Pfizer Inc.
235 East 42nd Street
New York, NY 10017

December 30, 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 Daurismo™ (glasdegib) into the commercial market on November 27, 2018. Pfizer anticipates Daurismo's™ WAC to exceed the threshold set for a specialty drug under the Medicare Part D Program.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Pfizer is not aware of any guidance issued by the Office or any Vermont regulation that defines "release of the drug in the commercial market" for the purpose of 18 V.S.A. § 4637.

As a result, Pfizer considers a drug to be "release[d] . . . in the commercial market" when Pfizer publishes a trade letter to wholesale customers announcing the introduction of the new drug and begins accepting orders for the drug.

Statutory Requirement	Reporting Information
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 prior to final approval?	Daurismo™ did not receive breakthrough designation by the federal FDA.[i]

Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	Daurismo™ received priority review by the federal FDA.[ii]
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,

Matt Shaulis
Regional President, North America
Pfizer Oncology

For any questions concerning this notification please contact: StateLawReporting@Pfizer.com

[i] U.S. Food and Drug Administration, Breakthrough Therapy Approvals. Available at: https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/ndaandblaapprovalreports/ucm373418.htm. Last accessed November 27, 2018.

[ii] U.S. FDA GRANTS PRIORITY REVIEW FOR PFIZER'S NEW DRUG APPLICATION FOR GLASDEGIB IN PATIENTS WITH PREVIOUSLY UNTREATED ACUTE MYELOID LEUKEMIA. Available at: https://www.pfizer.com/news/press-release/press-release-detail/u_s_fda_grants_priority_review_for_pfizer_s_new_drug_application_for_glasdegib_in_patients_with_previously_untreated_acute_myeloid_leukemia-0. Last accessed November 27, 2018.