Notice and Report of the Introduction of a New Prescription Drug Pursuant to 18 V.S.A. § 4637

Alexion Pharmaceuticals, Inc. ("Alexion") is issuing this notice and report pursuant to 18 V.S.A. § 4637, which 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 U.S. Food and Drug Administration ("FDA") approved Alexion's Biologics License Application for ULTOMIRIS (ravulizumab-cwvz) on December 21, 2018, for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria ("PNH"). The WAC for ULTOMIRIS 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), Alexion is limiting the information reported to that which is otherwise in the public domain or publicly available.

Statutory Requirement	Reporting Information
Date that ULTOMIRIS was released to the commercial market.	December 21, 2018[1]
A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.	As of December 2018, SOLIRIS (another Alexion prescription drug) and ULTOMIRIS were the only FDA-approved drugs indicated for the treatment of PNH. As a treatment for PNH, ULTOMIRIS is priced at roughly a 10% discount to SOLIRIS during the ongoing maintenance dosing period (i.e., after the initial "loading" dosing period). We have an established commercial organization that supports our marketed products in the U.S., Europe, Japan, Latin America, Asia Pacific countries, and other territories. We employ a sales force and commercial marketing functions to ensure that health care providers are informed about our products.

[1] 18 V.S.A. § 4637 does not currently define "introducing a new prescription drug to market" or "release of the drug in the commercial market," and Alexion is not aware of any regulation or formal guidance from the Office of Attorney General interpreting these phrases in the legislation. Absent further guidance from the state, Alexion considers the date of "release of the drug in the commercial market" to be the launch date that the company listed with publicly available prescription drug compendia.

Statutory Requirement	Reporting Information
The estimated volume of patients who may be prescribed the drug.	PNH is an ultra-rare disease; it affects fewer than 10,000 patients in the U.S.
Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval.	The FDA approval of ULTOMIRIS was expedited through Alexion's use of a rare disease priority review voucher. In addition, ULTOMIRIS received Orphan Drug Designation from FDA for the treatment of PNH.
The date and price of acquisition if the drug was not developed by the manufacturer.	N/A – ULTOMIRIS was developed by Alexion.