Merck to Present Data for Efinopegdutide (MK-6024), an Investigational GLP-1/Glucagon Receptor Co-agonist, in Patients with Nonalcoholic Fatty Liver Disease (NAFLD) at EASL 2023

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Merck granted Fast Track Designation by the U.S. FDA for MK-6024 for the treatment of Nonalcoholic Steatohepatitis (NASH)

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced that new findings for efinopegdutide (MK-6024), an investigational GLP-1/glucagon receptor co-agonist, have been accepted for oral presentation at the European Association for the Study of the Liver (EASL) Annual Congress from June 21-24. Data to be shared include results from the Phase 2a clinical trial evaluating efinopegdutide in adult patients with nonalcoholic fatty liver disease (NAFLD).

Separately, efinopegdutide was recently granted Fast Track Designation from the U.S. Food and Drug Administration (FDA) as a potential treatment for patients with nonalcoholic steatohepatitis (NASH), a more severe form of NAFLD that includes inflammation and damage to the liver. Fast Track is a process designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fulfill an unmet medical need. Currently, there are no approved therapies for NASH.

“We are looking forward to sharing detailed findings from the Phase 2a study of efinopegdutide with the scientific community at the EASL Congress,” said Sam Engel, associate vice president, global clinical development, Merck Research Laboratories. “Significant patient need remains for new treatment options for NASH. These compelling data in patients with NAFLD, along with the recent receipt of Fast Track Designation from the FDA, provide strong
rationale for advancing efinopegdutide into Phase 2b development for patients with NASH.”

Details on Featured Oral Presentation for efinopegdutide

- A Phase 2a, randomized, active-comparator-controlled, open-label study to evaluate the efficacy and safety of efinopegdutide in individuals with nonalcoholic fatty liver disease; Friday, June 23; 8:30-8:45 a.m. CEST.

About MK-6024 (efinopegdutide)

MK-6024 is an investigational peptide and dual agonist at glucagon-like peptide 1 (GLP-1) and glucagon receptors in clinical development for the treatment of NASH.

MK-6024 was investigated in a randomized, active comparator-controlled, open-label Phase 2a study to evaluate the compound’s efficacy in liver fat reduction and safety in participants with nonalcoholic fatty liver disease. MK-6024 is administered subcutaneously once per week. Data from this study informed the design of the Phase 2b study that Merck plans to start in June 2023.

MK-6024 is being developed under an exclusive licensing agreement between Merck and Hanmi Pharmaceutical for the treatment of patients with NASH.

More information about our clinical trials is available at www.merckclinicaltrials.com or on clinicaltrials.gov under NCT05877547 and NCT04944992.

About NAFLD and NASH

Nonalcoholic fatty liver disease (NAFLD) is a chronic and progressive condition in which fat builds up in the liver. Nonalcoholic steatohepatitis (NASH) is a more severe type of NAFLD that includes inflammation and damage to the liver and is closely related to obesity, pre-diabetes and diabetes. It is known as a silent disease with few or no symptoms, however, certain health conditions and disease – including obesity, metabolic syndrome, and type 2 diabetes – make you more likely to develop NAFLD. There are about 25% to 30% of people in the U.S. living with NAFLD and about 2% to 5% of people in the U.S. living with NASH.

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 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 the global outbreak of novel coronavirus disease (COVID-19); 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, 2022 and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

Media:
Julie Cunningham
(617) 519-6264
Courtney Ronaldo
(908) 442-5695
Investors:
Peter Dannenbaum
(732) 594-1579
Steven Graziano
(732) 594-1583

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