Apellis

June 17, 2021

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 (c)

Pursuant to 18 V.S.A. § 4637(c), Apellis Pharmaceuticals, Inc. ("Apellis") hereby submits information regarding a new prescription drug. 18 V.S.A. § 4637(c), requires prescription drug manufacturers to provide the Office of the Vermont Attorney General with certain information following the introduction of a new prescription drug to market at a wholesale acquisition cost (WAC) that exceeds the threshold set for a specialty drug under the Medicare Part D Program.

The table below provides the information required by 18 V.S.A. § 4637. Consistent with 18 V.S.A. § 4637 (d), this disclosure only contains information that Apellis has identified as being in the public domain or publicly available.

Drug Identification	National Drug Code (11 digit NDC Number)	73606-0010-01
	Drug Name	EMPAVELI™ (1080 mg/20 mL (54 mg/mL) in a single-dose vial)
	Commercial Availability Date	May 18, 2021
Drug Launch Information	Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	**Marketing** EMPAVELI™ is a FDA approved treatment for Paroxysmal Nocturnal Hemoglobinuria (PNH). PNH often presents with persistently low hemoglobin, thrombosis and debilitating symptoms. Apellis's approach will focus on educating healthcare providers and staff on how to diagnose PNH and provide information about treatment. Educational materials will be provided across the patient journey, to both HCPs and to families, and highlight access and affordability support to ensure rapid access to EMPAVELI. **Pricing** EMPAVELI™ has been developed for the treatment of patients with Paroxysmal Nocturnal Hemoglobinuria (PNH). EMPAVELI provides an option to deliver a safe, effective treatment that reduces the risk of persistently low hemoglobin and other debilitating symptoms in patients. EMPAVELI is priced responsibly compared to similar agents. Pricing accounts for development costs, complexity of manufacturing, distribution, and storage. Apellis demonstrates a strong commitment to patients and their ability to get access to care with support programs that leaves no patient behind.

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	Estimated volume of patients who may be prescribed the drug	In the United States, there are approximately 6,000 PNH patients.
	Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	EMPAVELI was reviewed by the FDA under priority review and was granted Orphan Drug Designation. EMPAVELI does not have a breakthrough therapy designation.
	Date and price of acquisition if the drug was not developed by the manufacturer	N/A – EMPAVELI was developed by Apellis.

Apellis provides this report consistent with its understanding and interpretation of 18 V.S.A. § 4637 and its provisions. In providing this notice, Apellis, reserves any and all rights or claims it may have with respect to 18 V.S.A. § 4637, the company's interpretation thereof, or the statute's application to Apellis.

Sincerely,

Michelle Cerruti

Michelle Cerruti
Director, Government Pricing