Mylan
Better Health for a Better World

To: Office of Attorney General
AGO.highcostprescriptiondrugs@vermont.gov

From: Mylan Institutional Inc.
1000 Mylan Boulevard
Canonsburg, Pennsylvania 15317

Date: December 26, 2019

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on December 2, 2019 Mylan Institutional Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced a new biosimilar prescription drug, Ogivri (trastuzumab-dkst) Injection ("the Product"), to the commercial market on November 29, 2019 at a wholesale acquisition cost that is over the threshold set for a specialty drug under the Medicare Part D program.

This letter provides the additional required information by 18 V.S.A. § 4637(c) regarding the Product. Mylan notes that the Office of the Attorney General has not yet prescribed a format for submissions under this section. Further, as authorized by 18 V.S.A. § 4637(d), Mylan has limited the information reported to that which is in the public domain or publicly available.

(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

Ogivri (trastuzumab-dkst) Injection is indicated for (1) Adjuvant Breast Cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, as part of a treatment regimen with docetaxel and carboplatin, or as a single agent following multi-modality anthracycline based therapy; (2) Metastatic Breast Cancer in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, or as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.; and (3) Metastatic Gastric Cancer in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Product	Package Size	WAC
67457-0991-15	Ogivri (trastuzumab-dkst) for Injection 150mg/vial, 1 vial	1	$1,324.66

67457-0847-44	Ogivri (trastuzumab-dkst) for Injection 420mg/vial, 1 vial	1	$3,697.26

The prices negotiated with customers as well as any marketing plans in the United States or internationally are confidential and not in the public domain or publicly available. In the United States, Mylan sells its products directly to wholesalers, distributors, and long-term care facilities. Mylan also sells its biosimilar products indirectly to several entities, including providers within managed care organization networks, hospitals, oncology clinics and practices, specialty pharmacies, etc. These customers, called "indirect customers," purchase our products primarily through our wholesale customers.

(2) the estimated volume of patients who may be prescribed the drug;

No information specific to the estimated number of patients that may be prescribed Mylan's Product is in the public domain or publicly available.

(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;

The Product was not granted breakthrough therapy designation or priority review by the FDA.

(4) the date and price of acquisition if the drug was not developed by the manufacturer.

The Product was not a result of an acquisition. Mylan co-developed the Product in collaboration with Biocon.