal antibody targeting TL1A, in patients with moderate-to-severe ulcerative colitis (UC) and Crohn's disease (CD), the two most common forms of inflammatory bowel disease (IBD). These results were shared in two oral presentations at the 20th Congress of the European Crohn's and Colitis Organisation (ECCO) in Berlin, Germany.

Ulcerative colitis

In the UC cohort of the RELIEVE UCCD study, 36% (450 mg dose) and 48% (900 mg dose) of patients treated with duvakitug achieved the primary endpoint of clinical remission (mMS)* at week 14 compared to 20% treated with placebo; placebo-adjusted rates were 16% (450 mg dose) and 27% (900 mg dose) (p=0.050 and 0.003, respectively).

In addition, higher clinical remission rates were observed for both doses of duvakitug versus placebo in both advanced therapy (AT) -experienced and AT-naïve subgroups of patients.

- AT-experienced: 29% (450 mg) and 36% (900 mg), with placebo-adjusted rates of 22% (450 mg) and 29% (900 mg).
- AT-naïve: 39% (450 mg) and 53% (900 mg), with placebo-adjusted rates of 12% (450 mg) and 26% (900 mg).

Additional endpoints observed*:

- Clinical response (mMS): 81% (450 mg) and 70% (900 mg) compared to 52% treated with placebo.
- Endoscopic improvement (MES): 45% (450 mg) and 50% (900 mg) compared to 23% treated with placebo.
- Histological-endoscopic mucosal improvement (HEMI): 30% (450 mg) and 33% (900 mg) compared to 16% treated with placebo.

> ***Walter Reinisch, MD, PhD,***
> Medical University of Vienna, and lead investigator of the RELIEVE UCCD study
> *"Patients, many of whom have spent years in a recurring cycle of remission and relapse, have been waiting a long time for better options in treating ulcerative colitis. We're highly encouraged by the significant treatment response, compared to placebo, seen in the study, both in advanced therapy naïve- and experienced patients," said Walter Reinisch, MD, PhD, Medical University of Vienna, and lead investigator of the RELIEVE UCCD study. "With this potential of duvakitug to reduce inflammation, we could truly transform treatment for patients with IBD in a safe manner."*

Crohn's disease

In the CD cohort of the RELIEVE UCCD study, 26% (450 mg dose) and 48% (900 mg dose) of patients treated with duvakitug achieved the primary endpoint of endoscopic response (SES-CD)* compared to 13% on placebo; placebo-adjusted rates were 13% (450 mg dose) and 35% (900 mg dose) at week 14 (p= 0.058 and <0.001, respectively).

In addition, higher endoscopic response rates were observed for both doses of duvakitug versus placebo in both AT-experienced and AT-naïve subgroups of patients.

- AT-experienced: 11% (450 mg) and 48% (900 mg), with placebo-adjusted rates of 7% (450 mg) and 44% (900 mg).
- AT-naïve: 47% (450 mg) and 47% (900 mg), with placebo-adjusted rates of 25% (450 mg) and 25% (900 mg).

Additional endpoints observed*:

- Endoscopic remission (SES-CD): 17% (450 mg) and 26% (900 mg) compared to 9% treated with placebo.
- Clinical remission (CDAI): 50% (450 mg) and 54% (900 mg) compared to 41% treated with placebo.
- Clinical response (CDAI): 61% (450 mg) and 62% (900 mg) compared to 41% treated with placebo.
- Clinical response (PRO2): 50% (450 mg) and 53% (900 mg) compared to 29% treated with placebo.

Vipul Jairath, MBChB, DPhil, FRCP, FRCPC
Professor of Medicine in the Departments of Medicine, Epidemiology and Biostatistics at Western University, and lead investigator of the RELIEVE UCCD study
"Every day, I see patients with Crohn's disease who continue to suffer from the often-severe symptoms of the disease despite available treatments," said Vipul Jairath, MBChB, DPhil, FRCP, FRCPC, Professor of Medicine in the Departments of Medicine, Epidemiology and Biostatistics at Western University, and lead investigator of the RELIEVE UCCD study. "The endoscopic response rates seen in this study support the potential of duvakitug as an effective new option for those who are in desperate need of relief."

RELIEVE UCCD safety data summary

In both the UC and CD cohorts, duvakitug was generally well tolerated with no emergent safety signals observed. No dose-dependent or adverse event (AE) pattern was observed for treatment-related AEs, serious adverse events (SAEs), AEs leading to discontinuation or adverse events of special interest (AESIs).

Duvakitug is currently under clinical investigation, and its efficacy and safety have not been evaluated by any regulatory authority.

About inflammatory bowel disease

UC and CD, the two main types of IBD, are chronic inflammatory conditions of the gastrointestinal (GI) tract resulting in debilitating and persistent symptoms such as abdominal pain, diarrhea, rectal bleeding, fatigue and weight loss. Prolonged inflammation can lead to damage within the GI tract, including fibrosis, a common complication of IBD characterized by an accumulation of scar tissue in the intestinal wall, which may cause narrowing and obstruction often requiring hospitalization and surgery. There is currently no cure for IBD – the goal of treatment is to induce and maintain remission and prevent flares.

