

December 19, 2019

Vermont Attorney General's Office 109 State Street Montpelier, VT 05609 (802) 828-3171 AGO.highcostprescriptiondrugs@vermont.gov

To Whom It May Concern:

Pursuant to Act 193, "Notice Of Introduction Of New High-Cost Prescription Drugs", § 4637, notice is hereby given that Seattle Genetics has introduced a new drug, PADCEVTM (enfortumab vedotin-ejfx injection for IV infusion 20 mg & 30 mg vials), on December 18, 2019 for distribution in Vermont with a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program.

Section 4637 does not currently define "release of the drug in the commercial market." Further, Seattle Genetics 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 § 4637. Accordingly, for the purpose of § 4637, Seattle Genetics considers a drug to be "release[d] . . . in the commercial market" when approved by FDA.

Please note that the WAC-related information referenced in this notice may be subject to change.

In the event that § 4637 is found invalid, Seattle Genetics reserves all of its legal rights. In issuing this notice in an attempt to comply with § 4637, Seattle Genetics does not waive any legal claims or legal rights related to potential constitutional defects within § 4637.

Sincerely,

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