



NEWS RELEASE

Merck's Tulsokibart Met Primary and Key Secondary Endpoints in Phase 2b Study in Patients With Moderate to Severe Hidradenitis Suppurativa (HS)

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Results mark the first positive Phase 2 data for an anti-TL1A monoclonal antibody in dermatology

Tulsokibart was designed to help address immuno-fibrosis, a key driver of disease progression in HS

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced the first presentation of results from MK-7240-012, a Phase 2b multicenter, randomized, double-blind, placebo-controlled trial evaluating tulsokibart, an investigational humanized monoclonal antibody targeting tumor necrosis factor-like cytokine 1A (TL1A), in patients with moderate to severe hidradenitis suppurativa (HS). These data will be presented in a Late-Breaking News session at the European Academy of Dermatology and Venereology (EADV) 2026 Congress (Abstract ID: LB-26).

The study met its primary endpoint of Hidradenitis Suppurativa Clinical Response 50 (HiSCR50) at week 16 for patients treated with both high-dose (480 mg Q2W) and medium-dose (480 mg Q4W) tulsokibart regimens, demonstrating superiority over placebo. Specifically, 72% of patients in the high-dose group (n=42) and 64% in the medium-dose group (n=42) achieved HiSCR50—representing a 37% and 29% improvement over the placebo group (35%, n=44), respectively. In an exploratory analysis, the low-dose group (n=21, 240 mg Q4W) achieved a 52% response rate, a 17% improvement over placebo. There was comparable safety between tulsokibart and placebo groups in this trial.

For the non-ranked key secondary endpoints at week 16, both the high- and medium- dose groups showed greater numerical improvement over placebo. HiSCR75 was achieved by 41% of high-dose, 40% of medium-dose, and 29% of low-dose patients, compared to 15% in the placebo group—representing numeric improvements over placebo of 27%, 24%, and 13%, respectively. Additionally, patient quality of life numerically improved, with mean Dermatology Life Quality Index (DLQI) reductions from baseline of -5.62 (a 3.16-point improvement over placebo) for the high-dose cohort and -3.50 (a 1.02-point improvement over placebo) for the medium-dose cohort, compared to a baseline reduction of -2.46 in the placebo group. The low-dose cohort showed no improvement over placebo.

“Hidradenitis suppurativa is a painful, chronic disease that can have a profound physical and emotional impact on patients,” said Alexa B. Kimball,* MD, MPH, lead investigator of the study, President and CEO of Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center, and Professor of Dermatology at Harvard Medical School. “Despite available advanced therapies, many still do not achieve long-term disease control. Results from the MK-7240-012 trial are promising and suggest the potential for meaningful improvement in the management of this difficult-to-treat condition.”

“We are excited to expand the clinical data for tulisokibart beyond inflammatory bowel disease with these positive Phase 2b results—the first for the anti-TL1A class in dermatology,” said Dr. Aileen Pangan, vice president and therapeutic area head, immunology clinical research, Merck Research Laboratories. “We look forward to advancing tulisokibart to Phase 3 for patients living with HS.”

Adverse events (AEs) occurred in 42.9%, 47.6%, and 52.4% of participants receiving high-, medium-, and low-dose tulisokibart, respectively, compared with 40.9% in the placebo group. Serious AEs were infrequent and occurred at similar rates across treatment groups: 2.4% in both the high- and medium-dose groups, 4.8% in the low-dose group, and 2.3% with placebo. No serious or opportunistic infections were observed in the study.

These data presented at EADV will inform Phase 3 development for tulisokibart in HS. Tulisokibart has the broadest development program in the novel anti-TL1A class and is currently being evaluated in six disease indications across multiple immune-mediated inflammatory diseases. Phase 3 studies include **ATLAS-UC (NCT06052059)** in ulcerative colitis (UC) and **ARES-CD (NCT06430801)** in Crohn’s disease (CD). Phase 2 studies are evaluating tulisokibart in rheumatoid arthritis (RA) (**NCT07176390**), psoriatic arthritis (PsA) (**NCT07486960**), radiographic axial spondyloarthritis (r-axSpA) (**NCT07133633**), and HS (**NCT06956235**). For an overview of Merck’s clinical development program in immunology, please click [here](#).

*Dr. Kimball is the lead investigator of the MK-7240-012 trial and a paid consultant to Merck.

About MK-7240-012

MK-7240-012 (**NCT06956235**) is a Phase 2b, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of tulsokibart in participants with moderate to severe HS. The study is investigating whether at least one dose of tulsokibart is superior to placebo in the proportion of participants achieving HiSCR50 at week 16. A participant is considered to have achieved HiSCR50 if they have at least a 50% reduction in total abscesses and inflammatory nodules with no increase in abscess count and no increase in draining tunnel count. Bayesian design was implemented to augment concurrent controls with historical placebo for the primary endpoint.

Participants were randomized to receive a high-dose, medium-dose, or low-dose tulsokibart regimen, or placebo, during a 16-week double-blind treatment period. Key secondary endpoints included the percentage of participants achieving HiSCR75 and the mean change from baseline in DLQI at week 16.

About hidradenitis suppurativa

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease characterized by painful nodules and abscesses that can progress to tunnels, fibrosis, and scarring. HS is a high-burden, progressive disease that remains undertreated, with persistent gaps in disease control and progression management. Worldwide, HS affects approximately 1 in 100 people.

About tulsokibart

Tulsokibart is an investigational anti-TL1A monoclonal antibody that blocks TL1A signaling, downregulating Th1, Th2, and Th17, thereby potentially disrupting the immuno-fibrotic loop in immune-mediated inflammatory diseases, including UC, CD, RA, PsA, r-axSpA, and HS.

About immuno-fibrosis

Immuno-fibrosis is the process by which inflammation and fibroblast activation drive disease activity and progression in many autoimmune conditions, including HS. Immuno-fibrotic diseases are chronic, progressive conditions marked by immune dysregulation, inflammation, and fibroblast activation. The impact of immuno-fibrosis may vary by disease, stage, and patient. The complexity of immuno-fibrosis underscores the need for treatment options that address both inflammation and fibrosis. Merck is advancing research to deepen the understanding of immuno-fibrosis and help translate the science into new approaches.

Merck's commitment to immunology

Advances in our understanding of human biology have led to the emergence of innovative medicines and new

modalities that aim to change approaches to the treatment of immune-mediated inflammatory diseases. Merck scientists are leveraging deep expertise in immunology to discover and develop therapies to help people living with these conditions. Our research is focused on investigating novel targets such as TL1A and CD30L, as well as newer modalities like T-cell engagers, and exploring their potential across a range of immune-mediated inflammatory diseases.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of

new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2025 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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