December 13, 2019

To: The Office of the Attorney General of Vermont

Via: Electronic Mail at AGO.highcostprescriptiondrugs@vermont.gov

Re: Notice of New Drug Introduction Pursuant to 18.V.S.A. § 4637(b)

Alnylam Pharmaceuticals, Inc. (Alnylam) hereby notifies the Attorney General of Vermont of the following new prescription drug pursuant to 18 V.S.A. § 4637(b), which requires prescription drug manufacturers to provide written notice within three (3) calendar days of releasing 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.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market" and Alnylam 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, for the purposes of compliance with 18 V.S.A. § 4637, Alnylam considers a drug to be "release[d] . . . in the commercial market" when Alnylam makes product available for shipment to its Wholesalers, Specialty Pharmacies and other customers who purchase directly from Alnylam.

NAME OF PRESCRIPTION DRUG	NDC NUMBER	DATE OF COMMERCIAL AVAILABILITY
Givlaari™ (givosiran) (189 mg/ml single dose vial)	71336-1001-01	December 12, 2019

Alnylam provides this report consistent with its understanding and interpretation of 18.V.S.A. § 4637 and its provisions. In providing this report, Alnylam does not waive any rights, claims, or legal challenges with respect to 18.V.S.A. § 4637 and related legislation (including but not limited to Act 193 of 2018) or any implementing regulations thereof.

Sincerely,

Lisa Kiniklis

Lisa Kiniklis
Director, Government Pricing & Reporting
Alnylam Pharmaceuticals