

UEG Week: Sanofi and Teva's duvakitug maintained long-term positive outcomes in new phase 2b data for ulcerative colitis and Crohn's disease

- In UC, duvakitug maintained high rates of clinical remission, clinical response, and endoscopic improvement at Week 44
- In CD, duvakitug maintained high rates of endoscopic response, clinical response, and clinical remission at Week 44
- Duvakitug was well tolerated and safety was consistent with the induction study

Paris and Parsippany, NJ. October 20, 2026. New positive data from the RELIEVE UCCD phase 2b long-term extension (LTE) study (clinical trial identifier: [NCT05668013](#)) in patients with moderately-to-severely active ulcerative colitis (UC) or Crohn's disease (CD) demonstrated that duvakitug maintained clinically meaningful efficacy improvements across multiple endpoints over 44 weeks. Duvakitug is an investigational human monoclonal antibody that targets TL1A, a protein that amplifies inflammation and potentially drives fibrosis in UC and CD.

In addition, biomarker findings that advance the understanding of how duvakitug may impact inflammation and tissue remodeling in inflammatory bowel disease (IBD) were shared. These data were presented today at United European Gastroenterology (UEG) Week 2026 in Barcelona.

The RELIEVE UCCD LTE study evaluated the efficacy, safety, and tolerability of duvakitug through 44 weeks of maintenance treatment after induction in patients with UC and CD, the two most common forms of IBD. Patients (n=130, 72 with UC and 58 with CD) who responded to duvakitug treatment in the 14-week induction study were randomized to receive either duvakitug 450 mg or 900 mg subcutaneously every four weeks (Q4W) for up to 58 weeks of total exposure.

UC Results

At Week 44, maintenance treatment with duvakitug demonstrated high rates of clinical remission and clinical response, as measured by the modified Mayo Score (mMS), meaning active UC symptoms such as rectal bleeding, increased stool frequency, and pain have stopped (remission) or improved (response). Duvakitug treatment also achieved high rates of endoscopic improvement, defined by a Mayo Endoscopic Score of 0 (inactive disease in the colon) or 1 (mild disease activity), which measures the presence and degree of intestinal inflammation. Efficacy outcomes were numerically higher at 900 mg compared to 450 mg, consistent with a dose response.

Efficacy in UC at Week 44 Maintenance Phase Endpoint		
	Duvakitug 450 mg Q4W (n=34)	Duvakitug 900 mg Q4W (n=38)
Clinical remission (mMS)	47% [95% CI: 30, 65]	58% [95% CI: 42, 73]

Clinical response (mMS)	82% [95% CI: 61, 91]	87% [95% CI: 71, 94]
Endoscopic improvement	59% [95% CI: 42, 76]	63% [95% CI: 47, 78]
Data are descriptive. Confidence intervals (CIs) are based on logistic regression.		

*"Ulcerative colitis can have a significant impact on patients that disrupts even the most basic daily activities. Despite available therapies, some patients continue to experience flares that impact their lives in various ways and may contribute to disease progression," said **Walter Reinisch, MD, PhD**, Director of the Inflammatory Bowel Disease Study Group at the Medical University of Vienna and a co-lead investigator of the RELIEVE UCCD LTE study. "These results underscore the potential of duvakitug to deliver effective and durable relief from persistent inflammation and symptoms, supporting better long-term disease management in patients with ulcerative colitis."*

CD Results

Duvakitug maintenance treatment demonstrated high rates of endoscopic response, defined as a 50% or more decrease from baseline in Simple Endoscopic Score for Crohn's Disease (SES-CD) at Week 44. SES-CD assesses mucosal ulcers, the ulcerated surface, the endoscopic extension, and the presence of stenosis in the colon as a gauge of disease severity. Additionally, duvakitug maintained high rates of clinical response and clinical remission as measured by the Crohn's Disease Activity Index (CDAI), meaning symptoms such as abdominal pain, diarrhea, and fatigue have stopped (remission) or improved (response). Duvakitug appeared to demonstrate a dose response, with numerically higher efficacy results achieved at the higher dose.

Efficacy in CD at Week 44 Maintenance Phase Endpoint		
	Duvakitug 450 mg Q4W (n=27)	Duvakitug 900 mg Q4W (n=31)
Endoscopic response	41% [95% CI: 25, 62]	55% [95% CI: 39, 75]
Clinical response (CDAI)	81% [95% CI: 63, 94]	87% [95% CI: 70, 96]
Clinical remission (CDAI)	81% [95% CI: 65, 95]	84% [95% CI: 68, 96]
Data are descriptive. Confidence intervals (CIs) are based on logistic regression.		

*"Due to the heterogeneous nature of Crohn's disease, many patients either stop responding or never respond to available therapies, leaving them with uncontrolled symptoms that cause physical distress," said **Vipul Jairath, MBChB, DPhil, FRCP, FRCP**, Professor of Medicine in the Departments of Medicine, Epidemiology and Biostatistics at Western University and a co-lead investigator of the RELIEVE UCCD LTE study. "The efficacy rates seen with duvakitug in the maintenance period highlight its potential as a new treatment option that could help more patients achieve sustained remission."*

Across both UC and CD, duvakitug was generally well tolerated throughout the maintenance period, with a safety profile consistent with the induction phase and no new safety concerns identified. The most frequently reported adverse events (AEs) occurring in $\geq 5\%$ of patients across pooled duvakitug dose groups in UC were upper respiratory tract infection and nasopharyngitis, and in CD were upper respiratory tract infection, CD, hypertension, nasopharyngitis, anemia, and influenza. The majority of AEs were mild or moderate in severity. Discontinuation rates due to AEs were low (*UC, 4% and 2% in the 450 mg and 900 mg arms, respectively, and in CD were 6% in each arm*).

