Pfizer Inc.
66 Hudson Blvd East
New York, NY 10001

May 31, 2024

BY ELECTRONIC DELIVERY

State of Vermont
Office of the Vermont Attorney General
AGO.highcostprescriptiondrugs@vermont.gov

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 BEQVEZ™ (fidanacogene elaparvovec) gene therapy (10^{13} vg/ml 4X1ml; 10^{13} vg/ml 5X1ml; 10^{13} vg/ml 6X1ml; 10^{13} vg/ml 7X1ml) into the commercial market on May 2, 2024. BEQVEZ™'s WAC exceeds 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 estimates that there are approximately 10-40 patients annually in the United States that could

	potentially receive BEQVEZ™ for the treatment of Hemophilia B.
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration prior to final approval?	BEQVEZ™ received breakthrough designation by the federal FDA.
Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	BEQVEZ™ did not receive priority review by the federal FDA.
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.