NEWS RELEASE

Merck Receives Fast Track Designation from the U.S. FDA for MK-2060, an Investigational Anticoagulant Therapy

8/23/2022

Phase 2 Study of MK-2060 Currently Ongoing in People with End-Stage Renal Disease Receiving Hemodialysi s

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck, (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for Merck's investigational anticoagulant therapy MK-2060 for the reduction in risk of major thrombotic cardiovascular events in patients with end-stage renal disease (ESRD). According to the FDA, 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. A therapeutic candidate that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan and, if relevant criteria are met, eligibility for Accelerated Approval and Priority Review.

"At Merck we are focusing our efforts where the needs are greatest, and we believe we have a significant opportunity with MK-2060 for the potential prevention of thrombosis in patients with advanced forms of kidney disease," said Dr. Eliav Barr, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "We are encouraged by this Fast Track designation because additional anticoagulation medicines are urgently needed for patients with ESRD who are susceptible to high rates of life-threatening thrombotic events as well as high bleeding risk. Today there is no anticoagulation standard of care for such patients."

MK-2060 is an investigational monoclonal antibody designed to inhibit Factor XI and its ability to activate downstream proteins involved in the blood coagulation cascade. MK-2060 is currently being evaluated in a Phase 2 study for the treatment of patients with ESRD receiving hemodialysis.

Earlier this year Merck highlighted its broad and growing cardiovascular portfolio and pipeline at an investor **event**, where MK-2060 was featured.

About MK-2060

MK-2060 is a novel inhibitor of Factor XI being investigated for the prevention of thrombosis in patients with end-stage renal disease (ESRD). MK-2060, administered intravenously, is designed to work through a dual mechanism of action both blocking the activation of Factor XI as well as the downstream activity of activated protein.

MK-2060 is being investigated in a Phase 2 study to evaluate the efficacy and safety of two different doses of MK-2060 in participants with ESRD receiving hemodialysis via an arteriovenous graft (AVG). Data from this study will be used to aid dose selection of MK-2060 in future studies.

More information about this study is available at **www.merckclinicaltrials.com** or can be found on **clinicaltrials.gov** under **NCT05027074**.

Merck's Focus on Cardiovascular and Pulmonary Disease

Merck has a long history of making an impact in cardiovascular disease. More than 60 years ago, we introduced our first cardiovascular therapy – and our scientific efforts to understand cardiovascular-related disorders continue. Cardiovascular disease remains one of the most serious health challenges of the 21st century. Approximately 18 million people across the globe die every year, and in the United States, one person dies every 36 seconds from cardiovascular disease.

Advancements in the treatment of cardiovascular and pulmonary disease can make a critical difference for patients 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 work with experts throughout the cardiovascular community to advance research that can help improve the lives of patients globally.

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, 2021 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20220823005228/en/**

Media Contacts:

Julie Cunningham
(617) 519-6264

Ian McConnell
(973) 901 5722

Investor Contacts:

Peter Dannenbaum
(908) 740-1037

Steve Graziano
(908) 740-6582

Source: Merck & Co., Inc.