Biomarker Results

Biomarker analyses from the RELIEVE UCCD induction study (clinical trial identifier: [NCT05499130](#)) were presented at UEG Week 2026. Duvakitug reduced blood levels of markers connected to multiple inflammatory pathways in UC and to the Th17 and Th1 immune pathways in CD, as well as markers of neutrophilic inflammation in both blood and tissue in CD and UC. In patients with CD, duvakitug also reduced markers of tissue remodeling. These findings provide additional mechanistic evidence that TL1A inhibition may address both inflammation and, potentially, fibrosis.

Additionally, clinical results from the RELIEVE UCCD induction study were recently published in *The Lancet Gastroenterology and Hepatology* for [UC](#) and [CD](#).

Duvakitug Clinical Development Program

Duvakitug is being investigated in the phase 3 SUNSCAPE-1 (clinical trial identifier: [NCT07184996](#)) and SUNSCAPE-2 (clinical trial identifier: [NCT07185009](#)) studies in moderately-to-severely active UC, and the phase 3 STARScape-1 (clinical trial identifier: [NCT07184931](#)) and STARScape-2 (clinical trial identifier: [NCT07184944](#)) studies in moderately-to-severely active CD. Sanofi and Teva have initiated the phase 2 AURALIGHT study (clinical trial identifier: [NCT07812116](#)) of duvakitug in moderate-to-severe hidradenitis suppurativa and are planning a phase 2 study of duvakitug in fibrostenotic Crohn's disease.

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

About IBD

Inflammatory bowel disease (IBD) is an autoimmune disorder characterized by chronic inflammation of the gastrointestinal (GI) tract. Globally, approximately 4.9 million cases of IBD have been identified, with incidence rising in several regions. The two main types of IBD are ulcerative colitis (UC) and Crohn's disease (CD), which are characterized by repetitive cycles of relapses and remission. Common symptoms of both conditions include persistent diarrhea, rectal bleeding, abdominal pain, loss of appetite, and weight loss.

Prolonged inflammation can lead to damage within the GI tract, including fibrosis, a common complication of IBD characterized by an excessive accumulation of scar tissue in the intestinal wall, which may cause narrowing and obstruction.

Currently, there is no cure for IBD. The goal of current treatment is to induce and maintain remission and prevent flares.

About the RELIEVE UCCD phase 2b program

The RELIEVE UCCD program is comprised of an induction study and a long-term extension (LTE).

RELIEVE UCCD: A 14-week phase 2b, randomized, double-blinded, dose-ranging induction study to evaluate the efficacy, safety, pharmacokinetics, and tolerability of duvakitug in adults with moderate-to-severe ulcerative colitis (UC) or Crohn's disease (CD). The study was an innovative and efficient basket study design allowing the inclusion of patients with either UC or CD. It is the first and only randomized, blinded and placebo-controlled phase 2 study to investigate the impact of TL1A inhibition in CD.

RELIEVE UCCD LTE: An ongoing phase 2b study to evaluate the long-term efficacy and safety of duvakitug. Patients who received duvakitug, completed the 14-week induction study, and were responders, entered a 44-week double-blind maintenance period and were re-randomized to receive either 450 mg or 900 mg of subcutaneous duvakitug every four weeks. Patients who completed the 44-week maintenance period may continue to receive duvakitug in an open-label extension.

Primary efficacy endpoints for both the 14-week induction study and the 44-week maintenance period are clinical remission (as defined by mMS) in the UC cohort or endoscopic response (as defined by SES-CD) in the CD cohort. The study includes sites in the US, Europe, Israel, and Asia.

About duvakitug

Duvakitug is a human monoclonal antibody targeting tumor necrosis factor-like ligand 1A (TL1A) being developed to reduce inflammation and potentially fibrosis. Duvakitug is currently in phase 3 clinical studies for the treatment of ulcerative colitis and Crohn's disease and is also being investigated in hidradenitis suppurativa and fibrostenotic Crohn's disease. The safety and efficacy of duvakitug have not been reviewed by any regulatory authority.

About the Sanofi and Teva collaboration

Sanofi and Teva are collaborating to co-develop and co-commercialize duvakitug for the treatment of ulcerative colitis and Crohn's disease, as well as fibrostenotic Crohn's disease and hidradenitis suppurativa. 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. 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 transforming into a leading innovative biopharmaceutical company, enabled by a world-class generics business. For over 120 years, Teva's commitment to bettering health has never wavered. From innovating in the fields of neuroscience and immunology to providing complex generic medicines, biosimilars and pharmacy brands worldwide, Teva is dedicated to addressing patients' needs, now and in the future. At Teva, We Are All In For Better Health. To learn more about how, visit www.tevapharm.com.

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

Sanofi 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

Sanofi Investor Relations

Thomas Kudsk Larsen | +44 7545 513 693 | thomas.larsen@sanofi.com

Alizé Kaissarian | +33 6 47 04 12 11 | alize.kaissarian@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

Teva Media Inquiries:

TevaCommunicationsNorthAmerica@tevapharm.com

Teva Investor Relations Inquiries:

TevaIR@Tevapharm.com

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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," "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) as well as fibrostenotic Crohn's disease and hidradenitis suppurativa; our ability to successfully compete in the marketplace, including our ability to develop and commercialize additional pharmaceutical products; our ability to successfully execute on our Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and to profitably commercialize our innovative medicines and biosimilar portfolio, whether organically or through business development; our significant indebtedness; our business and operations in general; compliance, regulatory and litigation matters; financial, economic and other risks; and other factors discussed in our Quarterly Report on Form 10-Q for the second quarter of 2026 and in our Annual Report on Form 10-K for the year ended December 31, 2025, including in the sections captioned "Risk Factors" and "Forward-Looking Statements." 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.