Press Release

Duvakitug positive phase 2b results demonstrate best-in-class potential in ulcerative colitis and Crohn's disease

- Primary endpoints met in ulcerative colitis (UC) and Crohn's disease (CD), the most common forms of inflammatory bowel disease (IBD)
- Primary endpoint results in UC and CD for high dose represent the highest achieved with any TL1A monoclonal antibody
- Sanofi and Teva plan to initiate phase 3 development in IBD, pending regulatory discussions
- Program underscores Sanofi's Immunology leadership ambition

Paris and Parsippany, NJ, December 17, 2024. Sanofi and Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd., today announced that the RELIEVE UCCD phase 2b study met its primary endpoints in patients with ulcerative colitis (UC) and Crohn's disease (CD). RELIEVE UCCD assessed duvakitug, a human IgG1-λ2 monoclonal antibody targeting TL1A, for the treatment of moderate-to-severe inflammatory bowel disease (IBD).

In the RELIEVE UCCD study, 36.2% (low dose) and 47.8% (high dose) of patients with UC treated with duvakitug achieved clinical remission* compared to 20.45% on placebo, placebo-adjusted rates were 15.7% (low dose) and 27.4% (high dose), at week 14 (p=0.050 and 0.003, respectively).* In patients with CD, 26.1% (low dose) and 47.8% (high dose) treated with duvakitug achieved endoscopic response* compared to 13.0% on placebo, placebo-adjusted rates were 13.0% (low dose) and 34.8% (high dose), at week 14 (p= 0.058 and <0.001, respectively).* Overall, the treatment effect was consistent across subgroups. This is the first and only randomized, placebo-controlled study to evaluate the impact of an anti-TL1A monoclonal antibody in CD. Detailed results are expected to be presented at a scientific forum in 2025.

Duvakitug was generally well tolerated in both UC and CD with no safety signal identified. Overall rates of treatment emergent adverse events (AE) were similar between duvakitug and placebo across both UC and CD (50% vs 50%). All AEs reported across both UC and CD were less than 5%.

Houman Ashrafian, MD, PhD
Executive Vice President, Head of Research & Development at Sanofi
"These unprecedented results show that duvakitug could represent the next frontier in treating ulcerative colitis and Crohn's disease. If the magnitude of effect persists in the phase 3 program, we believe we will have a differentiated medicine for IBD patients who are in urgent need of new options," said Houman Ashrafian, MD, PhD, Head of R&D at Sanofi. "The duvakitug program and this partnership underscore Sanofi's strategy of following the science to identify and rapidly advance breakthrough medicines for patients."

Eric Hughes, MD, PhD
Head of Global Research & Development and Chief Medical Officer at Teva
"The results from the RELIEVE UCCD study have exceeded our expectations, and I am deeply moved by the potential of duvakitug to help treat and meaningfully improve the quality of life of people living with IBD," said Eric Hughes, MD, PhD, Head of Global R&D and Chief Medical Officer at Teva. "These positive results reinforce Teva's ability to develop and accelerate access to innovative medicines. We are excited to collaborate on the next phase of development with our partner, Sanofi, and we would like to thank the investigators and patients who participated in this study."

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

About IBD

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 excessive 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 is 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. 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.

Participants who completed the 14-week induction study were eligible to participate in a long-term extension (LTE) study, currently ongoing. Responders from the induction study could enter the LTE directly into a 44-week maintenance period to receive a low or high dose every four weeks. Non-responders could enter a 14-week re-induction period. Responders to re-induction entered the 44-week maintenance period. Participants who responded during the maintenance period are eligible for an open-label period within the LTE. Primary efficacy endpoints for both the 14-week induction study and the 44-week maintenance study are the number of participants who show clinical remission (as defined by the modified Mayo score) in the UC cohort or the number of participants who show endoscopic response (as defined by the SES-CD endoscopic score for CD) in the CD cohort. The study includes 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, also known as TNF superfamily member 15. TL1A signaling is believed to amplify inflammation and drive fibrosis associated with IBD through binding its receptor, DR3; thus, targeting TL1A with duvakitug may mitigate the over-active immune response in these conditions. 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 Sanofi and Teva collaboration

Sanofi and Teva 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 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 global pharmaceutical leader with a category-defying portfolio, harnessing our generics expertise and stepping up innovation to continue the momentum behind the discovery, delivery, and expanded development of modern medicines. 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 58 markets to push the boundaries of scientific innovation and deliver quality medicines to help improve health outcomes of millions of patients every day. 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

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
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

Sanofi 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 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 pandemics or other 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, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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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.

*As measured by the Modified Mayo Score (MMS) and as measured by the Simple Endoscopic Score for Crohn's Disease (SES-CD), respectively. P-values reported are one-sided at a significance level of 0.10.