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Act 193 Report to Vermont Attorney General
Introduction of New Prescription Drug
WELIREG (belzutifan)

On August 31, 2021, Merck Sharp & Dohme Corp. ("Merck") submitted an "Introduction of New Prescription Drug" notice to the Vermont Attorney General pertaining for the prescription drug WELIREG.

As required by Act 193, Merck submits the following report that provides additional, publicly available information regarding this product.

A description of marketing and pricing plans used in the launch of the new drug in the United States and internationally.

Marketing: Promotional activities for WELIREG will primarily include detailing of the product by Merck sales representatives to health care professionals including physicians, pharmacists, payers, and other healthcare providers. WELIREG will also be marketed in the US with print distribution and digital resources to health care professionals and patients.

Pricing: Merck considers several factors in determining the price of our medications. These factors are listed below and are largely based on the value of the product, as well as the competitive landscape, and market for the medication.
•Value provided to patients: To what extent does a new medicine or vaccine establish a new standard of care that has the potential to significantly extend and improve patient lives?
•Value provided to healthcare systems: To what extent does a new medicine or vaccine reduce the costs associated with hospitalization and other costly complications of disease if not appropriately (or optimally) treated?
•Unmet need: Does a new medicine or vaccine address a critical unmet medical need for large numbers of people,
where few or no treatments exist?
•Access and Affordability: How can we assure that various customers-including national, regional or local institutional payers, physicians, employers and patients-can afford to pay for our products?
•R&D sustainability: Given the long-term risk and cost of capital, are we appropriately compensating our investors to ensure that we can continue the risky and capital-intensive biopharmaceutical research and development that will bring forward medically-important breakthroughs?
•Competition: What are the costs of other treatments and interventions currently on the market relative to the value provided by Merck's products?

The estimated volume of patients who may be prescribed the drug. 6,000. WELIREG is indicated for the treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery. Von Hippel-Lindau (VHL) disease is a rare hereditary tumor syndrome affecting an estimated 1/36,000 live births globally [NORD. Accessed January 28, 2021. https://rarediseases.org/rare-diseases/von-hippel-lindau-disease/]. It is estimated that 2020 US prevalence of VHL disease is 10,000 patients. At any given time, renal cell carcinoma (RCC) may affect up to 30% of VHL patients in the US [Chittiboina P, Lonser RR. Handb Clin Neurol. 2015;132:139–156.]. For patients with tumors that reach greater than 3cm in size, a partial nephrectomy may be performed to reduce the risk of metastasis while maintaining kidney function[Varshney N et al. J Kidney Cancer VHL. 2017;4:20–29.]. Additionally, it is estimated Central nervous system (CNS) hemangioblastomas affecting 60% to 80% of all patients [Varshney N, Kebede AA, Owusu-Dapaah H, et al. A review of von Hippel-Lindau syndrome. J Kidney Cancer VHL. 2017;4(3):20–29.] Finally, pancreatic neuroendocrine tumors (pNET) affect approximately 15% of VHL patients [Michael Charlesworth, Caroline S Verbeke, Gavin A Falk, et al. Pancreatic lesions in von Hippel-Lindau disease? A systematic review and meta-synthesis of the literature. J Gastrointest Surg. 2012 Jul;16(7):1422-8. doi: 10.1007/s11605-012-1847-0. Epub 2012 Feb 28.] However, we do not expect all of these patients would be eligible for therapy and not all of these patients will receive WELIREG.

Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval. WELIREG was granted breakthrough therapy designation and priority review by the FDA prior to approval.

The date and price of acquisition if the drug was not developed by the manufacturer. This drug was acquired in development stage from clinical-stage biopharmaceutical company. The acquisition date was July 11, 2019. Merck made an upfront payment of $1.2 billion for the asset acquisition of Peloton. Research and development expenses recorded at acquisition were $993 million.

Please send any questions or comments to my attention at Merck Sharp & Dohme Corp., 351 North Sumneytown Pike, Mailstop UG-4B35, North Wales, PA 19454-2505 or send an e-mail to joanne_lahner@merck.com.

Sincerely,

Joanne Lahner