NEWS RELEASE

FDA Grants Breakthrough Therapy Designation to Merck's Novel HIF-2α Inhibitor MK-6482 for Treatment of Certain Patients With Von Hippel-Lindau Disease- Associated Renal Cell Carcinoma

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Reinforces Important Progress in Merck's Oncology Pipeline to Advance Novel Therapeutic Candidates

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to the hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor MK-6482, a novel investigational candidate in Merck's oncology pipeline, for the treatment of patients with von Hippel-Lindau (VHL) disease-associated renal cell carcinoma (RCC)with nonmetastatic RCC tumors less than three centimeters in size, unless immediate surgery is required. The FDA also granted orphan drug designation to MK-6482 for VHL disease. These designations are based on data from a Phase 2 trial evaluating MK-6482 in patients with VHL-associated clear cell RCC, which were presented at the 2020 American Society of Clinical Oncology Annual Meeting.

"Merck's diverse and expansive oncology pipeline is focused on bringing forward innovative new treatments to patients in need and continues to show important progress," said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. "These designations for MK-6482 support the potential of targeting HIF-2α in certain patients with von Hippel-Lindau disease, who currently have limited treatment options and face an increased risk for benign tumors as well as several types of cancer, including renal cell carcinoma."

The FDA's Breakthrough Therapy designation is granted to expedite the development and review of medicines that

are intended to treat serious or life-threatening conditions and that have demonstrated preliminary clinical evidence indicating that the medicine may provide a substantial improvement over available therapy on at least one clinically significant endpoint. The FDA's orphan drug designation is granted to medicines that are intended for the treatment, prevention or diagnosis of rare diseases that affect fewer than 200,000 people in the U.S.

About MK-6482

MK-6482 (formerly PT2977) is an investigational, novel, potent, selective, oral HIF-2α inhibitor that is currently being evaluated in a Phase 3 trial in advanced RCC (**NCT04195750**), a Phase 2 trial in VHL-associated RCC (**NCT03401788**), and a Phase 1/2 dose-escalation and dose-expansion trial in advanced solid tumors, including advanced RCC (**NCT02974738**). Proteins known as hypoxia-inducible factors, including HIF-2α, can accumulate in patients when VHL, a tumor-suppressor protein, is inactivated. The accumulation of HIF-2α can lead to the formation of both benign and malignant tumors. This inactivation of VHL has been observed in more than 90% of ccRCC tumors. Research into VHL biology that led to the discovery of HIF-2α was awarded the Nobel Prize in Physiology or Medicine in 2019.

About Von Hippel-Lindau Disease and Renal Cell Carcinoma

Von Hippel-Lindau disease is a rare genetic disease that affects one in 36,000 people (200,000 cases worldwide and 10,000 cases in the U.S. alone). Patients with VHL disease are at risk for benign blood vessel tumors as well as several cancers, including RCC. As many as 60% of people with VHL disease develop RCC, which is a leading cause of death for patients with VHL disease.

Renal cell carcinoma is by far the most common type of kidney cancer; about nine of 10 kidney cancers are RCCs, and about seven of 10 RCCs are clear cell. Worldwide, it is estimated there were about 403,000 cases of kidney cancer diagnosed and about 175,000 deaths from the disease in 2018. In the U.S. alone, it is estimated there will be nearly 74,000 new cases of kidney cancer diagnosed and almost 15,000 deaths from the disease in 2020.

Merck's Focus on Cancer

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At Merck, the potential to bring new hope to people with cancer drives our purpose and supporting accessibility to our cancer medicines is our commitment. As part of our focus on cancer, Merck is committed to exploring the potential of immuno-oncology with one of the largest development programs in the industry across more than 30 tumor types. We also continue to strengthen our portfolio through strategic acquisitions and are prioritizing the development of several promising oncology candidates with the potential to improve the treatment of advanced cancers. For more information about our oncology clinical trials, visit **www.merck.com/clinicaltrials**.

About Merck

For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. 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., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, 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 products that the products 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 recent 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 2019 Annual Report on Form 10-K 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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Media:
Pamela Eisele
(267) 305-3558

Kristen Drake
(908) 740-1679

Investors:
Peter Dannenbaum
(908) 740-1037

Courtney Ronaldo
(908) 740-6132

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