Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

*VIA EMAIL (*AGO.highcostprescriptiondrugs@vermont.gov*)*

January 27, 2023

Vermont Attorney General's Office
109 State Street
Montpelier, VT 05609

RE: 18 V.S.A. § 4637 Notification and Report: Jaypirca™ (pirtobrutinib)

To Whom It May Concern:

Pursuant to18 V.S.A. § 4637(b), Eli Lilly and Company (Lilly) hereby notifies the Attorney General of Vermont of Lilly's new prescription drug, Jaypirca™ (pirtobrutinib), a highly selective, non-covalent (reversible) Bruton's tyrosine kinase (BTK) inhibitor. BTK plays a key role in the B-cell antigen receptor signaling pathway, which is required for the development, activation and survival of normal white blood cells, known as B-cells, and malignant B-cells.

Name of New Prescription Drug	NDC Number	Anticipated Market Entry Date	Wholesale Acquisition Cost (WAC)
Jaypirca 100mg 60 tablets	00002-7026-60	January 27, 2023	$21,000.00
Jaypirca 50mg 30 tablets	00002-6902-30	January 27, 2023	$7,000.00

Pursuant to18 V.S.A. § 4637(c), Lilly reports the following information regarding the above prescription drug. All information is provided by Lilly to the best of our knowledge at the time of submission. Lilly provides this report consistent with its understanding and interpretation of 18 V.S.A. § 4637 and its related provisions. In providing this report, Lilly does not waive any rights that it may have at law or in equity with respect to the applicability, interpretation, or application of 18 V.S.A. § 4637 as it may relate to Lilly or any of its affiliates now or in the future. Lilly, on behalf of itself and affiliates, expressly reserves all such rights. Consistent with the relevant statutes and regulations, all information contained in this report is limited to that which Lilly believes is otherwise in the public domain or publicly available. For more information, see https://investor.lilly.com/news-releases/news-release-details/us-fda-approves-jaypircatm-pirtobrutinib-first-and-only-non.

Section 4637(c)(1): A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.
Pursuant to 18 V.S.A. § 4637(d), Lilly is limiting its response to this question to what is in the public domain or otherwise publicly available. Lilly does not believe its marketing and pricing plan is in the public domain. For more information about Jaypirca, see https://investor.lilly.com/news-releases/news-release-details/us-fda-approves-jaypircatm-pirtobrutinib-first-and-only-non.

Section 4637(c)(2): The estimated volume of patients who may be prescribed the drug.
Based on data from the National Cancer Institutes' SEER Cancer Statistics Review, approximately 3500 patients in the US are diagnosed with Mantle-cell lymphoma (MCL) per year. MCL incidence is 0.8 per 100,000 people. (SEER, 2017. Trends in SEER Incidence and US Mortality; 1975-2017. Table 19.26 All Lymphoid Neoplasms with Detailed Non-Hodgkin Lymphoma Subtypes 2008-2017. Available at: Non-Hodgkin Lymphoma, CSR 1975-2017 (cancer.gov)). People with MCL may or may not use Jaypirca.

Section 4637(c)(3): Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval.
Jaypirca was not granted priority review or breakthrough therapy designation.

Section 4637(c)(4): The date and price of acquisition if the drug was not developed by the manufacturer.
Lilly acquired Loxo Oncology, Inc, on February 15, 2019 for a purchase price of approximately $6.92 billion, net of cash acquired. Under the terms of the agreement, Lilly acquired a pipeline of investigational medicines, including pirtobrutinib (Loxo-305). [https://investor.lilly.com/static-files/cd4a37af-ec28-449c-9bfb-ae380700209a]

***

Please let me know if you have any questions about this notification and report.

Sincerely,

Wilbur Van Tryon
Associate Vice President – Lilly Value and Access, Lilly USA

CC: Diane Hilligoss, Assistant General Counsel, Eli Lilly and Company
Ashlie Jonte, Associate Director – Government Pricing, Lilly USA