

# *Sanofi and Teva's duvakitug phase 2b maintenance data demonstrated clinically meaningful durable efficacy in ulcerative colitis and Crohn's disease*

- In the RELIEVE UCCD LTE phase 2b study, duvakitug showed robust, durable efficacy for an additional 44 weeks in UC and CD patients who had responded after 14 weeks of induction
- Duvakitug was well tolerated and safety was consistent with the induction study
- Findings reinforce the potential of duvakitug which is in ongoing phase 3 programs in UC and CD

**Paris and Parsippany, NJ, February 17, 2026.** Positive results from the RELIEVE UCCD long-term extension (LTE) study (clinical study identifier: [NCT05668013](#)) of duvakitug, an investigational human monoclonal antibody targeting TL1A, showed durable clinical and endoscopic efficacy maintained over 44 weeks in patients with ulcerative colitis (UC) and Crohn's disease (CD) that initially responded to the induction phase. RELIEVE UCCD LTE is a double-blind randomized study evaluating the long-term efficacy, safety, and tolerability of duvakitug in UC and CD, the two most common forms of inflammatory bowel disease (IBD).

These longer duration data reinforce the [efficacy](#) from the RELIEVE UCCD phase 2b induction study (clinical study identifier: [NCT05499130](#)), which demonstrated that patients achieved clinically meaningful response with duvakitug compared to placebo at week 14.

*"These results reinforce duvakitug's potential as a leading TL1A therapy and an important advancement in inflammatory bowel disease treatment with durable efficacy maintained for nearly one year in patients living with ulcerative colitis or Crohn's disease," said **Houman Ashrafian**, Executive Vice President, Head of Research and Development, Sanofi. "With phase 3 studies underway, we're committed to advancing duvakitug for patients who need new options, and it remains a key opportunity in our pipeline."*

The study enrolled 130 patients who responded to duvakitug in the RELIEVE UCCD induction study and entered a 44-week maintenance period. Patients were re-randomized to receive either a 450 mg or 900 mg subcutaneous dose of duvakitug every four weeks for up to a total of 58 weeks of exposure. At week 44 of the maintenance period:

- **UC:** 58% (900 mg) and 47% (450 mg) of patients treated with duvakitug achieved the primary endpoint of clinical remission per the modified Mayo score (mMS).
- **CD:** 55% (900 mg) and 41% (450 mg) of patients treated with duvakitug achieved the primary endpoint of endoscopic response as defined by the Simple Endoscopic Score for CD (SES-CD).
- In both UC and CD, consistent benefits were observed across additional efficacy endpoints.

Both doses of duvakitug were well tolerated. The most frequent observed adverse events ( $\geq 5\%$  of all patients) with pooled duvakitug doses were upper respiratory tract infection, nasopharyngitis, Crohn's disease, and hypertension and were consistent with the RELIEVE UCCD phase 2b induction study. Detailed results from the study will be presented at a forthcoming medical meeting.

*"One of the persistent challenges in treating ulcerative colitis and Crohn's disease isn't just achieving an initial response, but sustaining it," said **Eric Hughes**, MD, PhD, Executive Vice President, Global R&D and Chief Medical Officer, Teva. "These phase 2b results further reinforce TL1A as a compelling target and clearly strengthen the case that duvakitug has the potential to be a best-in-class therapy. They also provide further evidence to support additional indications we anticipate announcing this year, with the goal of bringing meaningful innovation to patients."*

### *About IBD*

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 UC and 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.

**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 UC or 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 in CD.

**RELIEVE UCCD LTE:** An ongoing 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, a human monoclonal antibody targeting TL1A, is currently in phase 3 clinical studies for the treatment of UC and CD. TL1A signaling is believed to amplify inflammation and drive fibrosis associated with IBD through binding to its receptor, DR3. Duvakitug preferentially inhibits TL1A-DR3 signaling over DcR3 (decoy receptor 3) binding, with the potential to reduce inflammation and fibrosis.

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 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 is leading 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 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](http://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

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#### **Sanofi forward-looking statements**

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, with the exception of Teva, a trademark of Teva Pharmaceutical Industries Ltd.

#### **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 and commercialize duvakitug (anti-TL1A) under the our collaboration with Sanofi; 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; our significant indebtedness; our business and operations in general; compliance, regulatory and litigation matters; other financial and economic risks; and other factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2025, including in the sections 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.