

**Pfizer Inc.**  
235 East 42<sup>nd</sup> Street  
New York, NY 10017



December 8, 2018

Office of the Vermont Attorney General

Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

Dear Office of the Vermont Attorney General,

Pfizer Inc. ("Pfizer") is issuing this notice pursuant to 18 V.S.A. § 4637(c), which requires prescription drug manufacturers to provide the Office of the Attorney General (the "Office") with certain information following the release of a drug in the commercial market whose Wholesale Acquisition Cost ("WAC") exceeds the threshold set for a specialty drug under the Medicare Part D Program.

Pfizer released Lorbrena<sup>®</sup> (lorlatinib) into the commercial market on November 5, 2018. Pfizer anticipates Lorbrena's<sup>®</sup> WAC to exceed the threshold set for a specialty drug under the Medicare Part D Program.

<b>Statutory Requirement</b>	<b>Reporting Information</b>
A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.	Pfizer does not believe this information is publicly available and has not released this information in the public domain. Accordingly, Pfizer is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).
The estimated volume of patients that may be prescribed the drug.	Pfizer does not believe this information is publicly available and has not released this information in the public domain. Accordingly, Pfizer is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration (FDA) prior to final approval?	Lorbrena <sup>®</sup> received breakthrough designation by the federal FDA. <sup>i</sup>
Did the drug receive a priority review by the federal FDA prior to final approval?	Lorbrena <sup>®</sup> received priority review by the federal FDA. <sup>ii</sup>
The date and price of acquisition if the drug was not developed by the manufacturer.	N/A

In the event Vermont S. 92 and the laws it implements, including 18 V.S.A. § 4637, are found invalid, Pfizer reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Pfizer does not waive any legal claims or legal rights related to potential constitutional defects with Vermont S. 92.

Sincerely,

A handwritten signature in blue ink, appearing to read 'M Shaulis', with a long horizontal stroke extending to the right.

Matt Shaulis  
Regional President, North America  
Pfizer Oncology

*For any questions concerning this notification please contact: [StateLawReporting@Pfizer.com](mailto:StateLawReporting@Pfizer.com)*

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<sup>i</sup> U.S. Food and Drug Administration, Breakthrough Therapy Approvals. Available at: <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/ndaandblaapprovalreports/ucm373418.htm>. Last accessed October 21, 2018.

<sup>ii</sup> U.S., EU and Japan Health Authorities Accept Regulatory Submissions for Review of Pfizer's Third-Generation ALK Inhibitor Lorlatinib. Available at: <https://press.pfizer.com/press-release/us-eu-and-japan-health-authorities-accept-regulatory-submissions-review-pfizers-third->. Last accessed October 22, 2018.