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Act 193 Report to Vermont Attorney General
Introduction of New Prescription Drug
WINREVAIR™ (sotatercept-csrk)

On April 10, 2024, Merck Sharp & Dohme LLC ("Merck") submitted an "Introduction of New Prescription Drug" notice to the Vermont Attorney General pertaining to the prescription drug WINREVAIR™ (sotatercept-csrk).

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 of WINREVAIR to physicians and other health professionals (HCPs) include detailing of the product by Merck sales representatives, print and digital educational resources, media placements, congress sponsorships and exhibit booths, and other related activities. In addition, Merck Medical Forums (educational speaker programs) for WINREVAIR will be available.
- Direct-to-consumer (DTC) promotional activities for WINREVAIR include print and digital educational materials and initiatives, such as a printed Welcome Kit, consumer website, and digital advertisements.

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 where few or no treatments exist?
- Access and Affordability: How can we assure that various customers 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.

Merck estimates that approximately 40,000 adults are diagnosed and treated with PAH in the United States. However, not all of these patients are expected to utilize WINREVAIR. In the Phase 3 registrational Clinical Trial, STELLAR, patients had to be on stable background therapy, with 96% of patients either receiving either double or triple therapy. According to published literature and market research, we estimate that approximately 50% of PAH patients are being treated with either double or triple therapy.

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

YES: WINREVAIR is designated as an Orphan Drug and was granted both Breakthrough therapy status and Priority Review by the FDA.

The date and price of acquisition if the drug was not developed by the manufacturer.

11/19/2021 - $11.5 billion

- Merck acquired Acceleron Pharma, Inc. for $180 per share in cash for an approximate total equity value of $11.5 billion. At the time of the acquisition, Acceleron had multiple pre-clinical and clinical programs underway.
- At the time of the acquisition, sotatercept was in Ph-3 clinical trials, so Merck continued and completed these Ph-3 trials, prepared the regulatory submission and then secured FDA approval of WINREVAIR™ (sotatercept-csrk) on March 26, 2024.

Please send any questions or comments to my attention at Merck Sharp & Dohme LLC, 351 North Sumneytown Pike, UG4B-35, North Wales, PA 19454-2505 or send an e-mail to yvonne.osirim@merck.com.

Sincerely,

Yvonne O. Osirim
Vice President, Human Health Ethics & Compliance