



November 15, 2019

Via E-mail: AGO.highcostprescriptiondrugs@vermont.gov

Subject: New Drug Introduction Report pursuant to 18 V.S.A. § 4637(c) and (d)

To the Office of the Attorney General of Vermont:

On November 5, 2019, and pursuant to 18 V.S.A. § 4637(b), Glenmark Pharmaceuticals Inc., USA (“Glenmark”) submitted a new drug notice for Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) NDC 68462-0317-32 (“Product”). Glenmark now provides the following additional information pursuant to 18 V.S.A. § 4637(c):

- 1) **US and International marketing and pricing plans used at launch:** Glenmark does not make its marketing or pricing plans (other than the wholesale acquisition costs identified above) publicly available, and does not believe that such information is in the public domain. Accordingly, pursuant to 18 V.S.A. § 4637(d), Glenmark will not be providing this information.
- 2) **Estimated volume of patients who may be prescribed the drug:** Estimated number of patients is not known.
- 3) **Whether the FDA granted breakthrough therapy designation or priority review:** The Product did not receive priority review or breakthrough status.
- 4) **Date and price of acquisition:** Not applicable. Drug was co-developed by Glenmark, and Glenmark is the ANDA holder.