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

From: Mylan Specialty L.P.
781 Chestnut Ridge Road
Morgantown, WV, 26505

Date: January 4, 2019

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on December 5, 2018 Mylan Specialty L.P. ("Mylan") provided written notice to the Office of the Attorney General that it introduced a new prescription drug, YUPELRI™ (revefenacin) inhalation solution 175 mcg/3mL ("the Product"), to the commercial market on December 3, 2018 at a wholesale acquisition cost that exceeds 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;

YUPELRI™ (revefenacin) inhalation solution, a branded drug approved under a New Drug Application (NDA), is an inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Product	Package Size	WAC
49502-0806-93	YUPELRI (revefenacin) inhalation solution 175mcg/3mL	30 vials	$1,030.00

The prices negotiated with customers are confidential and not in the public domain or publicly available. Mylan sells its products directly to wholesalers, distributors, retail pharmacy chains, long-term care facilities and mail order pharmacies. Mylan also contracts indirectly to several entities, including independent pharmacies, group purchasing organizations, hospitals, etc. These customers, called "indirect customers," purchase our products primarily through our wholesale customers. The Product has not yet launched in any international jurisdiction.

(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. The Product was developed as part of a strategic collaboration between Mylan and Theravance Biopharma, Inc. (Theravance).