NEWS RELEASE

Merck Announces Positive Results from Phase 2b Trial of Efinopegdutide in Adults with Metabolic Dysfunction-Associated Steatohepatitis (MASH) and Stage 2-3 Fibrosis

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Efinopegdutide demonstrated a statistically significant greater proportion of participants achieved MASH resolution without worsening of fibrosis versus placebo at 52 weeks

Meaningful improvements were observed in liver fibrosis without worsening of steatohepatitis, a key secondary histologic endpoint

Results presented at The Liver Meeting® and published in The Lancet

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced the presentation of positive results from the company's Phase 2b clinical trial that evaluated the safety and efficacy of three doses of once-weekly, subcutaneous efinopegdutide (4 mg, 7 mg and 10 mg), an investigational injectable GLP-1/glucagon receptor co-agonist, versus placebo for the treatment of adults with MASH and stage F2 or F3 liver fibrosis. The findings were presented during a late-breaking abstract session at The Liver Meeting (TLM), being held in Denver, Colo., and simultaneously published in The Lancet.

"MASH poses a substantial risk of progression to cirrhosis and ultimately liver failure, underscoring the urgent need for new treatment options," said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. "We are highly encouraged by these results which add to the evidence that efinopegdutide, a distinct GLP-1/glucagon receptor co-agonist, has the potential to provide clinically

meaningful responses for MASH resolution and fibrosis regression."

The Phase 2b MK-6024-013 trial evaluated the safety and efficacy of once-weekly, subcutaneous efinopegdutide (4 mg, 7 mg and 10 mg) in adults with biopsy-confirmed MASH with stage F2 or F3 liver fibrosis versus placebo and an active reference arm of open-label semaglutide (2.4 mg). The study met its primary efficacy endpoint of the percentage of participants demonstrating MASH resolution without worsening of fibrosis at 52 weeks as evaluated by the Non-alcoholic Steatohepatitis Clinical Research Network (NASH CRN) scoring system by Blinded Independent Central Review (BICR). The percentage of participants treated demonstrating MASH resolution at 52 weeks for the 4 mg, 7 mg and 10 mg weekly doses of efinopegdutide was 56% ($p<0.0001$), 63% ($p<0.0001$) and 61% ($p<0.0001$) versus 13% for placebo, respectively. At Week 52, meaningful improvements were observed in fibrosis of at least one stage without worsening of steatohepatitis, a key secondary histologic endpoint, with response rates of 43%, 52% and 34% across the 4 mg, 7 mg and 10 mg dose groups, respectively, compared with 21% for placebo.

"MASH is a chronic inflammatory liver disease, with limited treatment options. Achieving disease resolution establishes an important treatment goal," said Professor Jörn M. Schattenberg, M.D., Department of Internal Medicine II, Saarland University Medical Center, Homburg, Germany. "The improvements observed in fibrosis grading following efinopegdutide treatment in this study are notable and underscore its potential as a therapeutic option in patients with MASH and fibrosis."

The safety profile for efinopegdutide was generally consistent with that of semaglutide. Nausea occurred in 29%, 39% and 44% of participants receiving efinopegdutide 4 mg, 7 mg and 10 mg, respectively, versus 39% with open-label semaglutide and 11% with placebo. Corresponding rates of diarrhea were 29%, 26% and 22% versus 22% and 20%, while rates of vomiting were 20%, 8% and 28% versus 15% and 3%. Discontinuations due to adverse events occurred in 3%, 4% and 11% of participants receiving efinopegdutide 4 mg, 7 mg and 10 mg, respectively, compared with 1% for both open-label semaglutide and placebo.

About the MK-6024-013 Phase 2b trial

MK-6024-013 (**NCT05877547**) was a Phase 2b, multicenter, randomized, double-blind, placebo-controlled trial that evaluated the efficacy, safety and tolerability of once-weekly subcutaneous efinopegdutide after one year (52 weeks) of treatment. The trial included three blinded efinopegdutide dose groups (4 mg, 7 mg and 10 mg), a blinded placebo group, and an open-label once-weekly active reference arm (semaglutide 2.4 mg). The study enrolled 386 adults with biopsy-confirmed MASH and stage F2 or stage F3 fibrosis. Of these participants, 381 were randomized and received at least one dose of study intervention: efinopegdutide 4 mg (n=77), efinopegdutide 7 mg (n=77), efinopegdutide 10 mg (n=79), placebo (n=79) and open-label semaglutide (n=69); 92% (349/381) completed the study.

About efinopegdutide

Efinopegdutide (MK-6024) is an investigational, once-weekly, subcutaneous co-agonist targeting both glucagon-like peptide-1 (GLP-1) and glucagon receptors. By co-activating GLP-1 and glucagon receptors, efinopegdutide is designed to combine the metabolic and appetite-regulating actions of GLP-1 receptor agonism with the enhanced energy expenditure, lipid metabolism and direct hepatic anti-steatotic effects mediated via glucagon receptor activation. Efinopegdutide has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of MASH.

Efinopegdutide is being developed under an exclusive licensing agreement between Merck and Hanmi Pharmaceutical.

About metabolic dysfunction-associated steatohepatitis (MASH)

Metabolic dysfunction-associated steatohepatitis (MASH), previously referred to as non-alcoholic steatohepatitis (NASH), is a progressive, severe form of metabolic dysfunction-associated steatotic liver disease (MASLD). MASH is characterized by excessive hepatic fat accumulation accompanied by ongoing inflammation, cellular injury (hepatocyte ballooning) and varying stages of fibrosis. If left untreated, chronic liver inflammation and fibrotic tissue remodeling can progress to advanced stages of fibrosis (F2–F3), cirrhosis (F4) and ultimately liver failure. The burden of MASH continues to rise worldwide. Estimates suggest that approximately 5% of the global population may be living with the disease.

Merck’s focus on cardiometabolic and respiratory diseases

Merck has a long history of developing treatments for cardiometabolic and respiratory diseases. Building on a legacy that began nearly 70 years ago with the introduction of our first cardiovascular therapy, we are committed to advancing research for patients impacted by cardiometabolic and respiratory diseases. Our focus spans a range of diseases, including atherosclerotic cardiovascular disease, obesity, heart failure, pulmonary hypertension and chronic obstructive pulmonary disease (COPD).

Advancements in the treatment of cardiometabolic and respiratory diseases can make a critical difference for patients and health systems around the world. At Merck, we strive for scientific excellence and innovation in all stages of research, from discovery through approval and life cycle management. We partner with experts in the community to advance research that can help improve the lives of patients.

For more information, visit **https://www.merck.com/research/cardiometabolic-and-respiratory-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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