About the RELIEVE UCCD phase 2b study

RELIEVE UCCD was a 14-week phase 2b, randomized, double-blinded, dose-ranging study to determine the efficacy, safety, pharmacokinetics, and tolerability of duvakitug in adults with moderate-to-severe UC or CD. The study was an innovative and efficient basket study design allowing the inclusion of patients with either type UC and CD. It is also the first and only randomized, blinded and placebo-controlled phase 2 study to investigate the impact of TL1A in CD.

In the study, patients who met pre-specified inclusion criteria were randomized to receive one of two duvakitug doses or placebo, administered every two weeks subcutaneously, in a 1:1:1 ratio for each indication (UC or CD) stratified by previous exposure to advanced IBD therapies for 14 weeks. The UC cohort comprised adults with moderately to severely active disease with inadequate response, loss of response or intolerance to previous conventional and/or advanced therapies (AT). The CD cohort comprised adults with moderately to severely active disease with documented inadequate response, loss of response or intolerance to conventional and/or ATs.

Primary efficacy endpoints are the number of participants who showed clinical remission (as defined by the modified Mayo score) in the UC cohort or the number of participants who showed endoscopic response (as defined by the SES-CD endoscopic score for CD) in the CD cohort. The study included sites in the US, Europe, Israel, and Asia.

About duvakitug

Duvakitug is a potential best-in-class human IgG1-λ2 monoclonal antibody that targets tumor necrosis factor (TNF)-like ligand 1A (TL1A), also known as TNF superfamily member 15 (TNFSF15). TL1A signaling is believed to amplify inflammation and drive fibrosis associated with IBD through binding its receptor, death receptor 3 (DR3).

Duvakitug is uniquely designed to inhibit preferentially TL1A signaling via DR3, with the potential advantage of reduced TL1A-DcR3 inhibition.

Duvakitug is currently in a phase 2b clinical study for the treatment of UC and CD, the two most common types of IBD. The safety and efficacy of duvakitug have not been reviewed by any regulatory authority.

About the Teva and Sanofi collaboration

Teva and Sanofi are collaborating to co-develop and co-commercialize Teva's duvakitug for the treatment of UC and CD. Each company will equally share the development costs globally, and the net profits and losses in major markets, with other markets subject to a royalty arrangement. Sanofi will lead the phase 3 clinical development program. Teva will lead commercialization of the product in Europe, Israel and specified other countries, and Sanofi will lead commercialization in North America, Japan, other parts of Asia and the rest of the world.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a different kind of global pharmaceutical leader, one that operates across the full spectrum of innovation to reliably deliver medicines to patients worldwide. For over 120 years, Teva's commitment to bettering health has never wavered. Today, the company's global network of capabilities enables its 37,000 employees across 57 markets to advance health by developing medicines for the future while championing the production of generics and biologics. If patients have a need, we're already working to address it. To learn more about how Teva is all in for better health, visit www.tevapharm.com.

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

Media Relations

Sandrine Guendoul | +33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com
Nicolas Obrist | +33 6 77 21 27 55 | nicolas.obrist@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

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
Felix Lauscher | +1 908 612 7239 | felix.lauscher@sanofi.com
Keita Browne | +1 781 249 1766 | keita.browne@sanofi.com
Nathalie Pham | +33 7 85 93 30 17 | nathalie.pham@sanofi.com

Tarik Elgoutni | + 1 617 710 3587 | tarik.elgoutni@sanofi.com
Thibaud Châtelet | + 33 6 80 80 89 90 | thibaud.chatelet@sanofi.com

Teva Media Relations
TevaCommunicationsNorthAmerica@tevapharm.com

Teva Investor Relations
TevaIR@tevapharm.com

Sanofi forward-looking statement
This press release contains forward-looking statements as defined in 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 performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. 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 FDA or the EMA, 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, 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, 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 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, 2024. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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

Teva Cautionary note regarding forward-looking statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. You can identify these forward-looking statements by the use of words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to: our ability to successfully develop duvakitug for the treatment of ulcerative colitis (UC) and Crohn's disease (CD); our ability to successfully compete in the marketplace, including our ability to develop and commercialize additional pharmaceutical products; our ability to successfully execute our Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development, and to sustain and focus our portfolio of generic medicines; the effectiveness of our patents and other measures to protect our intellectual property rights; and other factors discussed in our Quarterly Report on Form 10-Q for the third quarter of 2024, and in our Annual Report on Form 10-K for the year ended December 31, 2023, including in the section captioned "Risk Factors." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

*P-values reported are one-sided at a significance level of 0.10.

mMS = modified Mayo Score; MES = Mayo Endoscopic Subscore; HEMI = Histological-Endoscopic Mucosal Improvement; SES-CD = Simple Endoscopic Score for Crohn's Disease; CDAI = Crohn's Disease Activity Index; PRO2 = 2-item Patient-Reported Outcome