teva | Legal Group

December 14, 2018

Via: Electronic Mail (AGO.highcostprescriptiondrugs@vermont.gov)

Re: New Product Introduction – Abiraterone Acetate Tablets 250mg 120

To Whom It May Concern:

On November 26, 2018, Teva Pharmaceuticals USA, Inc. ("Teva") provided a new product introduction notice for abiraterone acetate tablets 250mg 120 (NDC: 00093-1125-89)(the "Product"). The Product was commercially available on November 21, 2018.

Teva provides the following information pursuant to Vermont Act 165, as amended.

1. US and international marketing and pricing plans used at launch:

a. Teva declines to provide this information in accordance with 18 V.S.A. § 4637(d).

2. Estimated volume of patients:

Estimated Prevalence Counts, by Cancer Type, Race, and Sex, 5-year Limited Duration, United States, Invasive Cancers only, on January 1, 2015

CancerType	Duration	Race	Sex	Age	Total Cases During Full Period	Avg Cases Per Year
Prostate	5-year Limited Duration	All Races	Male	All Ages	897,634	179,527
Prostate	13-year Limited Duration	All Races	Male	All Ages	2,208,364	169,874

- Estimates are based on cases reported by NPCR registries from 2001-2014 and follow-up of patients through 2014.
- Data are compiled from 39 NPCR registries (Alabama, Alaska, Arizona, Arkansas, California, Colorado, Delaware, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming) that met the data quality criteria for survival analysis covering approximately 81% of the U.S population.

https://gis.cdc.gov/Cancer/USCS/DataViz.html

Teva Pharmaceuticals
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3. Whether the FDA granted breakthrough therapy designation or a priority review:

a. The Product received priority review.

4. For drugs acquired:

a. Teva developed the Product.

Teva provides this report consistent with its understanding and interpretation of Vermont Act 165 (18 V.S.A. § 4637) and its provisions. In providing this report, Teva does not waive any rights that it may have at law or in equity with respect to the applicability, interpretation, or application of Vermont Act 165 (18 V.S.A.§ 4637) as it may relate to Teva or any of its affiliates now or in the future. Teva, on behalf of itself and affiliates, expressly reserves all such rights.

Sincerely,

Jason B. Daly
VP & General Counsel |NA Commercial & Generics

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